

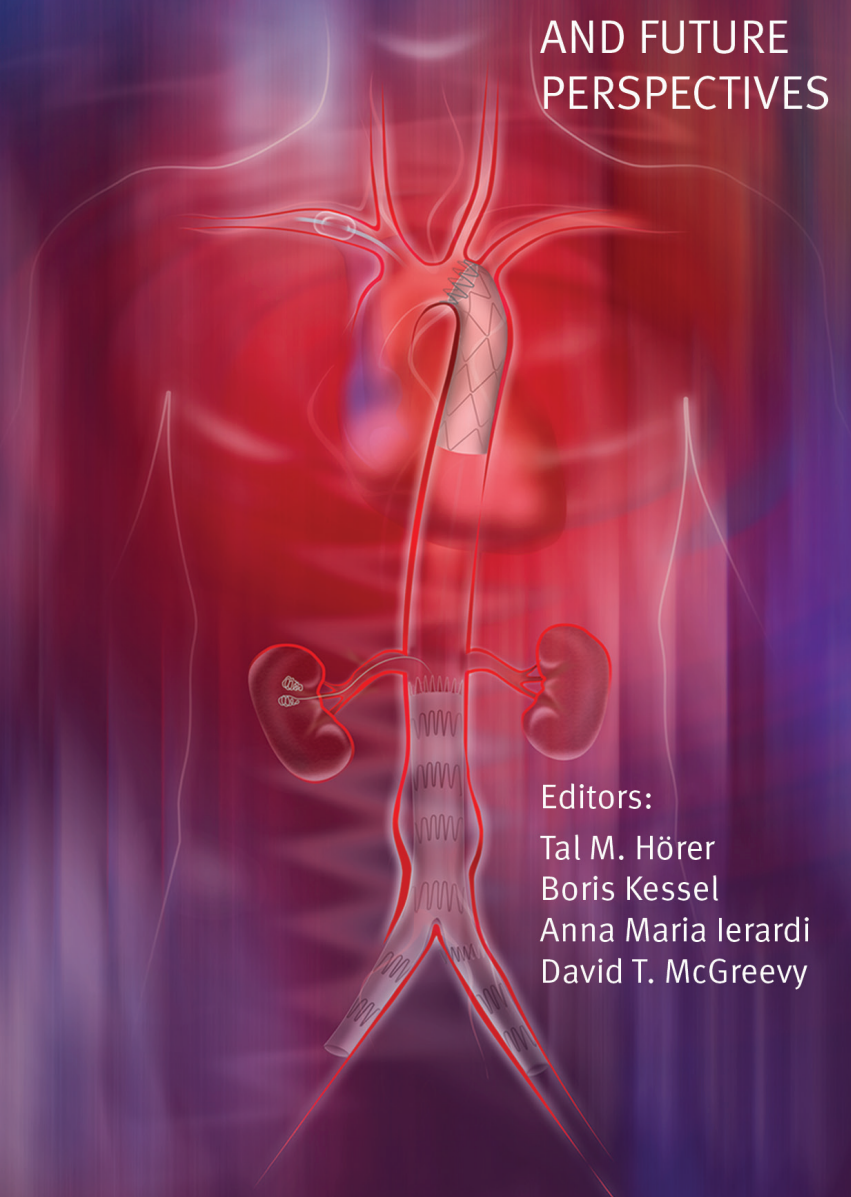


ENDOVASCULAR RESUSCITATION AND TRAUMA MANAGEMENT

LANDMARK ARTICLES

PAST
PRESENT
AND FUTURE
PERSPECTIVES

Editors:
Tal M. Hörer
Boris Kessel
Anna Maria Ierardi
David T. McGreevy





EVTM LANDMARK ARTICLES

Editors: Tal M. Hörer, Boris Kessel, Anna Maria Ierardi, David T. McGreevy

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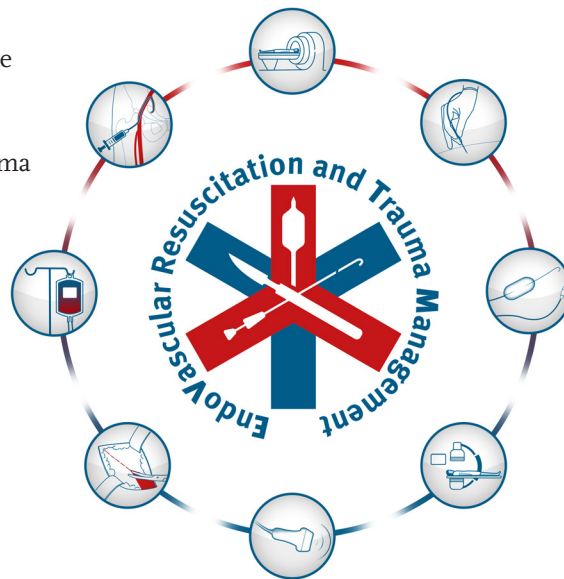
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The EVT™ Concept

During the past 15-20 years, endovascular surgery has developed rapidly. Endovascular techniques can now completely replace open surgery for both ruptured aortic abdominal and thoracic aneurysms, and are clinically the gold standard in many institutions worldwide. In addition to this, endovascular techniques are now being applied for hemorrhage control and resuscitation in other causes of both traumatic and non-traumatic hemodynamic instability. EVT™, EndoVascular resuscitation and Trauma Management, is a multidisciplinary concept to enhance treatment of hemodynamically unstable patients. It aims to combine modern endovascular techniques and procedures, traditional Advanced Trauma Life Support (ATLS) and Definitive Surgical Trauma Care (DSTC) strategies with early multidisciplinary evaluation, resuscitation, and definitive management. Tools such as endovascular balloons, endografts, embolization agents, as well as dedicated imaging protocols with CT and ultrasound, together with traditional open surgery, are used by a multidisciplinary team for both traumatic and non-traumatic bleeding control and resuscitation internationally. The EVT™ concept does not replace traditional surgical solutions, but instead incorporates them into a common trunk. This enables fast goal-directed treatment, based on clinical examination and CTA findings and, at times, spare the need for opening new cavities or performing unnecessary open explorations. This can result in effective bleeding control, minimized blood loss and less extensive surgical insult. The multidisciplinary mindset helps surgical teams to quickly assemble the necessary resources and save precious time and might be of major importance in centers with low trauma load and therefore low per-surgeon trauma volumes and experience.

More information about EVT™ can be found online at www.jevtm.com and in the peer-reviewed journal of EndoVascular resuscitation and Trauma Management (JEVT™).



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Introduction

“EVTM Landmark Articles” is a compendium of the most influential publications that have promulgated the field of endovascular resuscitation and trauma management (EVTM). The text is edited by Tal Hörer, Boris Kessel, Anna Maria Ierardi and David McGreevy, representing a multidisciplinary editorial team who have successfully championed this concept.

EVTM brings together the disciplines of vascular surgery, trauma surgery, interventional radiology, emergency medicine, intensivists and obstetrics. Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) has stimulated the interests of multiple specialties beyond endovascular work. The advantages of performing simultaneous open and endovascular procedures has led to propagation of hybrid operating rooms that include CT scanning capabilities.

The early chapters appropriately focus on vascular access, emphasizing the key role of ultrasound for safe arterial cannulation. The common femoral artery is the typical entry site, but there are alternative sites, including the radial artery. Ensuing chapters highlight specific problems, beginning with trauma. Endovascular stenting has revolutionized the treatment of a torn thoracic aorta (TEVAR) as well as ruptured abdominal aortic aneurysm (rAAA). Stenting has become standard for contained lesions of the subclavian-axillary system and is commonly employed for visceral arteries (celiac, superior mesenteric, and renal arteries). Stenting is also used for certain high grade extracranial arterial lesions and is now being evaluated for peripheral vascular injuries. Selective angioembolization (SAE) has become routine for solid organ injuries, although the specific indications remain debated. Pelvic fracture hemorrhage is treated effectively with Zone III REBOA and preperitoneal pelvic packing (PPP) in most patients, with SAE added for the 10% who have persistent arterial bleeding.

REBOA and SAE have been useful for a number of non-trauma entities, including acute GI bleeding. The hybrid options have extended their use in a number of elective complex tumor resections. REBOA has also been a helpful adjunct for managing post-partum hemorrhage due to morbidly adherent placentas (MAP).

Finally, EVTm techniques have been applied for advanced resuscitation/salvage. Prehospital REBOA has been extended experimentally to selective aortic arch perfusion (SAAP) for near exsanguinating events.

In sum, this text nicely summarizes the advances facilitated by EVTm in an evolving field that applies to multiple disciplines confronted with limb and life-threatening bleeding from diverse sources.

Ernest E. Moore, MD

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Foreword

Over the past 20 years we have learnt that it is possible to perform endovascular aortic repair (EVAR) on 100% of ruptured abdominal aortic aneurysms (rAAA), with a low exclusion rate and a mortality rate of just over 20% (1, 2). The treatment of these patients using the EndoVascular resuscitation and Trauma Management (EVTM) concept (3-5) has been continuously developing at Örebro University Hospital and since November 2009 all rAAA have been operated with EVAR and different endovascular complementary methods, maintaining the same low mortality rate and an exclusion rate under 5%. This is now a general trend in modern vascular centers and many centers are following the same path.

We consider the fact that 100% of rAAA can be treated by EVAR to be a successful proof of concept for using endovascular and hybrid tools to treat life-threatening hemorrhage and hemodynamically unstable patients. We believe this is a significant breakthrough in EVTM and will continue to explore the possibilities of helping our patients, by good clinical practice, collaboration and science. This book aims to present landmark scientific articles of EVTM and we hope it will increase the interest, research and implementation of the EVTM concept.

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CHAPTER 1.

Vascular access in acute vascular and critical care

Author: *David T. McGreevy*

Introduction

Before immersing oneself in the exciting details that this book has to offer regarding EndoVascular resuscitation and Trauma Management (EVTM), it is important to first consider vascular access. It was not by chance that this critical rate-limiting step became the first chapter of this fascinating book. Adequate vascular access is a prerequisite for endovascular procedures and is, therefore, essential. Apart from enabling endovascular procedures, it provides a possibility for invasive blood pressure monitoring, blood analysis, arterial fluid resuscitation and medical therapy. Vascular access is acquired using the Seldinger technique either percutaneously using ultrasound or anatomical landmarks, or by surgical cut-down. The common femoral artery is frequently the cornerstone access vessel; however, radial or axillary/brachial vascular access are becoming increasingly used. Venous access follows the same principles of arterial access with the common femoral vein being the most used site. Appropriateness of access location is related to both the vessels that are intended to be treated, size of devices needed and important not to forget, the ability to obtain hemostasis for safe completion post-procedure. Obtaining vascular access can prove challenging, especially in hemodynamically decompensated patients or while cardiopulmonary resuscitation (CPR) is in progress. For this reason, the suggestion has been made to add another A for early "Access" or C for "Circulation" to the traditional ABCDE strategy of ATLS initial trauma care. Placing a 4-5 French sheath (Fr), before the patient deteriorates, allows easy upgrading to a larger sheath upon circulatory collapse, widening the array of treatment strategies for these patients that you can read more about in the following chapters of this book.

A thorough search of the relevant literature regarding vascular access did not yield any randomized controlled studies. At present, articles related to this topic are mostly limited to retrospective studies; however, we have included one prospective study. We hereby review, in our opinion, five of the most relevant studies that have investigated the benefits and limitations of vascular access as part of the EVTm concept.

ARTICLE NUMBER 1

Time to aortic occlusion: It's all about access.

J Trauma Acute Care Surg. 2017 Dec;83(6):1161-1164.

Romagnoli A, Teeter W, Pasley J, Hu P, Hoehn M, Stein D, Scalea T, Brenner M.

Abstract

Introduction: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a less invasive method of proximal aortic occlusion compared with resuscitative thoracotomy with aortic cross-clamping (RTACC). This study compared time to aortic occlusion with REBOA and RTACC, both including and excluding time required for common femoral artery (CFA) cannulation.

Methods: This was a retrospective, single-institution review of REBOA or RTACC performed between February 2013 and January 2016. Time of skin incision to aortic cross-clamp for RTACC, time required for CFA cannulation by percutaneous and open methods, and time from guide-wire insertion to balloon inflation at Zone 1 for REBOA, were obtained from videographic recordings.

Results: Eighteen RTACC and 21 REBOAs were performed. Median (Q1, Q3) time from skin incision to aortic cross-clamping was 317 seconds (227, 551 seconds). Median (Q1, Q3) time from start of arterial access to Zone 1 balloon occlusion was 474 seconds (431, 572 seconds) (vs. RTACC, $p = 0.01$). All REBOA procedures were performed with the same device. The median time to complete CFA cannulation was 247 seconds (range, 164–343 seconds), with no difference between percutaneous or open procedures ($p = 0.07$). The median (Q1, Q3) time to aortic occlusion in REBOA once arterial access had been established was 245 seconds (179, 295.5 seconds), which was significantly shorter than RTACC ($p = 0.003$).

Conclusions: Once CFA access is achieved, time to aortic occlusion is faster with REBOA. Time to aortic occlusion is less than the time required to cannulate the CFA either by percutaneous or open approaches, emphasizing the importance of accurate and expedient CFA access. Resuscitative endovascular balloon occlusion of the aorta may represent a feasible alternative to thoracotomy for aortic occlusion. Time to aortic occlusion will likely decrease with the advent of newer REBOA technology. The rate-limiting portion of REBOA continues to be obtaining CFA access.

Article review and analysis

Aim of this study: The aim was to compare procedural time to aortic occlusion in RTACC (Resuscitative Thoracotomy with Aortic Cross-Clamping) with Zone 1 REBOA (Resuscitative Endovascular Balloon Occlusion of the Aorta).

Methods

Pros: The most noticeable benefit of this study was the use of videographic recordings to provide precise objective data on procedural duration, since many other previous studies concerning this issue have been based on the physicians' subjective recall. Additional benefits were that time to arterial access was evaluated relative to body mass index, that the timing of all procedure steps were recorded and that an analysis was made regarding surgeon practice experience and procedure time.

Cons: A significant limitation to the study is that the comparison is made with REBOA with a balloon requiring a guidewire and 12 Fr sheath. With arterial access contributing to over 50% of the overall procedure time in REBOA, the use of a REBOA catheter that passes through a 7 Fr sheath is likely to decrease procedural time.

Another limitation to the study is that it was performed at one of the world's busiest trauma centers where RTACC is frequently performed. If the study included patients in hospitals where RTACC is seldom practiced, procedural time may be more in favor of arterial access and REBOA.

Results, conclusion, and what it means

This study emphasizes the importance of early, rapid and accurate arterial access, since this is the significant rate-limiting step when comparing REBOA to RTACC. Once arterial access is gained, the study demonstrates that aortic occlusion using REBOA is faster. Previous studies have shown that successful arterial access can be performed despite medical specialty¹ and this study further suggests that even physicians with little experience can quickly perform the procedure. The study, however, failed to demonstrate a difference in time between percutaneous or cut-down procedures. Nevertheless, the importance of having physicians who are highly skilled at obtaining arterial access is paramount in these critical patients with potential anatomical and physiological features that complicate the procedure.

1. Hilbert-Carius P, McGreevy D, Abu-Zidan FM, Hörer TM; ABOTrauma Registry research group. Successfully REBOA performance: does medical specialty matter? International data from the ABOTrauma Registry. World J Emerg Surg. 2020 Nov 23;15(1):62.

Comments and future research

Since 7 Fr REBOA catheters are becoming increasingly used worldwide, it would be of interest to compare procedure times with RTACC. It would also be of interest to perform a similar study, preferably at multiple centers, where there is less experience in RTACC to gain a better idea of real world experience with both procedures.

i Related important publications

Hilbert-Carius P, McGreevy D, Abu-Zidan FM, Hörer TM; ABOTrauma Registry research group. Successfully REBOA performance: does medical specialty matter? International data from the ABOTrauma Registry. World J Emerg Surg. 2020 Nov 23;15(1):62.

Moore LJ, Brenner M, Kozar RA, Pasley J, Wade CE, Baraniuk MS, Scalea T, Holcomb JB. Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage. J Trauma Acute Care Surg. 2015 Oct;79(4):523-30; discussion 530-2.

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ARTICLE NUMBER 2

Early arterial access for resuscitative endovascular balloon occlusion of the aorta is related to survival outcome in trauma.*J Trauma Acute Care Surg. 2018 Sep;85(3):507-511.**Matsumura Y, Matsumoto J, Kondo H, Idoguchi K, Ishida T, Okada Y, Kon Y, Oka K, Ishida K, Toyoda Y, Funabiki T; DIRECT-IABO Investigators.***Abstract**

Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been used in refractory hemorrhagic shock patients. Since the optimal timing of arterial access remains unclear, we evaluated the preocclusion status of patients, and elapsed time from the arrival to the hospital is associated with the survival outcomes in the REBOA patients.

Methods: From August 2011 to December 2016, The Diagnostic and Interventional Radiology in Emergency, Critical care and Trauma- Intra-Aortic Balloon Occlusion (DIRECT-IABO) investigators registered refractory hemorrhagic shock patients undergoing REBOA from 23 hospitals in Japan. Patient characteristics, mechanism of injury, Injury Severity Score (ISS), preocclusion and postocclusion systolic blood pressure, duration of aortic occlusion, clinical time course, and survival outcome were recorded and analyzed. Binary logistic regression analysis was used with mortality and Kaplan-Meier survival analysis was conducted to demonstrate the difference between early and delayed access groups.

Results: Among the enrolled 207 cases, the following patients were excluded from the analysis: five since they were younger than 18 years, nine due to failed attempts at REBOA, 51 nontrauma patients, and 33 who received resuscitative thoracotomy plus REBOA. Thus, the remaining 109 cases were analyzed (30 day survivors, n = 60; nonsurvivors, n = 49). The preocclusion systolic blood pressure was higher, and both hospital arrival to initial arterial access and duration of occlusion were shorter in the survivors. Lower ISS (odds ratio, 0.944; 95% confidence interval, 0.907–0.982; p = 0.0039) and shorter arrival to access (odds ratio, 0.989; 95% confidence interval, 0.979–0.999; p = 0.034) were significantly associated with 30-day survival in the logistic regression analysis. The cutoff point of 21.5 minutes was used in the receiver operating characteristic analysis. The early access group showed a significantly shorter time of arrival to definitive hemostasis and also demonstrated a significantly higher survival in the Kaplan-Meier survival analysis (p = 0.014, Log-rank test).

Conclusion: The arrival to access time and ISS were significantly associated with mortality in the REBOA patients in Japan. The early access group demonstrated better survival. The proactive early access in the resuscitation phase might be related to better patient outcomes.

Article review and analysis

Aim of this study: To identify factors associated with better survival when using REBOA in trauma.

Methods

Pros: In contrast to the authors, we believe that using data registered from multiple institutions strengthens the study's conclusion that early arterial access is associated with better survival. The data was not obtained from one single center, which minimizes potential bias associated with experience of obtaining arterial access and REBOA use.

Cons: As with all retrospective registry-based studies, the reliability of the data can always be questioned. Additionally, being a multi-institutional study can also be seen as a limitation to this study as the indications for and use of arterial access and REBOA probably vary widely and are therefore difficult to compare. Another limitation to the study is that the in-hospital location of the patient when arterial access is performed is not stated. With time from arrival to access ranging from 10 to 83 minutes, and arrival to inflation ranging from 28 to 101 minutes, it is clear that the hemodynamic condition of the patients upon arrival has varied.

Results, conclusion, and what it means

This study demonstrates that, in patients with hemodynamic shock who are candidates for REBOA, making the decision to gain arterial access early is associated with both shorter time to definitive hemostasis and, subsequently, a better survival outcome. With difficulty obtaining arterial access increasing exponentially with hemodynamic instability, the study could demonstrate that a delay of 10 minutes decreases the survival rate by approximately 10%. Arterial access was gained in 95% with blind percutaneous puncture of the common femoral artery, demonstrating that surgical cut down is not necessary in most cases and the authors further encourage the use of ultrasound guided puncture.

Comments and future research

It would be beneficial to perform a similar study using worldwide REBOA data to even more accurately study the importance of early arterial access in a wide range of scenarios, by practitioners from different specialties and in multiple geographical locations. Additionally, since the study reported a median body mass index (BMI) of 23 kg/m², this reflects a generally lean Japanese population. Results might, however, differ using worldwide data since 39% of the world's population are overweight or obese, conditions which increase the difficulty of obtaining vascular access and the risk for related complications.

i Related important publications

Matsumoto J, Lohman BD, Morimoto K, Ichinose Y, Hattori T, Taira Y. Damage control interventional radiology (DCIR) in prompt and rapid endovascular strategies in trauma occasions (PRESTO): A new paradigm. *Diagn Interv Imaging*. 2015 Jul-Aug;96(7-8):687-91.

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Matsumura Y, Matsumoto J, Kondo H, Idoguchi K, Ishida T, Kon Y, Tomita K, Ishida K, Hirose T, Umakoshi K, Funabiki T; DIRECT-IABO Investigators. Fewer REBOA complications with smaller devices and partial occlusion: evidence from a multicentre registry in Japan. *Emerg Med J*. 2017 Dec;34(12):793-799.

ARTICLE NUMBER 3

A meta-analysis of the incidence of complications associated with groin access after the use of resuscitative endovascular balloon occlusion of the aorta in trauma patients.

J Trauma Acute Care Surg. 2018 Sep;85(3):626-634.

Manzano-Nunez R, Orlas CP, Herrera-Escobar JP, Galvagno S, DuBose J, Melendez JJ, Serna JJ, Salcedo A, Peña CA, Angamarca E, Horer T, Salazar CJ, Lopez-Castilla V, Ruiz-Yucuma J, Rodriguez F, Parra MW, Ordoñez CA.

Abstract

Background: Serious complications related to groin access have been reported with the use of resuscitative endovascular balloon occlusion of the aorta (REBOA). We performed a systematic review and meta-analysis to estimate the incidence of complications related to groin access from the use of REBOA in adult trauma patients.

Methods: We identified articles in MEDLINE and EMBASE. We reviewed all studies that involved adult trauma patients who underwent the placement of a REBOA and included only those that reported the incidence of complications related to groin access. A meta-analysis of proportions was performed.

Results: We identified 13 studies with a total of 424 patients. REBOA was inserted most commonly by trauma surgeons or emergency room physicians. Information regarding puncture technique was reported in 12 studies and was available for a total of 414 patients. Percutaneous access and surgical cutdown were performed in 304 (73.4%) and 110 (26.5%) patients, respectively. Overall, complications related to groin access occurred in 5.6% of patients (n = 24/424). Lower limb amputation was required in 2.1% of patients (9/424), of which three cases (3/424 [0.7%]) were directly related to the vascular puncture from the REBOA insertion. A meta-analysis that used the logit transformation showed a 5% (95% CI 3%–9%) incidence of complications without significant heterogeneity (LR test: $\chi^2=0.73$, $p=0.2$, Tau-square = 0.2). In a second meta-analysis, we used the Freeman–Tukey double arcsine transformation and found an incidence of complications of 4% (95% CI 2%–7%) with low heterogeneity ($I^2=16.3\%$).

Conclusion: We found that the incidence of complications related to groin access was of 4–5% based on a meta-analysis of 13 studies published worldwide. Currently, there are no benchmarks or quality measures as a reference to compare, and thus, further work is required to identify these benchmarks and improve the practice of REBOA in trauma surgery.

Article review and analysis

Aim of this study: The aim was to estimate the incidence of complications related to common femoral artery access when using REBOA in adult trauma patients.

Methods

Pros: This was the first meta-analysis to be performed concerning vascular access complications with the use of REBOA in trauma patients, an important issue that is highly responsible for patient morbidity and frequent readmissions. Subgroup analysis was also performed in this study looking at vascular access complications in regard to provider specialty and access technique. These are two issues that are highly discussed with regard to the use of REBOA; who should be performing this technique and how should it be performed. This study laid the foundation for studies that later discussed these issues [1] and highlighted the importance of vascular access training prior to REBOA use, as well as a routine for extremity monitoring post-procedure. It also emphasized the importance of REBOA multinational registries to advance endovascular use in trauma, with the only currently existing such being the ABO Trauma registry.

Cons: Despite including data published worldwide, this meta-analysis only included a total of 13 studies, 12 of which were single-center case series with high risk for selection bias and 9 with high risk of overlapping populations. Additionally, none of the studies included follow-up data, which is crucial in determining the frequency of some of the access-related complications included in this meta-analysis, such as pseudoaneurysm formation.

Results, conclusion, and what it means

This study demonstrated an overall complication rate related to vascular access between 4-5%, with complications being less when performed by emergency physicians using a percutaneous technique. With limited inclusion and containing data from Japanese registries to a high extent, with an increased risk of overlapping data as well as bias, we believe that it is important to interpret the data presented in this study carefully, especially with regard to the issues of “by who” and “how” vascular access and REBOA is performed. Ten of the thirteen studies included patients who received larger sheaths (10 – 14 Fr) with 6 of these studies only including patients with sheath sizes >10 Fr. Just one study was performed using only the new 7 Fr sheaths. Nevertheless, this study was the first meta-analysis estimating the incidence of access-related complications with the use of REBOA in trauma.

Comments and future research

The need for a comprehensive multinational REBOA registry to further the understanding of access-related complications as well as other aspects related to the use of REBOA in hemodynamic shock is vital. This will help determine the level of REBOA training needed and refine the use of REBOA in clinical practice.

i Related important publications

Hilbert-Carius P, McGreevy D, Abu-Zidan FM, Hörer TM; ABOTrauma Registry research group. Successfully REBOA performance: does medical specialty matter? International data from the ABOTrauma Registry. *World J Emerg Surg.* 2020 Nov 23;15(1):62.

Sadeghi M, Nilsson KF, Larzon T, Pirouzram A, Toivola A, Skoog P, Idoguchi K, Kon Y, Ishida T, Matsumara Y, Matsumoto J, Reva V, Maszkowski M, Bersztel A, Caragounis E, Falkenberg M, Handolin L, Kessel B, Hebron D, Coccolini F, Ansaloni L, Madurska MJ, Morrison JJ, Hörer TM. The use of aortic balloon occlusion in traumatic shock: first report from the ABO trauma registry. *Eur J Trauma Emerg Surg.* 2018 Aug;44(4):491-501.

ARTICLE NUMBER 4

Safety and efficacy of radial access in trauma in 65 trauma endovascular cases.*J Vasc Surg. 2020 May;71(5):1564-1571.**Adnan SM, Romagnoli AN, Madurska MJ, Dubose JJ, Scalea TM, Morrison JJ.***Abstract**

Objective: Endovascular techniques in trauma surgery are becoming increasingly important in patient management, with procedures such as pelvic and splenic angioembolization becoming the standard of care for certain injuries. Traditionally, such interventions are performed via femoral access, although the morbidity of this approach is not insignificant (3%-10%). Transradial access (TRA) is an attractive alternative, pioneered by cardiologists, with low rates of access site complications in patients undergoing coronary intervention. Recently, this technology has extended to other interventions. The aim of this study was to present the initial experience of a radial program in a busy trauma center, with specific regard to safety and complications.

Methods: The medical records of trauma patients undergoing endovascular procedures via TRA between March 2018 and December 2018 were queried for procedural and postoperative data. Demography and injury characteristics were presented for the overall cohort, followed by a comparison of procedural data and complications between laterality. Continuous variables were compared using a two-tailed t-test and categorical variables were compared using a χ^2 test.

Results: Over a 9-month period, 65 patients underwent 81 interventions via TRA, most commonly solid organ or pelvic angiography/embolization. Radial artery access was achieved in all patients, with procedural success achieved in all but two patients (n/4 63 [96.9%]) who had hypoplastic radial artery anatomy, who underwent ulnar access. The overall technique-related complication rate was 1.5% with no difference observed between laterality (n/4 1; P/4 .523). One patient with an admission Glasgow Coma Score of 3 and coagulopathy developed radial artery thrombosis after pelvic angiography via right TRA. Mortality was seen in seven patients (10.8%) owing to hemorrhagic shock (n/4 3 [42.8%]) or multiorgan failure (n/4 4 [57.1%]). There were no cases of postprocedural access site bleeding, hematoma, pseudoaneurysm, vascular injury, intraoperative arrhythmia or cerebrovascular accident, arteriovenous fistula formation, or infection.

Conclusions: TRA is a feasible and low-risk alternative for endovascular intervention in the trauma patient. It yields good technical success with low morbidity. Although larger studies are needed to establish the full efficacy of TRA at the multi-institutional level, this single-institution study demonstrates the legitimacy of an alternative means for endovascular intervention in the trauma patient.

Article review and analysis

Aim of this study: The aim was to present the use of transradial vascular access in the endovascular management of trauma patients.

Methods

Pros: This single-institution study is the first to present results that demonstrate that transradial arterial access for endovascular procedures in trauma is possible and may be related to a reduced procedural risk of complications. This center has pioneered this innovative technique within trauma, otherwise frequently used by cardiologists, and demonstrated an impressive success rate. The technique gives the EVT/M physician another arrow to their bow when faced with patient features such as obesity, anticoagulation or unforgiving femoral/iliac vessels.

Cons: The main limitation of the study is its nonrandomized, retrospective design, and therefore conclusions must be drawn with caution.

The study reports a complication rate of 1.5%, with one observed incidence of radial artery thrombosis. However, just as the authors pointed out, the consistent collateral circulation via the ulnar artery is sufficient to prevent symptoms from radial artery thrombosis and occlusion. Thus, without a postoperative duplex ultrasonography examination, it is highly likely that this asymptomatic complication was underdiagnosed.

The use of transradial access may be sufficient in most cases; however, technical limitations exist when larger sheath sizes are required for interventions. Additionally, with transradial access comes the requirement for longer device lengths, especially in tall patients, which may also negatively impact how easy they are to use in the correct way, with pushability and control diminishing with length.

Results, conclusion, and what it means

This study has suggested that endovascular procedures may be safely conducted using a transradial approach with no significant increase in complications or decrease in procedure success.

Comments and future research

This exciting technique needs further investigation within the scope of EVT/M and a multi-institutional study should preferably be conducted.

i Related important publications

Campeau L. Percutaneous radial artery approach for coronary angiography. *Cathet Cardiovasc Diagn.* 1989 Jan;16(1):3-7.

Meertens MM, Ng E, Loh SEK, Samuel M, Mees BME, Choong AMTL. Transradial Approach for Aortoiliac and Femoropopliteal Interventions: A Systematic Review and Meta-analysis. *J Endovasc Ther.* 2018 Oct;25(5):599-607.

Stern JR, Elmously A, Smith MC, Connolly PH, Meltzer AJ, Schneider DB, Ellozy SH. Transradial interventions in contemporary vascular surgery practice. *Vascular.* 2019 Feb;27(1):110-116.

CHAPTER 2.

Prehospital and austere environments

– pushing the boundaries of endovascular resuscitation

Authors: *Surgeon Commander Paul Rees, Lt Col Jon Barratt and Major Max Marsden*

Introduction

As well as their developing role in hospital trauma care, endovascular techniques are now being employed in some niche resuscitation environments. The ability to swiftly control bleeding and avert cardiovascular collapse has particular applicability to the peri-arrest trauma patient – hypotensive, tachycardiac, pale and sweaty, with life-threatening pelvic or junctional bleeding. The data on bleeding deaths from both military and civilian cohorts suggest death is rapid; perhaps operationalizing endovascular services in the pre-hospital domain is the most effective place to save lives. As a minimum, pre-hospital REBOA may be a way to reduce the number of patients dying before they arrive in hospital. London's Air Ambulance is the first prehospital helicopter emergency medical service (HEMS) to deploy REBOA “on the streets”, and below we evaluate their first, detailed report on 19 consecutive attempted Zone 3 REBOA cases. Since this was published, they have now carefully expanded their system to deliver Zone 1 REBOA, and we eagerly await the data from their prospective registry.

REBOA is not merely about “turning off the tap” in trauma. For many years we have had data (mostly overlooked) showing improved coronary perfusion related to aortic balloon occlusion in animal models of cardiac arrest. Augmented coronary perfusion in these animal models is associated with improved rates of return of spontaneous circulation (ROSC), improved arrhythmia profiles, improved survival and better neurological outcomes. In a ground-breaking study, our Norwegian HEMS colleagues have shown that intra-arrest REBOA is feasible, and likely to result in a better circulation during CPR.

A prime utility for REBOA is in the austere damage control resuscitation, as a direct adjunct to emergency surgery and within the damage control resuscitation paradigm. A few military services have managed to incorporate REBOA into their major trauma pathways, few with such enthusiasm as the US Air Force Special Operations Surgical Teams. They report on 20 cases of REBOA within a far-forward austere surgical resuscitation unit, with detailed hemodynamic data outlining the response to REBOA, and highlighting some often-overlooked factors – REBOA as an adjunct to damage control surgery can afford the surgeon with a patient who has avoided cardiac arrest, and in whom the operative field is relatively dry, with good visibility. It might also reduce overall blood product requirements - an important logistical consideration in the remote military operational setting.

Beyond REBOA we look to the other tools in the endovascular resuscitation toolkit. Subsequent generation devices should allow rapid aortic occlusion, and at the same time permit retrograde aortic perfusion to protect the heart and brain during damage control surgery. The concept of selective aortic arch perfusion (SAAP) is not new, but perhaps has also been overlooked. Below we examine a complex large animal model addressing its utility in the setting of hemorrhagic hypovolemic cardiac arrest. In the future, SAAP is a natural progression of REBOA, which might offer solutions to both traumatic and medical cardiac arrest support. Finally, we present a US case report of an extra-corporeal membrane oxygenation (ECMO) retrieval, where care was required for a deployed military contractor with refractory severe respiratory failure. With a reduction in global military medical footprint, the US has withdrawn its “standby” worldwide ECMO retrieval capability. Deployed critical care resources are often limited, and the authors suggest that using forward deployed, prepositioned ECMO equipment might be a solution. As ECMO becomes more of a core “firm base” facility, military systems will have to plan how to deliver this to ensure that deployed care keeps up with what would be expected in a similar civilian setting. Future advanced resuscitation systems currently being trialed, such as Emergency Preservation for Cardiac Arrest and Trauma (EPR-CAT), will mandate an ECMO capability.

The endovascular future is near – plan for it now.

ARTICLE NUMBER 1

Pre-hospital Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for exsanguinating pelvic haemorrhage.

Resuscitation. 2019 Feb;135:6-13.

Lendrum R, Perkins Z, Chana M, Marsden M, Davenport R, Grier G, Sadek S, Davies G.

Abstract

Aim: To report the initial experience and outcomes of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an adjunct to pre-hospital resuscitation of patients with exsanguinating pelvic haemorrhage.

Methods: Descriptive case series of consecutive adult patients, treated with pre-hospital Zone III REBOA by a physician-led pre-hospital trauma service, between January 2014 and July 2018.

Results: REBOA was attempted in 19 trauma patients (13 successful, six failed attempts) and two non-trauma patients (both successful) with exsanguinating pelvic haemorrhage. Trauma patients were severely injured (median ISS 34, IQR: 27-43) and profoundly hypotensive (median systolic blood pressure [SBP] 57, IQR: 40-68 mmHg). REBOA significantly improved blood pressure (Pre-REBOA median SBP 57, IQR: 35-67 mmHg versus Post- REBOA SBP 114, IQR: 86-132 mmHg; Median of differences 66, 95% CI: 25-74 mmHg; $P < 0.001$). REBOA was associated with significantly lower risk of pre-hospital cardiac arrest (REBOA 0/13 [0%] versus no REBOA 3/6 [50%], $P = 0.021$) and death from exsanguination (REBOA 0/13 [0%] versus no REBOA 4/6 [67%], $P = 0.004$), when compared to patients with a failed attempt. Successful REBOA was associated with improved survival (REBOA 8/13 [62%] versus no REBOA 2/6 [33%]; $P = 0.350$). Distal arterial thrombus requiring thrombectomy was common in the REBOA group (10/13, 77%).

Conclusion: REBOA is a feasible pre-hospital resuscitation strategy for patients with exsanguinating pelvic hemorrhage. REBOA significantly improves blood pressure and may reduce the risk of pre-hospital hypovolemic cardiac arrest and early death due to exsanguination. Distal arterial thrombus formation is common and should be actively managed.

Article review and analysis

Aim of this study: This is the first report of the delivery of a prehospital Zone 3 REBOA service. Only 0.003% of all patients attended by the air ambulance service had REBOA attempted. REBOA was attempted in 21 patients pre-hospital, of which 15 successfully achieved pre-hospital REBOA; 13 for blunt injury and two who sustained junctional vascular injury following recreational drug injection. The included trauma patients had a median ISS of 34, and a median initial SBP of 57mmHg. Prehospital Zone 3 REBOA

was associated with a significant improvement in blood pressure and a reduction in pre-hospital cardiac arrest from hypovolemia. This paper neatly highlights the important elements of a REBOA program, in particular complications relating to access; either difficulty achieving it, or complications arising from it. The paper highlights that in the patients that had REBOA attempted but balloon inflation was unsuccessful due to a failure to gain arterial access, four out of six of these patients died from hemorrhage.

Methods

London Air Ambulance introduced a Zone 3 REBOA service in 2014 after multispecialty engagement across a regional, high-volume major trauma service. This was primarily as a response to an identified clinical need to find a solution to address a small but high-profile number of cases of young patients dying from exsanguination due to pelvic trauma – most frequently the result of collisions between pedal cyclists and heavy goods vehicles during turning maneuvers. A structured training and clinical governance program was designed and delivered to initiate and support the project. REBOA provision was by physician-delivered ultrasound guided percutaneous access using a 7F sheath, through which a 13mm compliant balloon was delivered over a 145cm 0.035" guidewire. The device was advanced to 40cm, deployed and then allowed to dislodge caudally, to settle at the aorto-iliac bifurcation. Following this, rapid patient packaging was performed, and the patient was transported to a pre-alerted major trauma center. Additional therapies, such as pelvic stabilization, tranexamic acid and blood product transfusion, were available and performed as indicated.

Pros: As the only HEMS service routinely providing an endovascular resuscitation facility within a closely governed trauma system, this paper provides a robust and valuable first look at the safety and efficacy of prehospital REBOA. Importantly, it highlights the need to develop this as part of a multispecialty approach, to be meticulous about vascular access, and to appreciate the natural history of the progression of these cases once they have been delivered to a major trauma center. A signal (11/13 patients) indicating the need for high levels of surveillance for access-associated thrombus is noted and should be taken on board by all clinicians, especially surgeons, managing these patients. Unanswered questions remain about the need for routine (bilateral) arterial exploration and thrombectomy after REBOA and fasciotomy. More broadly, questions about appropriate patient selection are raised.

Cons: It is worth being clear that the LAA model of care is to deploy a consultant-led-and-delivered team, with a senior paramedic with specialist additional training and experience. This team is often augmented by a second LAA physician. These findings might not be extrapolated outside of this highly-specialist setting. The authors also describe "robust education and a strong governance culture" operating alongside the REBOA program – without this system it is unlikely such promising results would be achieved.

Including an analysis of diastolic blood pressure and differential upstream and downstream/sheath sidearm pressures would have been useful. However, the device used

for balloon occlusion in this case series precluded the gathering of such data. Has REBOA in these cases avoided cardiac arrest by merely stopping bleeding, or actually represented true endovascular resuscitation by augmenting coronary perfusion in a downward hemodynamic spiral pre-arrest phase, buying time for blood product loading and transport for definitive care?

As LAA is exclusively a trauma service, this case series excludes any bleeding etiology other than direct traumatic injury (for example, international hemorrhage and blood product usage databases indicate that a significant number of bleeding cases are particularly noted in the setting of peripartum hemorrhage). That said, most datasets also primarily focus on REBOA delivery in the setting of trauma. In addition, this is effectively a retrospective case series, with all the usual attendant biases, and contains fairly small numbers overall. It is possible that some cases where Zone 3 REBOA might have been delivered, (and might have been beneficial), may not have been offered the therapy (due to crew composition, decision-making challenges, environmental factors, proximity to hospital). Alternatively, the small number of patients identified as being amenable to REBOA may delineate the rarity of true Zone 3 REBOA cases and the difficulty of patient selection.

Finally, comparison of outcomes in patients that did and didn't have successful balloon inflation is potentially a little misleading. The authors do point this out in the limitations, but it bears repeating – patients in this study were not randomly allocated to receive the REBOA intervention. Thus the patient groups may well contain significant confounders. For example, one could imagine the group of patients that did not successfully achieve arterial access represented a group with more profound hypovolemia. It is interesting to note that no open access strategy for arterial cannulation is discussed.

Results, conclusion, and what it means

Firstly - it can save lives – Zone 3 REBOA is a deliverable prehospital therapy which improves hemodynamics, averts cardiovascular collapse and cardiac arrest, and reduces early hemorrhagic death in the setting of prehospital exsanguinating trauma.

Secondly, it's challenging – of the 19 cases where it was attempted due to exsanguinating pelvic hemorrhage, REBOA was only successful in 13 – the procedure failed in almost a third of cases. The limiting factor here was the operator's ability to gain access to the CFA using ultrasound guidance in the setting of shock. These patients did poorly. Where access was achieved, inadvertent SFA cannulation was common, and thrombus was ubiquitous across almost all trauma cases (11/13). The authors reasonably cite regional hypoperfusion, large access sheath size, direct arterial injury and concurrent administration of antifibrinolytics and procoagulant blood products as likely mediators. Thirdly, it's rare – during the study period, LAA attended over 8,000 patients. Zone 3 REBOA was only attempted in 21 patients, which represents 0.003%. The low frequency makes skill retention and case selection even more challenging.

Comments and future research

This is a valuable study outlining the benefits available from REBOA delivered by a closely-governed prehospital trauma resuscitation service in a tightly-compressed urban population. This kind of outcome is not generalizable across all prehospital services or regions by any means. In a relatively short time, LAA have now become skilled at nuanced aortic resuscitation, supported by prehospital blood products and backed-up by a world-leading hospital major trauma system. Future research with regards to Zoner REBOA, and human selective aortic arch perfusion, is ongoing.

ARTICLE NUMBER 2

Feasibility of Pre-Hospital Resuscitative Endovascular Balloon Occlusion of the Aorta in Non-Traumatic Out-of-Hospital Cardiac Arrest.

J Am Heart Assoc. 2019 Nov 19;8(22):e014394.

Brede JR, Lafrenz T, Klepstad P, Skjærseth EA, Nordseth T, Søvik E, Krüger AJ.

Abstract

Background: Few patients survive after out-of-hospital cardiac arrest and any measure that improves circulation during cardiopulmonary resuscitation is beneficial. Animal studies support that resuscitative endovascular balloon occlusion of the aorta (REBOA) during cardiopulmonary resuscitation might benefit patients suffering from out-of-hospital cardiac arrest, but human data are scarce.

Methods and Results: We performed an observational study at the helicopter emergency medical service in Trondheim (Norway) to assess the feasibility and safety of establishing REBOA in patients with out-of-hospital cardiac arrest (OHCA). All patients received advanced cardiac life support during the procedure. End-tidal CO₂ was measured before and after REBOA placement as a proxy measure of central circulation. A safety-monitoring program assessed if the procedure interfered with the quality of advanced cardiac life support. REBOA was initiated in 10 patients. The mean age was 63 years (range 50–74 years) and 7 patients were men. The REBOA procedure was successful in all cases, with 80% success rate on first cannulation attempt. Mean procedural time was 11.7 minutes (SD 3.2, range 8–16). Mean end-tidal CO₂ increased by 1.75 kPa after 60 seconds compared with baseline ($P < 0.001$). Six patients achieved return of spontaneous circulation (60%), 3 patients were admitted to hospital, and 1 patient survived past 30 days. The safety-monitoring program identified no negative influence on the advanced cardiac life support quality.

Conclusions: To our knowledge, this is the first study to demonstrate that REBOA is feasible during non-traumatic out-of-hospital cardiac arrest. The REBOA procedure did not interfere with the quality of the advanced cardiac life support. The significant increase in end-tidal CO₂ after occlusion suggests improved organ circulation during cardiopulmonary resuscitation.

Article review and analysis

Aim of this study: There are no existing clinical data on the use of REBOA in non-traumatic OHCA; however, there is physiological plausibility that it may be beneficial. Prior to undertaking a controlled clinical trial, the authors aimed to assess the feasibility of performing REBOA for non-traumatic OHCA. The primary aim was, therefore, to assess the feasibility of pre-hospital REBOA in patients with cardiac arrest. A secondary

aim was to observe changes in end-tidal CO₂ (EtCO₂) as a proxy measure of the effect on circulation from use of REBOA in OHCA.

Methods

Pros: This study used a convenience sample of patients who met pre-defined eligibility criteria and who were attended to by a team who had undergone a structured training program and achieved a specified competency level. The REBOA procedure used is standardized with an emphasis on safety, adequacy of ACLS and ensuring correct placement of the catheter. Ultrasound images were saved and reviewed, and a safety monitoring program was in place throughout. The study was prospectively approved by a regional ethics committee.

Cons: In this study patients were recruited regardless of presenting rhythm, with the commonest presenting rhythm being asystole. This is likely to have an adverse effect on outcomes of patients who undergo the procedure, as it essentially preselects a cohort where survival is extremely unlikely, no matter what resuscitation interventions are performed. During the REBOA procedure, EtCO₂ has been used to measure centralization of cardiac output, rather than an improvement in proximal invasive blood pressure. Post-mortem autopsy data were unavailable in the non-survivors, so potential adverse side effects of REBOA are unknown.

Results, conclusion, and what it means

The REBOA procedure was successfully undertaken in 10 patients who met the eligibility criteria; 5 other patients met eligibility criteria but REBOA was not undertaken. The predominant presenting rhythm was asystole (6/10), followed by VF/VT (3/10) and PEA (1/10). The authors report success in undertaking the REBOA procedure without any negative effects on the quality of ACLS, which is important in determining the feasibility of undertaking this procedure, in this patient group, in further research studies. In other words, REBOA did not hamper conventional resuscitation efforts. The REBOA procedure was associated with a return of spontaneous circulation (ROSC) in six out of ten patients, three survived to hospital admission and one was discharged after initiation of ECMO at day 8 with a good cerebral outcome. These results are in keeping with other reported OHCA survival rates (c.10%). The authors have been able to demonstrate that REBOA is feasible in a patient group with non-traumatic OHCA. However, it is worth considering the large proportion of asystolic patients in this study and low total numbers, making meaningful conclusions about survivability more challenging. They recommend further clinical trials to assess whether this procedure will result in improved patient outcomes.

Comments and future research

This is the first study of REBOA in medical OHCA, and paves the way for further assessment and development of this technique as a potential bridge to ROSC, or bridge to ECPR for services with advanced vascular access capabilities. In terms of future research, a study of the effects of in-arrest REBOA on coronary perfusion pressure in OHCA is planned in the UK (IRAS ID 296654). Additionally, a US study of REBOA in OHCA cases brought to hospital has published its protocol (Resuscitative EndoVascular Aortic Occlusion for Maximal Perfusion (REVAMP, Clinical Trials.gov Identifier NCT03703453) and Norwegian HEMS has a follow-on study planned.

ARTICLE NUMBER 3

Recent advances in austere combat surgery: Use of aortic balloon occlusion as well as blood challenges by special operations medical forces in recent combat operations.

J Trauma Acute Care Surg. 2018 Jul;85(1S Suppl 2):S98-S103.

Northern DM, Manley JD, Lyon R, Farber D, Mitchell BJ, Filak KJ, Lundy J, DuBose JJ, Rasmussen TE, Holcomb JB.

Abstract

Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) for control of noncompressible torso hemorrhage is a technology that is increasingly being utilized in the combat casualty setting. Its use in the resource restricted environment holds potential to improve hemorrhage control, decrease blood product utilization, decrease morbidity, and improve combat mortality. The objective of this report is to present the single largest series of REBOA use on severely injured combat casualties.

Methods: Over an 18-month period, austere surgical teams comprised of coalition partners provided initial damage control resuscitation (DCR) and surgical stabilization for over 2,300 combat casualties prior to transferring patients to the next level of trauma care.

Results: Twenty patients presented with injuries from explosion and gunshot wounds with mean initial heart rate of 129 bpm and mean initial systolic blood pressure of 71 mm Hg.

Femoral cutdowns were used in six patients. Aortic occlusion was achieved with REBOA catheter placement in Zone 1 (n = 17) and Zone 3 (n = 2). Systolic blood pressure increased an average of 56 mm Hg with aortic occlusion. There were no access related site complications. All patients survived transport to the next level of care. The majority of blood products transfused in this cohort were whole blood, largely supported by emergent blood drives.

Conclusions: This series demonstrates the potential for REBOA as a life-saving technique for the patient who presents with hemodynamic instability and noncompressible torso hemorrhage. Resuscitative endovascular balloon occlusion of the aorta allows austere surgical teams to rapidly stabilize severely injured combat casualties, expand capability, and provide enhanced DCR while minimizing personnel, resources, and blood product utilization. The use of “whole blood only” strategy for DCR shows potential to be superior to traditional component therapy, and when combined with “proactive” REBOA utilization, provides significant improvements in hemodynamics and hemorrhage control.

Article review and analysis

Aim of this study: Non-compressible torso hemorrhage presents a difficult problem for trauma teams. In the austere military setting, with limited staff, reduced blood stocks and basic equipment, this is multiplied manyfold. Perhaps the strongest argument for the use of endovascular resuscitation is in the setting of a remote military surgical capability, in the truly peri-arrest patient. REBOA in this cohort could allow immediate control of bleeding, offering the damage control resuscitation team a few moments in which to gain rapid venous access, start blood product administration and facilitate rapid anesthesia without inducing cardiovascular collapse, with immediate access to damage control surgery to follow.

Methods

This study is a retrospective case series reporting on a group of twenty patients who underwent damage control resuscitation with REBOA, blood products and emergency surgery. The unusual aspect here is the setting and the patient cohort; care was delivered by a United States Air Force Special Operations Surgical Team (SOST) – a six-person far-forward resuscitation and surgery team designed to support special operations missions. The cohort is exclusively ballistic trauma casualties from combat operations, presenting with shock.

Pros: This is the largest cases series of combat REBOA cases, where REBOA has been used as a formally-integrated adjunct to resuscitation immediately followed by open surgery. The authors have collected extensive data on mechanism of injury, time from point of injury, conscious level, baseline and subsequent hemodynamics, femoral access strategy, balloon occlusion zone and duration, surgical procedure(s), REBOA operator specialty, REBOA assistant specialty, and blood product requirements. The individual patient-level data is presented in a large, easy-to-read table. Additionally, they report on the access-site management, and a case of failed balloon deployment. They also go on to provide an extensive revision of deployed blood component therapy, and its challenges. Usefully, they describe the use of REBOA where the surgical facility is saturated with cases. This is an important concept for the EVTM community, where a lot of time and effort has been spent discussing, at length, “who should place REBOA”. These conversations usually end up with a circular debate between general surgery, trauma surgery and vascular surgery, with interventional radiology colleagues occasionally invited to wave their flag. In this paper, REBOA allowed EM specialists to rapidly gain hemodynamic control of dying, shocked patients, whilst the single surgeon finished the case currently on the table.

Cons: The caseload here is necessarily unusual. The 20 NCTH cases that are reported occurred over an 18-month period. During the surgical facility’s busiest 6 months, they report seeing 10-15 patients per day, of which 1 or 2 were surgical cases. We do not know the denominator here, i.e., how many similar cases existed who were not treated with REBOA, and what factors influenced these decisions. Did the SOST change personnel

during this time? Were there inter-operator differences in strategy and patient selection which might have caused a biased cohort? Were some surgeons more willing to embrace REBOA than others? What happened when the SOST were augmented by personnel from the US Army during a very busy period, for example.

Tantalizingly, we are told “it is likely that these 20 patients survived”. Due to their geographical location, and because patients were transferred out to host-nation facilities for further care (from which we can infer that these were all non-US nationals), no follow-up data are available to inform us about downstream thrombotic and vascular complications, or indeed survival outcomes. Would the effects of shock and subsequent balloon occlusion have manifested in multiple organ dysfunction and patient death after a longer period of observation? The authors describe a conservative approach to access site management, which perhaps reflects quite short aortic occlusions and vascular sheath times. Had these times been longer, it is likely that thrombus formation and embolization might have been an issue.

Results, conclusion, and what it means

This was a sick patient group, with a mean heart rate of 129 bpm and a mean systolic BP of 71 mmHg. All patients underwent eFAST, of which 19 were positive. Patients received immediate whole blood (mean dose 6.4 units). Arterial access was percutaneous in 14 cases, and open in 6. A 7-Fr sheath was used to deliver an ER-REBOA catheter, using an in-line transducer device (Centurion) in 15 cases. Using external landmark measurements alone, since fluoroscopy was unavailable, mean insertion depths were 47cm for Zone 1 and 26cm for Zone 3 deployments. The mean increase in SBP was 56 mmHg after balloon deployment, and mean balloon inflation times were short – a respectable 21 minutes (range, 7-34 minutes) across all cases. Partial REBOA was used where possible (mean time, 5.7 minutes).

REBOA was successful in 19 cases, who went on to have surgery which identified abdominal and pelvic injuries which were controlled. One case is reported where REBOA was not successful, possibly due to inadvertent balloon rupture. This patient underwent groin exploration, with successful surgical intervention on vascular injuries from a contralateral groin gunshot wound. The REBOA access site was explored and the device removed, with no device-related injury detected at surgery. At the end of the case, all balloon catheters and vascular sheaths were removed. Only 2 of the 14 percutaneous cases underwent arteriotomy and repair due to concern regarding puncture site bleeding; the remainder had 30 minutes of manual compression of the site, and subsequent physical assessment and Doppler confirmed good distal blood flow. Importantly for the deployed setting, REBOA was used to bridge access to surgical intervention in 8 cases where surgical capacity was exceeded by demand, due to multiple simultaneous cases arriving at the facility from mass-casualty incidents. Also reported are the intraoperative considerations that are not usually noted; REBOA was able to allow a relatively dry operative field – the advantages to a single surgeon, with no scrubbed assistant, using only a head-mounted torch, without cautery, are considerable.

The authors go on to outline the importance of avoiding excessive duration of aortic occlusion, and in particular caution regarding the proximity of surgery required to make REBOA a viable prehospital therapy, in its current format. They state that this paper solidifies the use of REBOA as a proactive resuscitation technique, aimed at preventing cardiovascular collapse. They go on to discuss the issue of access to low-tire type O whole blood, which removes the need for complex storage solutions, and increases the efficiency of blood stocks, since each unit contains all the elements required in a physiologically ideal hemostatic ratio, and they suggest that freeze-dried plasma should be pushed forward to medics at the point of injury.

Comments and future research

The skilled use of REBOA in the setting of a critically hypotensive NCTH patient about to undergo DCS is very much the sweet spot of basic endovascular resuscitation. For a resuscitation team working in an austere military setting, it can afford rapid hemodynamic optimization, averting cardiac arrest. Intraoperatively, REBOA can help the solo surgeon with visualization, offering a rapidly dry operating field and, in the setting of multiple casualties, REBOA can be used as a bridge to the operating table. REBOA needs to be delivered as part of a whole-system approach, linked in with training, access to resuscitation experts, blood products, and an experienced damage control surgeon.

REBOA should be viewed as an essential capability to be formally incorporated into military damage control surgery doctrine. The civilian sector should take heed of this case series, and learn to use it as a surgical adjunct, not a holding pattern tool.

ARTICLE NUMBER 4

A comparison of Selective Aortic Arch Perfusion and Resuscitative Endovascular Balloon Occlusion of the Aorta for the management of hemorrhage-induced traumatic cardiac arrest: A translational model in large swine.

PLoS Med. 2017 Jul 25;14(7):e1002349.

Barnard EBG, Manning JE, Smith JE, Rall JM, Cox JM, Ross JD.

Abstract

Background: Survival rates remain low after hemorrhage-induced traumatic cardiac arrest (TCA). Noncompressible torso hemorrhage (NCTH) is a major cause of potentially survivable trauma death. Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) at the thoracic aorta (Zone 1) can limit subdiaphragmatic blood loss and allow for IV fluid resuscitation when intrinsic cardiac activity is still present. Selective Aortic Arch Perfusion (SAAP) combines thoracic aortic balloon hemorrhage control with intra-aortic oxygenated perfusion to achieve return of spontaneous circulation (ROSC) when cardiac arrest has occurred.

Methods and findings: Male Yorkshire Landrace cross swine (80.0 ± 6.0 kg) underwent anesthesia, instrumentation for monitoring, and splenectomy. TCA was induced by laparoscopic liver lobe resection combined with arterial catheter blood withdrawal to achieve a sustained systolic blood pressure <10 mmHg, cardiac arrest. After 3 minutes of arrest, swine were allocated to one of three interventions: (1) REBOA plus 4 units of IV fresh whole blood (FWB), (2) SAAP with oxygenated lactated Ringer's (LR), 1,600 mL/2 min, or (3) SAAP with oxygenated FWB 1,600 mL/2 min. Primary endpoint was survival to the end of 60 min of resuscitation, a simulated prehospital phase. Thirty animals were allocated to 3 groups (10 per group)-5 protocol exclusions resulted in a total of 35 animals being used. Baseline measurements and time to cardiac arrest were not different amongst groups. ROSC was achieved in 0/10 (0%, 95% CI 0.00-30.9) REBOA, 6/10 (60%, 95% CI 26.2-87.8) SAAP-LR and 10/10 (100%, 95% CI 69.2-100.0) SAAP-FWB animals, $p < 0.001$. Survival to end of simulated 60-minute prehospital resuscitation was 0/10 (0%, 95% CI 0.00-30.9) for REBOA, 1/10 (10%, 95% CI 0.25-44.5) for SAAP-LR and 9/10 (90%, 95% CI 55.5-99.7) for SAAP-FWB, $p < 0.001$. Total FWB infusion volume was similar for REBOA ($2,452 \pm 0$ mL) and SAAP-FWB ($2,250 \pm 594$ mL). This study was undertaken in laboratory conditions, and as such may have practical limitations when applied clinically. Cardiac arrest in this study was defined by intra-aortic pressure monitoring that is not feasible in clinical practice, and as such limits the generalizability of findings. Clinical trials are needed to determine if the beneficial effects of SAAP-FWB observed in this laboratory study will translate into improved survival in clinical practice.

Conclusions: SAAP conferred a superior short-term survival over REBOA in this large animal model of hemorrhage-induced traumatic cardiac arrest with NCTH. SAAP using an oxygen-carrying perfusate was more effective in this study than non-oxygen carrying solutions in TCA. SAAP can effect ROSC from hemorrhage-induced electrocardiographic asystole in large swine.

Article review and analysis

Aim of this study: In this large animal model, 80kg pigs were exsanguinated to the point of cardiac arrest. The study compared three interventions to resuscitate the swine 3 minutes after they sustained arrest. The three interventions were: 1) thoracic REBOA with IV fresh whole blood (FWB), 2) SAAP with intra-aortic (IA) LR solution and 3) SAAP with FWB. Study timings were designed to model the prehospital phase of care and thus survival at 60 minutes was chosen as the primary end point. At 60 minutes, 0/10 of the REBOA pigs were alive, compared to 1/10 of the SAAP-LR group and 9/10 of the SAAP with IA FWB. The study also examined the effect of each intervention on the likelihood of gaining ROSC. ROSC was achieved in the SAAP groups (6/10 and 10/10) but not in the REBOA group (0/10). The study concluded that SAAP with IA FWB confers a significant survival advantage over the other two interventions in hemorrhage induced TCA in this animal model.

The study aimed to compare the ability of REBOA and SAAP in hemorrhage-induced TCA. In effect, the study is modelling current (both at the time of study design and still today in 2021) best endovascular practice – REBOA with intravenous FWB – vs a more elaborate endovascular intervention. The authors demonstrate that, in the presence of cardiac arrest, infusion of blood into the venous system while occluding the thoracic aorta is not sufficient to restore myocardial or cerebral blood flow. The study is an eloquent demonstration of a SAAP system improving outcomes in a model of hemorrhage-induced cardiac arrest.

Methods

Pros: As far as animal modelling goes, this really is as good as it gets. Large animal modelling is expensive, time-consuming and requires considerable expertise. The authors have a long history of excellence in trauma modelling at the United States Air Force Trauma and Resuscitation research program in San Antonio, Texas. The model of inducing hemorrhage by laparoscopic liver injury and uncontrolled hemorrhage was reproducible and is clinically relevant. The model addresses subjects with such profound blood loss that they have suffered a cardiac arrest and differentiates between subjects with low (cardiac) output state in trauma (LOST) and no-output state in trauma (NOST). Identification and differentiation of these two clinical states appears important due to their probable influence on selecting an effective endovascular strategy. The authors suggest that LOST may be resuscitable with REBOA but NOST most likely needs a different approach.

Quantification of the survivor's physiology at the end of the experimental protocol compared to the beginning is informative, as is the comparative relationships of SBP, EtCO₂, carotid artery blood flow and NIRS between the 3 different groups. Looking at these figures gives the impression that the SAAP-FWB group are pretty stable at 60 minutes while the remaining SAAP-LR group are starting to fade away at the end of the experimental protocol.

Cons: To achieve reproducible TCA the authors required a hybrid injury. Blood loss was achieved by both a laparoscopic injury to the left lobe of the liver (true NCTH and uncontrolled hemorrhage) and additional blood loss was achieved by controlled hemorrhage at 3mls/kg/min from the femoral artery. This was all after a laparotomy and splenectomy. As such, the injury mechanism doesn't perfectly model a realistic injury mechanism in humans. Nonetheless, the method resulted in a largely reproducible model of hemorrhage. Creating a reproducible model to compare the interventions is more important, in terms of interpreting the study intervention, than any translational deficits to humans. Notably, in the one death in the SAAP-FWB group at 60 minutes, the authors describe the inadvertent creation of a more severe injury which likely contributed to the animal's death. Thus, the usual caveats regarding the limitations of animal modelling should be acknowledged.

With all good studies the audience is left wanting more. Here the study concludes at 60 minutes and the reader is left wondering what happens next. It is not clear whether deflation of the balloon occlusion at this point would have been possible or whether the surviving pigs were dependent on the balloon for on-going cardiac output. Animal recovery including an assessment of the degree of end organ dysfunction following intervention would be clinically useful. Functional outcome here remains a big question. Would all of these surviving animals have developed fatal multiple organ dysfunction syndrome, for example?

Results, conclusion, and what it means

The study design addresses an important question: is it possible to do better than REBOA and IV FWB in cardiac arrest following exsanguination. The finding that SAAP can alter the survival of pigs in TCA after hemorrhage is important. The study demonstrates that survival is possible following TCA but is unlikely with REBOA and IV fluids alone. As such the study sheds light on which patients might be best suited to REBOA, i.e., those with NCTH that still have an intrinsic circulation (LOST). Whereas REBOA is unlikely to improve outcomes in patients with no-output (NOST), SAAP may be beneficial.

The inclusion of two SAAP groups is useful for conceptualizing how SAAP may be operationalized in human trauma systems; the effect of SAAP with a crystalloid infusate being demonstrably superior to REBOA and IV blood transfusion, but inferior to SAAP and intra-aortic infusion of FWB.

Comments and future research

The paper hints towards a world of potentially implementable endovascular resuscitation. The present pre-hospital/austere endovascular 'tool kit' consists really only of REBOA. In the future, it would be useful to consider a tailored approach to endovascular intervention based on the patient's clinical presentation. SAAP has the potential to facilitate emergency abdominopelvic hemorrhage control (and access to a (new) bleeding-free surgical field) with concomitant perfusion and thermal regulation or aortic arch, with preservation of cerebral and cardiac perfusion. Current practice in most austere settings for a potentially salvageable patient with no cardiac output would be thoracotomy for aortic control and open cardiac massage. This would be followed almost certainly by massive blood transfusion, laparotomy and almost certain patient death. SAAP offers a different strategy, with rapid resuscitation of central blood volume and perhaps a short hop to further extension, such as extra-corporeal life support.

Coming back to the present, while efforts to translate these findings into humans continue, the world still does not have a regulatory approved SAAP catheter for use in humans. As such, no in-human evaluations have been performed. Questions such as the technical challenges of emergency femoral artery access with 14Fr sheaths (current device size) in cardiac arrest remain unanswered.

Related important publications

For further reading on emerging endovascular techniques the reader is directed to this useful editorial:

Manning JE, Rasmussen TE, Tisherman SA, Cannon JW. Emerging hemorrhage control and resuscitation strategies in trauma: Endovascular to extracorporeal. *J Trauma Acute Care Surg.* 2020 Aug;89(2S Suppl 2):S50-S58.

ARTICLE NUMBER 5

Case Report of Extracorporeal Membrane Oxygenation and Aeromedical Evacuation at a Deployed Military Hospital.*Mil Med.* 2018 Mar 1;183(suppl_1):203-206.*Hamm MS, Sams VG, Della Volpe MJD, Lantry JH, Mason PE.***Abstract**

The U.S. Military no longer maintains overseas extracorporeal membrane oxygenation (ECMO) capability for patients with severe lung injury, including acute respiratory distress syndrome (ARDS). The authors present a case of severe ARDS at a military hospital in Afghanistan with limited capability for rescue therapies to include presentation, treatment, transport, and use of ECMO in the deployed military environment at one Role 3 medical facility. Lack of ECMO in the overseas environment is a significant gap in U.S. Military medical capability. The authors propose a novel solution, “ECMO packs,” for prepositioning at strategic Role 3 facilities for early intervention in patients with severe lung injury, to close this lethal and unnecessary capability gap.

Article review and analysis

Aim of this study: This article is presented as a case report which details the care of a UK contractor who contracted influenza B then developed ARDS/severe respiratory failure in a deployed setting. With only limited intensive care treatment available in the austere location, the patient required repatriation and transfer on VV-ECMO from a dedicated team based in the US. The authors highlight the capability gap now that the U.S. Military no longer have a dedicated rapidly deployable ECMO retrieval team. The authors highlight that, in the deployed environment, the availability of strategies beyond conventional ventilation and vasopressors is likely to be limited; this is likely to continue with a move to expeditionary style operations with scaled down medical facilities. Options such as airway pressure release ventilation, inhaled vasodilators (inhaled nitric oxide or epoprostenol sodium), high-frequency oscillatory ventilation and rotational beds are unlikely to be available. Despite extensive randomized controlled trial data for the use of ECMO in ARDS, there are very limited data from the deployed or austere setting and it may be difficult to extrapolate the results from these studies to this challenging environment.

Methods

The authors have produced a clear, narrative case report outlining the challenges in projecting and delivering advanced extracorporeal respiratory support for international retrieval of deployed personnel, in this case a military contractor.

Results, conclusions, and what it means

The authors conclude that it is likely, given the recent drawdown in overseas deployed facilities, that military and other services will need to address novel ways of delivering advanced respiratory support.

Comments and future research

Systems providing medical support to military deployments are currently developing to be much more agile than the traditional fixed-location field hospitals of old. This presents significant challenges as complex, logistically-burdensome equipment may be a hindrance to mobility. Most military medical services do not offer a dedicated ECMO-capable service across their deployed footprint as a matter of routine; basic endovascular techniques are only just becoming available in the deployed setting. One model of addressing this might be by partnering with host national civilian specialist centers, augmented with a hub of specially-trained critical care military retrieval specialists with endovascular and ECMO expertise.

i Related important publications

For further reading on long-distance, military-integrated ECMO delivery and retrieval services, the reader is directed to this interesting paper:

Lebreton G, Sanchez B, Hennequin JL, Resière D, Hommel D, Léonard C, Mehdaoui H, Roques F. The French airbridge for circulatory support in the Carribean. *Interact Cardiovasc Thorac Surg.* 2012 Sep;15(3):420-5.

CHAPTER 3.

Damage Control Resuscitation (DCR) in trauma

Authors: Miklosh Bala and Asaf Kedar

Introduction

The optimal strategy for managing hemorrhaging trauma patients is now called damage control resuscitation (DCR). DCR began in the 1980s as trauma surgeons looked for better ways to take care of critically injured patients. It has grown into a set of principles allowing immediately life-threatening procedures in metabolically deranged patients (Figure 1). This provides time to correct coagulopathy and complete resuscitation before definitive management of injuries. DCR aims to limit blood loss and prevent coagulopathy by combining hypotensive resuscitation, early airway control, and early and balanced use of blood products and other hemostatic agents.

It has proven successful in combat casualty care, guiding the translation of DCR principles to civilian trauma care as well. During the past decade, the practice of massive transfusion (MT) has expanded considerably from simply a definition to now being a more comprehensive management strategy for hemorrhagic shock. Moreover, many resuscitation principles developed in the context of care of the seriously injured patient are applicable to the management of severe hemorrhage occurring as a complication in other specialties, such as vascular and cardiovascular surgery, transplant surgery, critical care, cardiology, general surgery, obstetrics, and neurosurgery.

Damage control resuscitation is not a single technique, but a group of strategies which address the lethal triad of coagulopathy, acidosis, and hypothermia. In this chapter, we describe this approach to trauma resuscitation and the supporting evidence base.

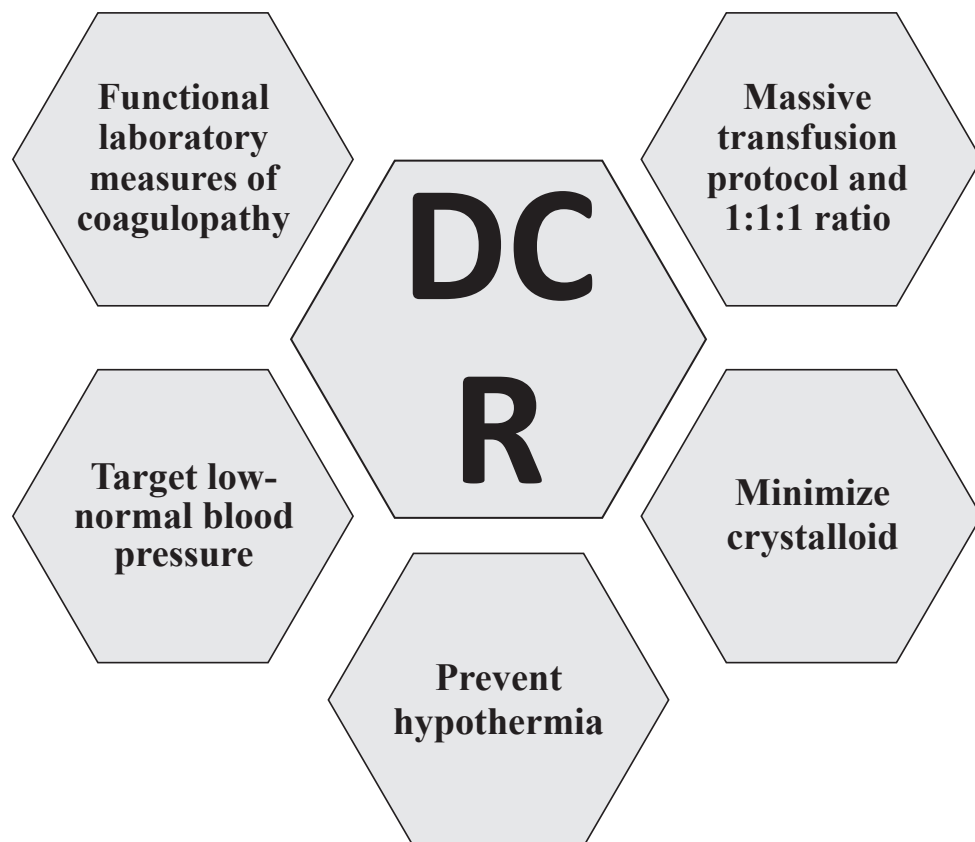


Figure 1. Philosophies of DCR

ARTICLE NUMBER 1

Transfusion of Plasma, Platelets, and Red Blood Cells in a 1:1:1 vs a 1:1:2 Ratio and Mortality in Patients With Severe Trauma: The PROPPR Randomized Clinical Trial.

JAMA. 2015 Feb 3;313(5):471-82.

Holcomb JB, Tilley BC, Baraniuk S, Fox EE, Wade CE, Podbielski JM, del Junco DJ, Brasel KJ, Bulger EM, Callcut RA, Cohen MJ, Cotton BA, Fabian TC, Inaba K, Kerby JD, Muskat P, O'Keeffe T, Rizoli S, Robinson BR, Scalea TM, Schreiber MA, Stein DM, Weinberg JA, Callum JL, Hess JR, Matijevic N, Miller CN, Pittet JF, Hoyt DB, Pearson GD, Leroux B, van Belle G; PROPPR Study Group.

Abstract

Importance: Severely injured patients experiencing hemorrhagic shock often require massive transfusion. Earlier transfusion with higher blood product ratios (plasma, platelets, and red blood cells), defined as damage control resuscitation, has been associated with improved outcomes; however, there have been no large multicenter clinical trials.

Objective: To determine the effectiveness and safety of transfusing patients with severe trauma and major bleeding using plasma, platelets, and red blood cells in a 1:1:1 ratio compared with a 1:1:2 ratio.

Design, setting, and participants: Pragmatic, phase 3, multisite, randomized clinical trial of 680 severely injured patients who arrived at 1 of 12 level I trauma centers in North America directly from the scene and were predicted to require massive transfusion between August 2012 and December 2013.

Interventions: Blood product ratios of 1:1:1 (338 patients) vs 1:1:2 (342 patients) during active resuscitation in addition to all local standard-of-care interventions (uncontrolled).

Main outcomes and measures: Primary outcomes were 24-hour and 30-day all-cause mortality. Prespecified ancillary outcomes included time to hemostasis, blood product volumes transfused, complications, incidence of surgical procedures, and functional status.

Results: No significant differences were detected in mortality at 24 hours (12.7% in 1:1:1 group vs 17.0% in 1:1:2 group; difference, -4.2% [95% CI, -9.6% to 1.1%]; $P = .12$) or at 30 days (22.4% vs 26.1%, respectively; difference, -3.7% [95% CI, -10.2% to 2.7%]; $P = .26$). Exsanguination, which was the predominant cause of death within the first 24 hours, was significantly decreased in the 1:1:1 group (9.2% vs 14.6% in 1:1:2 group; difference, -5.4% [95% CI, -10.4% to -0.5%]; $P = .03$). More patients in the 1:1:1 group achieved hemostasis than in the 1:1:2 group (86% vs 78%, respectively; $P = .006$). Despite the 1:1:1 group receiving more plasma (median of 7 U vs 5 U, $P < .001$) and platelets (12 U vs 6 U, $P < .001$) and similar amounts of red blood cells (9 U) over the first 24 hours, no differences between the 2 groups were found for the 23 prespecified complications, including acute respiratory distress syndrome, multiple organ failure, venous thromboembolism, sepsis, and transfusion-related complications.

Conclusions and relevance: Among patients with severe trauma and major bleeding, early administration of plasma, platelets, and red blood cells in a 1:1:1 ratio compared with a 1:1:2 ratio did not result in significant differences in mortality at 24 hours or at 30 days. However, more patients in the 1:1:1 group achieved hemostasis and fewer experienced death due to exsanguination by 24 hours. Even though there was an increased use of plasma and platelets transfused in the 1:1:1 group, no other safety differences were identified between the 2 groups.

Article review and analysis

Aim of this study: The Pragmatic, Randomized Optimal Platelet and Plasma Ratios (PROPPR) Trial was designed to address the effectiveness and safety of a 1:1:1 transfusion ratio vs a 1:1:2 ratio in patients with trauma who were predicted to require a massive transfusion.

Methods

Pros: PROPPR was designed as a randomized, two-group, Phase III trial conducted in subjects with the highest level of trauma activation and predicted to require a massive transfusion. Subjects at 12 North American Level I civilian trauma centers were randomized to one of two standard transfusion ratio interventions: 1:1:1 or 1:1:2, (plasma, platelets, and red blood cells). While the assignment of transfusion ratios was randomized, no other clinical procedures or aspects of patient care were altered by the study.

Clinical data, serial blood samples and outcomes were collected. Mortality endpoints of 24 hours and 30 days were evaluated. The clinical hypotheses were to show that 1:1:1 is better compared to 1:1:2.

PROPPR incorporated complex inclusion and exclusion criteria to facilitate enrollment of severely injured patients who had a high risk of mortality from bleeding and to reduce selection bias to a minimum.

Cons: This study could not definitively establish a benefit of < 10% difference in mortality between 1:1:1 and 1:1:2 groups. The Kaplan-Meier curves for a 3-hour endpoint showed a statistically significant mortality difference between the two groups, but this was not one of the allowed primary outcomes. Physicians were not blinded once the transfusion protocol begun. The protocol used was unable to completely exclude patients with an unsurvivable brain injury (23% of deaths at 24 hours and 38% of deaths at 30 days).

Results, conclusion, and what it means

- No statistically significant difference in mortality at 24 hours or at 30 days.
- Exsanguination in first 24 hours (secondary outcome) significantly decreased in the 1:1:1 group vs the 1:1:2 group (9.2% vs 14.6%; $p = 0.03$).
- More patients achieved hemostasis in the 1:1:1 group vs the 1:1:2 group (86% vs 78%; $p = 0.006$).
- More plasma (Median 7 Units vs 5 Units) and platelets (Median 12 Units vs 6 Units) were used in the 1:1:1 ratio vs the 1:1:2 ratio.
- No difference in complications between the two strategies.

The PROPPR trial demonstrated that early hemostatic intervention is important in a proportion of severely injured patients. This asymmetry in platelet administration between groups can be seen clearly in the results of the PROPPR trial, which reported a median platelet dose of 12 units in the 1:1:1 group but only 6 in the 1:1:2 group ($P < 0.001$). Cryoprecipitate administration in the PROPPR study was not controlled.

In addition, because PROPPR subjects were >75% men of approximately 34 years of age, clinicians should be cautious in applying these findings to major obstetrical, gastrointestinal, or cardiac surgery hemorrhage.

Comments and future research

Rather than focusing our efforts on finding an ideal resuscitative transfusion formula, we advocate continuous reassessment of ongoing hemostasis changes in individual patients guided by point-of-care coagulation monitoring. This approach turns the massive “transfusion” protocol into a massive “hemorrhage” protocol. The indications and end point of plasma use, platelet administration, and cryoprecipitate could perhaps be better guided by viscoelastic testing than by empiric formulas. Holcomb et al. suggest that point-of-care testing using thromboelastography predicts transfusion needs and correlates with mortality. Another dose-guided algorithm for use in trauma patients has been suggested by Johansson et al., which indicates a dose of transfusion therapy that is graded to the degree of hemostatic impairment. Tapia et al. have used point-of-care viscoelastic testing in an algorithmic fashion for determining transfusion therapy for trauma patients.

Rather than focusing on the application of a massive transfusion protocol, it may be more appropriate for clinicians to focus on a massive hemorrhage protocol that addresses patient-specific factors, source control of bleeding, hemostatic monitoring, and the optimization of relevant physiologic parameters.

i Related important publications

Holcomb JB, Minei KM, Scerbo ML, Radwan ZA, Wade CE, Kozar RA, Gill BS, Albarado R, McNutt MK, Khan S, Adams PR, McCarthy JJ, Cotton BA. Admission rapid thrombelastography can replace conventional coagulation tests in the emergency department: experience with 1974 consecutive trauma patients. *Ann Surg*. 2012 Sep;256(3):476-86.

Johansson PI, Sørensen AM, Larsen CF, Windeløv NA, Stensballe J, Perner A, Rasmussen LS, Ostrowski SR. Low hemorrhage-related mortality in trauma patients in a Level I trauma center employing transfusion packages and early thromboelastography-directed hemostatic resuscitation with plasma and platelets. *Transfusion*. 2013 Dec;53(12):3088-99.

Tapia NM, Chang A, Norman M, Welsh F, Scott B, Wall MJ Jr, Mattox KL, Suliburk J. TEG-guided resuscitation is superior to standardized MTP resuscitation in massively transfused penetrating trauma patients. *J Trauma Acute Care Surg*. 2013 Feb;74(2):378-85; discussion 385-6.

ARTICLE NUMBER 2

A controlled resuscitation strategy is feasible and safe in hypotensive trauma patients: results of a prospective randomized pilot trial.

J Trauma Acute Care Surg. 2015 Apr;78(4):687-95; discussion 695-7.

Schreiber MA, Meier EN, Tisherman SA, Kerby JD, Newgard CD, Brasel K, Egan D, Witham W, Williams C, Daya M, Beeson J, McCully BH, Wheeler S, Kannas D, May S, McKnight B, Hoyt DB; ROC Investigators.

Abstract

Background: Optimal resuscitation of hypotensive trauma patients has not been defined. This trial was performed to assess the feasibility and safety of controlled resuscitation (CR) versus standard resuscitation (SR) in hypotensive trauma patients.

Methods: Patients were enrolled and randomized in the out-of-hospital setting. Nineteen emergency medical services (EMS) systems in the Resuscitation Outcome Consortium participated. Eligible patients had an out-of-hospital systolic blood pressure (SBP) of 90 mm Hg or lower. CR patients received 250 mL of fluid if they had no radial pulse or an SBP lower than 70 mm Hg and additional 250-mL boluses to maintain a radial pulse or an SBP of 70 mm Hg or greater. The SR group patients received 2 L initially and additional fluid as needed to maintain an SBP of 110 mm Hg or greater. The crystalloid protocol was maintained until hemorrhage control or 2 hours after hospital arrival.

Results: A total of 192 patients were randomized (97 CR and 95 SR). The CR and SR groups were similar at baseline. The mean (SD) crystalloid volume administered during the study period was 1.0 L (1.5) in the CR group and 2.0 L (1.4) in the SR group, a difference of 1.0 L (95% confidence interval [CI], 0.6-1.4). Intensive care unit-free days, ventilator-free days, renal injury, and renal failure did not differ between the groups. At 24 hours after admission, there were 5 deaths (5%) in the CR group and 14 (15%) in the SR group (adjusted odds ratio, 0.39; 95% CI, 0.12-1.26). Among patients with blunt trauma, 24-hour mortality was 3% (CR) and 18% (SR) with an adjusted odds ratio of 0.17 (0.03-0.92). There was no difference among patients with penetrating trauma (9% vs. 9%; adjusted odds ratio, 1.93; 95% CI, 0.19-19.17).

Conclusion: CR is achievable in out-of-hospital and hospital settings and may offer an early survival advantage in blunt trauma. A large-scale, Phase III trial to examine its effects on survival and other clinical outcomes is warranted.

Article review and analysis

Aim of this study: This out-of-hospital, prospective, randomized pilot trial was performed to assess the feasibility and safety of hypotension for the early resuscitation of patients with traumatic shock caused by blunt or penetrating mechanisms. The

authors hypothesized that controlled resuscitation would result in a significant reduction in the quantity of early crystalloid administration without an increase in morbidity or mortality.

Methods

Pros: This is a complex and thus unique study performed in an out-of-hospital environment, but well controlled by a strict protocol. The protocol used is well described and can be used as an example of the feasibility of randomization of sick trauma patients: quickly and effectively. Coordination of the study performed by 19 EMS from 2 countries required a huge amount of work and pushes large-scale study protocols out of the emergency department into the field.

Cons: The authors looked at 24-hour mortality as a primary outcome. But the question is: did survival curves showed a more specific time of death? Probably in this type of study when an intervention is short, it is better to use short outcome frames: 6 hours, 12 and 24 hours. Indeed, 11 hemorrhagic shock deaths occurred within a few hours. The protocol requires the training of EMS agencies in making an exception to informed consent and assessing the patient's status at the scene. Lastly, it is hard to justify a "standard" initial 2 L bolus of fluid, with additional fluid to maintain SBP, when all modern evidence (even the 10th Edition of ATLS) is against using crystalloids.

Results, conclusion, and what it means

- No difference in 24-hour mortality (5.2% versus 14.7%) or in-hospital mortality (8.4% versus 16.5%) for the controlled versus standard resuscitation
- The blunt trauma subgroup with controlled resuscitation had decreased mortality (3.2% versus 17.7%)
- No differences were seen in major surgical procedures, renal function, ICU-free days, or ventilator-free days

Schreiber et al. concluded that hypotensive resuscitation is feasible and safe for the initial resuscitation of trauma patients in a civilian environment, beginning in the out-of-hospital setting and extending into early hospital care. This strategy resulted in a reduction of early crystalloid resuscitation volume of approximately one liter and an increase in early blood product transfusion and, of course, that large volume crystalloid resuscitation is not advantageous and that a period of hypotension is reasonably well tolerated.

The study protocol declared that the SBP of 90 mmHg or lower might not be low enough to exclude minimally injured patients; however, 2/3 of their patients still had an ISS lower than 15.

Based on this, and a few other studies, the 10th edition of the Advanced Trauma Life Support (ATLS) course made content changes related to resuscitation strategies.

Similarly, an updated European guideline on the management of bleeding and coagulopathy following major trauma focused on targeting systolic blood pressure to 80 mm Hg. These guidelines also provide a contraindication to the hypotensive approach for patients with TBI and spinal injuries, and careful consideration must be given when treating elderly patients or those with chronic arterial hypertension.

Comments and future research

The randomized controlled trials have demonstrated that aggressive fluid resuscitation in the prehospital and hospital setting leads to more complications than hypotensive resuscitation, especially in penetrating torso trauma. The vital sign definition is not well defined and may vary due to age and comorbidities. There is still a need for a large, multicenter trial that can examine the benefit of hypotensive resuscitation in both blunt and penetrating trauma patients.

Growing evidence has accumulated regarding the negative effects of overly aggressive crystalloid resuscitation and the benefits of early prehospital blood product transfusion in those with significant risk of hemorrhage. In both military and civilian settings, packed red blood cell transfusion, when initiated early after injury, has been shown to be associated with a survival benefit for air medical transport patients. Prehospital plasma has similarly been demonstrated to reduce mortality in patients at risk of hemorrhagic shock. Cold-stored whole-blood transfusion has become available for civilian in-hospital resuscitation.

i Related important publications

Bickell WH, Wall MJ Jr, Pepe PE, Martin RR, Ginger VF, Allen MK, Mattox KL. Immediate versus delayed fluid resuscitation for hypotensive patients with penetrating torso injuries. *N Engl J Med*. 1994 Oct 27;331(17):1105-9.

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Sperry JL, Guyette FX, Brown JB, Yazer MH, Triulzi DJ, Early-Young BJ, Adams PW, Daley BJ, Miller RS, Harbrecht BG, Claridge JA, Phelan HA, Witham WR, Putnam AT, Duane TM, Alarcon LH, Callaway CW, Zuckerbraun BS, Neal MD, Rosengart MR, Forsythe RM, Billiar TR, Yealy DM, Peitzman AB, Zenati MS; PAMPer Study Group. Prehospital Plasma during Air Medical Transport in Trauma Patients at Risk for Hemorrhagic Shock. *N Engl J Med*. 2018 Jul 26;379(4):315-326.

Yazer MH, Jackson B, Sperry JL, Alarcon L, Triulzi DJ, Murdock AD. Initial safety and feasibility of cold-stored uncrossmatched whole blood transfusion in civilian trauma patients. *J Trauma Acute Care Surg*. 2016 Jul;81(1):21-6.

ARTICLE NUMBER 3

Goal-directed Hemostatic Resuscitation of Trauma-induced Coagulopathy: A Pragmatic Randomized Clinical Trial Comparing a Viscoelastic Assay to Conventional Coagulation Assays.

Ann Surg. 2016 Jun;263(6):1051-9.

MP, Chin TL, Ghasabyan A, Wohlaue MV, Barnett CC, Bensard DD, Biffl WL, Burlew CC, Johnson JL, Pieracci FM, Jurkovich GJ, Banerjee A, Silliman CC, Sauaia A.

Abstract

Background: Massive transfusion protocols (MTPs) have become standard of care in the management of bleeding injured patients, yet strategies to guide them vary widely. We conducted a pragmatic, randomized clinical trial (RCT) to test the hypothesis that an MTP goal directed by the viscoelastic assay thrombelastography (TEG) improves survival compared with an MTP guided by conventional coagulation assays (CCA).

Methods: This RCT enrolled injured patients from an academic level-1 trauma center meeting criteria for MTP activation. Upon MTP activation, patients were randomized to be managed either by an MTP goal directed by TEG or by CCA (ie, international normalized ratio, fibrinogen, platelet count). Primary outcome was 28-day survival.

Results: One hundred eleven patients were included in an intent-to-treat analysis (TEG = 56, CCA = 55). Survival in the TEG group was significantly higher than the CCA group (log-rank $P = 0.032$, Wilcoxon $P = 0.027$); 20 deaths in the CCA group (36.4%) compared with 11 in the TEG group (19.6%) ($P = 0.049$). Most deaths occurred within the first 6 hours from arrival (21.8% CCA group vs 7.1% TEG group) ($P = 0.032$). CCA patients required similar number of red blood cell units as the TEG patients [CCA: 5.0 (2-11), TEG: 4.5 (2-8)] ($P = 0.317$), but more plasma units [CCA: 2.0 (0-4), TEG: 0.0 (0-3)] ($P = 0.022$), and more platelets units [CCA: 0.0 (0-1), TEG: 0.0 (0-0)] ($P = 0.041$) in the first 2 hours of resuscitation.

Conclusions: Utilization of a goal-directed, TEG-guided MTP to resuscitate severely injured patients improves survival compared with an MTP guided by CCA and utilizes less plasma and platelet transfusions during the early phase of resuscitation.

Article review and analysis

Aim of this study: This is a well-designed, randomized trial at a single institution to compare the effect of an MTP goal directed by TEG to a standard MTP guided by CCA, with survival as a primary outcome.

Methods

Pros: The Denver trauma group conducted a randomized study: MTP activation was a trigger to start randomization (on alternate weeks – because it is a single institution

and involved the same treating team). The institution already had experience with all coagulation assays: TEG, ROTEM and CCA. An initiation of MTP was not related to assay results, and initially patients received 4 PC and 2 FFP per protocol.

Cons: The alternative to conventional laboratory assessment of clotting functions is whole blood viscoelastic hemostatic assays (VHA). The current US FDA approved methods are TEG and ROTEM. In trauma, especially in the US, TEG has preference even though ROTEM gives more precise data on thrombocyte function.

Despite the similarity in demographics, injury severity, coagulopathy score, and coagulation assays upon ED arrival between the study groups, it is possible that the 2 groups differed regarding unmeasured variables and that the increased mortality seen in the CCA group could be explained by greater risk of death.

Results, conclusion, and what it means

- Survival in the TEG group was significantly higher than the CCA group (log-rank $P = 0.032$, Wilcoxon $P = 0.027$); 20 deaths in the CCA group (36.4%) compared with 11 in the TEG group (19.6%) ($P = 0.049$).
- Most deaths occurred within the first 6 hours after arrival (21.8% CCA group vs 7.1% TEG group) ($P = 0.032$).
- CCA patients required a similar number of red blood cell units as the TEG patients, but more plasma units and more platelet units during the first 2 hours of resuscitation.

MTP protocols were designed to establish the timely and coordinated delivery of blood products throughout the hospital and clearly became evidence-based guidelines for the management of bleeding trauma patients. The role of point-of-care-testing (TEG) is in guiding use of therapeutic adjuncts to blood products such as calcium, tranexamic acid and prothrombin complex concentrates. Thus, the question is: what is the impact of MTP on survival and how “much” did TEG augment the survival?

The 2 groups were managed similarly regarding crystalloid administration and RBC transfusion at every time point. The TEG group received less PLA and FFP. The implications of plasma and platelet transfusion on the development of organ dysfunction after trauma have been well documented¹ and influence mortality.

The study was designed not to test one coagulation assay against the other, but to characterize how trauma care delivered in 2 real-world clinical scenarios: a trauma center that only has CCA available to guide an MTP and a trauma center that has TEG available to guide an MTP.

Comments and future research

An economic evaluation for both TEG and ROTEM was performed for NICE (National Institute for Health and Care Excellence). It was found that TEG (or ROTEM) was more cost effective than standard care tests². However, as there were limited data available from trauma patients, results were extrapolated from other populations. Although

there was a reduction in wastage of all blood products in this group compared to the pre-TEG group. This is of particular importance given that blood product resources are highly valuable, and their collection, processing, and storage are associated with significant costs. A multicenter, international study is required to finalize the benefit of viscoelastic assays given the disparity of transfusion protocols.

Clinical studies are required to compare the efficacy and cost effectiveness of viscoelastic assays transfusion algorithms with standard care during obstetric and transplant bleedings. The routine use of TEG is still not studied in routine trauma practice, when there is no need for immediate MTP activation.

i Related important publications

Johnson JL, Moore EE, Kashuk JL, Banerjee A, Cothren CC, Biffi WL, Sauaia A. Effect of blood products transfusion on the development of postinjury multiple organ failure. *Arch Surg.* 2010 Oct;145(10):973-7.

Cochrane C, Chinna S, Um JY, Dias JD, Hartmann J, Bradley J, Brooks A. Site-Of-Care Viscoelastic Assay in Major Trauma Improves Outcomes and Is Cost Neutral Compared with Standard Coagulation Tests. *Diagnostics (Basel).* 2020 Jul 17;10(7):486.

ARTICLE NUMBER 4

Improving mortality in trauma laparotomy through the evolution of damage control resuscitation: Analysis of 1,030 consecutive trauma laparotomies.

J Trauma Acute Care Surg. 2017 Feb;82(2):328-333.

Joseph B, Azim A, Zangbar B, Bauman Z, O'Keeffe T, Ibraheem K, Kulvatunyou N, Tang A, Latifi R, Rhee P.

Abstract

Background: The aim of this study was to evaluate the related change in outcomes (mortality, complications) in patients undergoing trauma laparotomy (TL) with the implementation of damage control resuscitation (DCR). We hypothesized that the implementation of DCR in patients undergoing TL is associated with better outcomes.

Methods: We analyzed 1,030 consecutive patients with TL. Patients were stratified into three phases: pre-DCR (2006-2007), transient (2008-2009), and post-DCR (2010-2013). Resuscitation fluids (crystalloids and blood products), injury severity score (ISS), vital signs, and laboratory (hemoglobin, international normalized ratio, lactate) parameters were recorded. Regression analysis was performed after adjusting for age, ISS, laboratory and vital parameters, comorbidities, and resuscitation fluids to identify independent predictors for outcomes in each phase.

Results: Patient demographics and ISS remained the same throughout the three phases. There was a significant reduction in the volume of crystalloid ($p = 0.001$) and a concomitant increase in the blood product resuscitation ($p = 0.04$) in the post-DCR phase compared to the pre-DCR and transient DCR phases. Volume of crystalloid resuscitation was an independent predictor of mortality in the pre-DCR (OR [95% CI]: 1.071 [1.03-1.1], $p = 0.01$) and transient (OR [95% CI]: 1.05 [1.01-1.14], $p = 0.01$) phases; however, it was not associated with mortality in the post-DCR phase (OR [95% CI]: 1.01 [0.96-1.09], $p = 0.1$). Coagulopathy ($p = 0.01$) and acidosis ($p = 0.02$) were independently associated with mortality in all three phases.

Conclusion: The implementation of DCR was associated with improved outcome in patients undergoing TL. There was a decrease in the use of damage control laparotomy, with a decrease in the use of crystalloid and an increase in the use of blood products.

Article review and analysis

Aim of this study: This is a retrospective work to observe the outcome over time of patients undergoing trauma laparotomy from the phases pre-DCR period, transient period and the period where DCR is well established.

Methods

Pros: The transition period or the learning curve period can be challenging to evaluate. In this work the division into three time periods, pre-, transition and post-, allows the isolation of this learning curve period and observes the trends of change until it is stabilized and has become statistically significant in the post-period. Also, most of the important elements of DCR were addressed: use of blood and blood products, use of crystalloids, damage control laparotomy (DCL), acidosis and coagulopathy. Every trauma center has slightly different trauma systems and protocols, a single center study eliminates the bias from the different trauma systems in a multicenter study.

Cons: One of the strongest cons of many trauma studies is that they are retrospective. No one will argue that a well-designed randomized prospective study will provide a stronger level of evidence. One of the cornerstones of DCR is permissive hypotension; however, it was not stated what the goals of resuscitation were. It did not elaborate on what injuries were observed and the action taken during trauma laparotomy, similarly little information of associated injuries is given. Perhaps details of the injuries and procedures would give a better understanding of the trauma patients with DCL & DCR.

Results, conclusion, and what it means

The three study groups, pre-, transient, and post-, were similar concerning age, gender, mechanism, ISS. The difference in time period, pre, transient (2 years) and post (4 years), contributed significantly more patients in the post group.

It is possible to observe the shift in treatment paradigm:

- Significant reduction in volume of crystalloid, from 9.1 L in the pre period to 5.1 L in the post period ($p < 0.001$).
- Significant increase of blood products from 0.85 L to 1.91 L ($p = 0.03$), also the ratio of FFP/platelets/pRBC has improved from 10:8:17 to 7:7:8, a ratio that is practically 1:1:1.

A proper resuscitation allowed more trauma laparotomies to be accomplished without open abdomen (reduction of 24.5%). The reduction in patients with open abdomen has a dramatic effect on ICU-LOS (pre-DCR= 4, post-DCR=1, $p < 0.001$), complication rate (pre-DCR 38%, post-DCR 19%, $p = 0.001$), resource usage (e.g., hospital costs pre-DCR 25,738\$, post-DCR 18,656\$, $p = 0.04$), the rate of reconstruction of abdominal wall surgery, and much more.

The reduction of the mortality rate is impressive, from 17% in the pre-period to 11% in the post- period ($p = 0.001$).

Acidosis and coagulopathy are independently associated with mortality in all phases, hence the triad of death is valid and the resuscitation needs to tackle acidosis, coagulopathy and hypothermia (which aggravates acidosis and coagulopathy).

The results of this work demonstrate a significant improvement in outcome for trauma patients using the principles of DCR. The improvement in outcome is probably due

to the synergy between the different elements of DCR and not a single one, hence we should use all the elements of DCR and not just a few of them while resuscitating a trauma patient.

Comments and future research

Conducting a prospective randomized controlled study comparing DCR to other methods of resuscitation will not be ethical, since there is huge body of evidence concerning its usefulness. However, a better understanding of how the different elements of DCR are contributing would be useful and perhaps try to reduce surgeon-related factors. In addition, understand better who could benefit the most from DCR-DCL.

i Related important publications

Cannon JW, Khan MA, Raja AS, Cohen MJ, Como JJ, Cotton BA, Dubose JJ, Fox EE, Inaba K, Rodriguez CJ, Holcomb JB, Duchesne JC. Damage control resuscitation in patients with severe traumatic hemorrhage: A practice management guideline from the Eastern Association for the Surgery of Trauma. *J Trauma Acute Care Surg.* 2017 Mar;82(3):605-617.

Duchesne JC, McSwain NE Jr, Cotton BA, Hunt JP, Dellavolpe J, Lafaro K, Marr AB, Gonzalez EA, Phelan HA, Bilski T, Greiffenstein P, Barbeau JM, Rennie KV, Baker CC, Brohi K, Jenkins DH, Rotondo M. Damage control resuscitation: the new face of damage control. *J Trauma.* 2010 Oct;69(4):976-90.

Naumann DN, Khan MA, Smith JE, Rickard R, Woolley T. Future strategies for remote damage control resuscitation after traumatic hemorrhage. *J Trauma Acute Care Surg.* 2019 Jan;86(1):163-166.

CHAPTER 4.

Hybrid suites and treatment of bleeders

Authors: *Matteo Renzulli, Daniele Spinelli, Nicolò Brandi and Rita Golfieri*

Introduction

Over the past decades, many tertiary and non-tertiary trauma centers around the world have adopted a new profile in the structure of their emergency departments, placing the operating theaters side by side with the radiological diagnostic and interventional rooms. The intent of this structural renewal was to reduce treatment delays resulting from transferring patients from computed tomography (CT) scanners to surgical or interventional rooms. Reducing this downtime represents one of the most important paradigms of the Advanced Trauma Life Support (ATLS), which suggests avoiding any waste of time in order to increase the survival chances of trauma patients. The revolution in the treatment of trauma patients subsequently continued with the introduction of the Hybrid Emergency Room System (HERS). In fact, in 2011, HERS was introduced to continue the path of change that started with the restyling of emergency departments, initiated in order to reduce the time between diagnosis and treatment of trauma patients, maximizing the workflow efficiency. In fact HERS is composed of a sliding CT scanner system combined with an interventional radiological system (IRS), for example, a self-propelled C-Arm angiograph. Furthermore, the same suite room that hosts the CT scanner system and the angiograph could also be equipped with high-performance ultrasound (US), useful for performing FAST-US (Focused Assessment with Sonography for Trauma) and central venous catheter (CVC) positioning, a monitoring screen, and a mechanical ventilator in order to be able to perform in the same space, and possibly at the same time, all the examinations and life-saving maneuvers required for trauma patients. In other words, HERS offers the possibility of performing the diagnostic and interventional/surgical procedures in a single room,

making a sort of “one-step” move of severe trauma patients from the first access to their diagnosis and treatment phases. Moreover, trauma patients can benefit from a further reduction of unnecessary time elapsing between the diagnostic and treatment phases as well as between different types of operative procedures, from resuscitation to interventional procedures, thanks to the possibility of being able to complete all these procedures on the same table, without the patient having to be transferred to other rooms or departments.

The adoption of this new approach requires the implementation of new executive protocols for trauma teams. Moreover, trauma teams will need specific preparation in order to be capable of achieving top performances in these new operating contexts.

For these reasons, in the present as well as in the near future, the entire EVTm scientific community recommends and appreciates the fervent activity to publish all that will help to evaluate the effective validity of this new operative concept and guide the processes of adaptation and renewal of the existing structures towards this promising and intriguing approach to trauma treatment.

The aim of this chapter is to review and discuss five important and influential papers that have analyzed the performance capabilities of HERS, highlighting if the great theoretical advantages of these new suites can actually be reflected in daily clinical practice.

ARTICLE NUMBER 1

The Survival Benefit of a Novel Trauma Workflow that Includes Immediate Whole-body Computed Tomography, Surgery, and Interventional Radiology, All in One Trauma Resuscitation Room.

Ann Surg. 2019 Feb;269(2):370-376.

Kinoshita T, Yamakawa K, Matsuda H, Yoshikawa Y, Wada D, Hamasaki T, Ono K, Nakamori Y, Fujimi S.

Abstract

Objective: The aim of this study was to evaluate the impact of a novel trauma workflow, using an interventional radiology (IVR)–computed tomography (CT) system in severe trauma.

Background: In August 2011, we installed an IVR-CT system in our trauma resuscitation room. We named it the Hybrid emergency room (ER), as it enabled us to perform all examinations and treatments required for trauma in a single place.

Methods: This retrospective historical control study conducted in Japan included consecutive severe (injury severity score ≥ 16) blunt trauma patients. Patients were divided into 2 groups: Conventional (from August 2007 to July 2011) or Hybrid ER (from August 2011 to July 2015). We set the primary endpoint as 28-day mortality. The secondary endpoints included cause of death and time course from arrival to start of CT and surgery. Multivariable logistic regression analysis adjusted for clinically important variables was performed to evaluate the clinical outcomes.

Results: We included 696 patients: 360 in the Conventional group and 336 in the Hybrid ER group. The Hybrid ER group was significantly associated with decreased mortality [adjusted odds ratio (OR), 0.50 (95% confidence interval, 95% CI, 0.29–0.85); $P = 0.011$] and reduced deaths from exsanguination [0.17 (0.06–0.47); $P = 0.001$]. The time to CT initiation [Conventional 26 (21 to 32) minutes vs Hybrid ER 11 (8 to 16) minutes; $P < 0.0001$] and emergency procedure [68 (51 to 85) minutes vs 47 (37 to 57) minutes; $P < 0.0001$] were both shorter in the Hybrid ER group.

Conclusions: This novel trauma workflow, comprising immediate CT diagnosis and rapid bleeding control without patient transfer, as realized in the Hybrid ER, may improve mortality in severe trauma.

Article review and analysis

Aim of this study: In the summer of 2011, a group of Japanese experts in treating trauma patients installed a novel-concept IVR-CT room equipped with a movable ultrasound and mechanical ventilator. Consequently, this resuscitation room allowed operators (the trauma team) to perform important diagnostic and interventional procedures in the same room, eliminating the inter-room (internal/intra-hospital) transportations

that represent a risky and superfluous loss of time for patients in life-threatening conditions. In other words, the elimination of transfer times and the ease of access to these instruments could ideally lead to a wide improvement in trauma workflow. This study aimed to evaluate the impact of this novel-concept IVR-CT in the workflow of severe trauma patients.

Methods

Pros: An important strength of this study is the large patient population, composed of two almost equal groups (Conventional and Hybrid ER groups) both constituted from continuous blunt severe trauma patient enrollment. Furthermore, another important strength of this study was the multiple physiological and laboratory data collected by the authors in order to accurately depict the clinical condition of patients at their arrival in the emergency department. The third main strength of this study is the evaluation of 28-day mortality as the primary endpoint, followed by, as the secondary endpoints, cause of death and the assessment of time elapsed from arrival to start of CT and/or surgery. With this study design, the authors immediately aimed to compare the most important medical data available between the two groups, such as the decrease in mortality and therefore the importance that the adoption of this hybrid room and the new workflow could have in reducing mortality in severe bleeding/status patients. In addition, the authors analyzed if a single specific cause of death could be reduced with the use of the hybrid room; this is extremely important because this type of arrangement could have proved effective in preventing one cause of death but not others. The final important point is the analysis of the amount of time that elapsed between access and operation (CT/resuscitation), which gives an idea of how the hybrid room impacts in terms of efficiency and time saving, which are very important parameters in the ATLS guidelines.

Cons: The retrospective design is the most important limitation of this study. Moreover, these consecutive patients may not have been carefully assessed regarding previous diseases, which can in turn affect mortality. In addition, the study is based on a single center experience and the hospital could be used for receiving specific trauma cases that are efficiently treated, although this specific workflow may not be as efficient in other types of trauma. Moreover, the location and/or facilities of the hospital could positively or negatively alter the evaluation of arrival and treatment times of patients.

Results, conclusion, and what it means

The results showed that the Hybrid Room had an important impact in terms of decreased mortality, reduced deaths from exsanguination, and reduced time to access CT and/or emergency procedures. As far as we know this was the first study to assess and quantify such a critical and careful evaluation of hybrid room impact in clinical practice. Even with the limitations mentioned before, these are the first results to give great stimulation to the use of this instrumentation in the clinical environment and, above all, they consequently have encouraged other series in evaluating the advantages

of using this innovative methodology in “real-life medicine” and not only speculating about it. From this study, it can be easily concluded that the adoption of a renewed workflow for trauma linked to the adoption of new technologies, such as a hybrid room, can represent a definite future source to be used in the treatment of severe bleeding patients.

Comments and future research

Future prospective studies are required to establish the real usefulness of this setting in clinical practice. Furthermore, referring to the limits mentioned above, it is essential to make a comparison between this experience and that of other important tertiary centers characterized by different environmental contexts (both in physical-geographical terms and in terms of access cases and various clinical contexts). Unfortunately, for ethical reasons, it will be impossible to plan a randomized trial to evaluate trauma patients treated in a hybrid context or not. Therefore, it will be necessary to use all the possible methodological instruments, such as propensity score analysis, to match previously published series not treated in a hybrid context and the future study population.

Related important publications

Watanabe H, Shimojo Y, Hira E, Kuramoto S, Muronoi T, Oka K, Kidani A. First establishment of a new table-rotated-type hybrid emergency room system. *Scand J Trauma Resusc Emerg Med*. 2018 Sep 17;26(1):80.

Umemura Y, Watanabe A, Kinoshita T, Morita N, Yamakawa K, Fujimi S. Hybrid emergency room shows maximum effect on trauma resuscitation when used in patients with higher severity. *J Trauma Acute Care Surg*. 2020 Nov 5.

Founding members of the Japanese Association for Hybrid Emergency Room System (JA-HERS). The hybrid emergency room system: a novel trauma evaluation and care system created in Japan. *Acute Med Surg*. 2019 Apr 10;6(3):247-251.

Wada D, Nakamori Y, Yamakawa K, Fujimi S. First clinical experience with IVR-CT system in the emergency room: positive impact on trauma workflow. *Scand J Trauma Resusc Emerg Med*. 2012 Aug 7;20:52.

ARTICLE NUMBER 2

The need for a rapid transfer to a hybrid operating theatre: Do we lose benefit with poor efficiency?

Injury. 2020 Sep;51(9):1987-1993.

Jang JY, Oh J, Shim H, Kim S, Jung PY, Kim S, Bae KS.

Abstract

Purpose: Recent studies on hybrid operating rooms (ORs) have mainly reported their applications in orthopedic surgery and interventional radiology (IR); there are few studies assessing severely injured patients who underwent IR or surgery in hybrid ORs for haemostasis. Therefore, this study aimed to evaluate our early experience with the use of hybrid OR to control haemorrhage in severe trauma patients.

Methods: Medical charts of patients who underwent an emergency surgery or IR for haemostasis were analyzed retrospectively between January and December 2015.

Results: Of the 95 patients directly transported to the general or hybrid OR, 69 (73%) were transported to the non-hybrid OR and underwent emergency surgeries, whereas 26 (27%) were transported to the hybrid OR and underwent emergency IR or surgery on-site. Patients transported to the hybrid OR had a higher median Injury Severity Score (median: 29, interquartile range [IQR]: 21–36.5 vs median: 21, IQR: 16–27) and lower median initial systolic blood pressure (median: 96, IQR: 82.75–128.75 vs median: 114, IQR: 95–151.5) than those transported to the non-hybrid OR. The median time from the emergency room (ER) arrival to the start of the emergency procedure in the hybrid OR group was similar with that in the non-hybrid OR group (median: 80, IQR: 62.75–91.5 vs median: 75, IQR: 56.5–99). Seven patients underwent IR and surgery concurrently in the hybrid OR because of a haemodynamically unstable pelvic fracture, severe liver injury, and severe brain haemorrhage. The median time from the ER arrival to the start of the haemostatic procedure or operation was 64 (43–97) minutes.

Conclusions: Although the hybrid OR may be used for haemostasis in severely injured patients, the long median time from ER arrival to the start of a haemostatic procedure in hybrid OR indicates the need for a new workflow to reduce this time and to facilitate hybrid OR use.

Article review and analysis

Aim of this study: The authors performed a retrospective analysis of their experience as a Level I trauma center in western Korea with the main purpose of evaluating the early experience with their hybrid room in the treatment of bleeding patients with severe trauma. As mentioned by the authors, few studies to date have assessed the effectiveness of HERS in clinical practice, especially in traumatic severely injured patients with active bleeding.

Methods

Pros: Since the introduction of hybrid rooms, it has been well known that the use of this new equipment in emergency departments requires new operating protocols to really benefit from these new machines. However, the design of this study really allows the identification of the limitations of using hybrid rooms with an “old” workflow. In fact, with such a workflow, the authors showed that the added value of a hybrid room was lost. This result offers the scientific support to adopt a new workflow if using hybrid rooms in the emergency department. The present study shows an excellent variability of cases; in fact, bleeding sites originate in various parts of the body and this helps to define the applicability of HERS in almost all body areas. Moreover, another strength of the study is the detailed clinical and laboratory data concerning the patients that helps in completing a careful comparison between patients referred to a general OR (group 1) and those to a hybrid OR (group 2). Finally, another merit of the study is the interesting sub-group analysis performed between patients who underwent interventional radiology (IR) only and those who underwent IR and concurrent surgery. This helps to better define the added benefits of HERS by identifying trauma/bleeding cases in which these benefits are real.

Cons: This study suffers from many limitations. First, the sample size is small. The authors declared that this small population was due to the assessment of only 1-years’ experience of patients at a single institution. However, not elucidated is why they analyzed only the year 2015 when this paper was published in 2020. The possible reason could be that, after these results, the authors and the hospital establishment changed the executive protocols. Second, an important limitation is the absence of clarification concerning the exclusion of 63 (40%) patients from the starting cohort (158 patients). In fact, the authors stated that, of the 158 trauma patients with Injury Severity Scores (ISSs) ≥ 9 directly transported from the trauma resuscitation room for surgery or IR, 63 who underwent surgery or intervention after 2 hours were excluded. It might be interesting to know why this delay occurred and also to know the clinical outcome of the patients who underwent interventions after 2 hours. Finally, in the limitations section, it is reported that the protocol for hybrid OR operation was not complete. It would be interesting to know why this incomplete protocol for the hybrid OR remained incomplete (but was applied) for one year because this will be useful for those emergency departments starting to use a hybrid OR.

Results, conclusion, and what it means

The study showed a great authenticity of content which underlined data that could help in the optimization of the hybrid OR. Despite the worse clinical condition of patients transported to the hybrid OR (higher median Injury Severity Score [median: 29 vs median: 21 in the other group] and lower median initial systolic blood pressure [median: 96 mmHg vs median: 114 mmHg in the other group]) with respect to those transported to the non-hybrid OR, the median time from emergency room

arrival to start of the emergency procedure in the hybrid OR group was similar to that in the non-hybrid (general) OR group (median: 80 minutes, vs median: 75 minutes). In fact, the authors concluded that, although the hybrid OR may be used for hemostasis in severely injured patients, the long median time from emergency room arrival to start of a hemostatic procedure in hybrid OR indicates the need for a new workflow to reduce this time and to facilitate hybrid OR use.

The median time from ER arrival to the start of the hemostatic procedure or operation was 64 (43–97) minutes due to the time required to stabilize the patient from a hemodynamic point of view and the time required to set up the hybrid room with its own staff, while the IR group had a shorter time to initiation of the procedure. This result suggests that initial selection of patients who are most suitable for treatment in HR would be of great help.

In their experience, interestingly, hemodynamically unstable patients necessitated a median of 80 minutes before starting the procedure, longer than that for hemodynamically stable patients who, conversely, do not need a prompt intervention. Therefore, if the patients' status was known in advance, it would be possible to immediately organize the care for each patient and avoid any waste of time. In fact, the authors stated that their hospital is developing a system that allows physicians to receive information about patients before they arrive at the hospital in order to precisely select patients suitable for conventional OR or hybrid room, and this will certainly represent a crucial turning point in shortening the operating times.

Moreover, at the end of the paper, the authors also highlighted that structural renewal of the hospital may be necessary in order to avoid any temporal obstacle to the treatment of patients and to favor a more efficient workflow of HERS. In the text, is it clearly appreciable how the fact that hybrid OR was located on the third floor, whereas the trauma resuscitation and CT rooms were located on the first floor, almost certainly represented a further avoidable waste of time in all patients who needed resuscitation before accessing the hybrid OR. In the near future, in the construction of newly designed emergency departments, this will definitely be a factor to take into account in order to obtain the maximum performance from hybrid ORs providing a structural "environment" that is as predisposed as possible to their use.

In conclusion, the study results highlight how the whole trauma team must work in perfect coordination to fulfil its full potential. Furthermore, the study underlines many common in-hospital weaknesses that must be discussed and faced in an important context such as that of EVTm. The capacity of being able to face them in the best possible way, and to create a quality standard to be used as a reference point for groups/trauma teams approaching this novel concept of treatment, is fundamental.

Comments and future research

Further prospective studies reporting single-center and multicentric experiences are needed to highlight the potential of the hybrid room. Besides ensuring that there are constant improvements and updates of this renewed clinical practice, papers that can

provide various "food for thought" and also underline the limitations of this technique will certainly be welcomed and appreciated by the entire EVTm community in order to avoid making the same mistakes when using or starting to use this new technology to treat trauma.

Related important publications

Hertault A, Sobocinski J, Spear R, Azzaoui R, Delloye M, Fabre D, Haulon S. What should we expect from the hybrid room? *J Cardiovasc Surg (Torino)*. 2017 Apr;58(2):264-269.

Kataoka Y, Minehara H, Kashimi F, Hanajima T, Yamaya T, Nishimaki H, Asari Y. Hybrid treatment combining emergency surgery and intraoperative interventional radiology for severe trauma. *Injury*. 2016 Jan;47(1):59-63. doi: 10.1016/j.injury.2015.09.022. Epub 2015 Oct 9. PMID: 26508437.

Kirkpatrick AW, Vis C, Dubé M, Biesbroek S, Ball CG, Laberge J, Shultz J, Rea K, Sadler D, Holcomb JB, Kortbeek J. The evolution of a purpose designed hybrid trauma operating room from the trauma service perspective: the RAPTOR (Resuscitation with Angiography Percutaneous Treatments and Operative Resuscitations). *Injury*. 2014 Sep;45(9):1413-21.

ARTICLE NUMBER 3

Clinical Impact of a Dedicated Trauma Hybrid Operating Room.*J Am Coll Surg.* 2020 Nov 20;S1072-7515(20)32509-6.

Loftus TJ, Croft CA, Rosenthal MD, Mohr AM, Efron PA, Moore FA, Upchurch GR Jr, Smith RS.

Abstract

Background: Early hemorrhage control is essential to optimal trauma care. Hybrid operating rooms offer early, concomitant performance of advanced angiographic and operative hemostasis techniques, but their clinical impact is unclear. Herein, we present our initial experience with a dedicated, trauma hybrid operating room.

Study Design: This retrospective cohort analysis of 292 adult trauma patients undergoing immediate surgery at a Level I trauma center compared patients managed after implementation of a dedicated, trauma hybrid operating room ($n=186$) with historic controls ($n=106$). The primary outcomes were time to hemorrhage control (systolic blood pressure ≥ 100 mmHg without ongoing vasopressor or transfusion requirements), early blood product administration, and complications.

Results: Patient characteristics were similar between cohorts (age 41 years, 25% female, 38% penetrating trauma). The hybrid cohort had lower initial hemoglobin (10.2 vs. 11.1 g/dL, $p=0.001$) and a greater proportion of patients undergoing resuscitative endovascular balloon occlusion of the aorta (9% vs. 1%, $p=0.007$). Cohorts had similar case mixes and intraoperative consultations with cardiothoracic or vascular surgery (13%). Twenty-one percent of all hybrid cases included angiography. The interval between OR arrival and hemorrhage control was shorter in the hybrid cohort (49 vs. 60 minutes, $p=0.005$). From 4-24 hours after arrival, the hybrid cohort had fewer red cell (0.0 vs. 1.0, $p=0.001$) and plasma transfusions (0.0 vs. 1.0, $p<0.001$). The hybrid cohort had fewer infectious complications (15% vs. 27%, $p=0.009$) and ventilator days (2.0 vs. 3.0, $p=0.011$), and similar in-hospital mortality (13% vs. 10%, $p=0.579$).

Conclusions: Implementation of a dedicated, trauma hybrid operating room was associated with earlier hemorrhage control and fewer early blood transfusions, infectious complications, and ventilator days.

Article review and analysis

Aim of this study: Almost a decade after the first introduction of HERS, its clinical usability and efficiency for severe bleeding patients still lacks important clinical studies based on direct experience of its use in emergency medicine. The clinical validation of the use of HERS for trauma patients would lead to considerable clinical advantages and would open the possible scenario of using HERS in all trauma centers, possibly also with a continuous 24/7 schedule. Nonetheless, the authors did not forget that HERS

has a high manufacturing and operating cost, so it is very important that these technologies bring significant benefits in clinical practice and that they are worth the economic efforts made to maintain them. Therefore, the aim of this study was to report hybrid room use in the experience of a Level I trauma center in the US, with the final intent to evaluate if this technique actually brings advantages in terms of time to hemorrhage control and morbidity reduction that are theoretically guaranteed by this new technology.

Methods

Pros: An important strength of this study is the long study period with a total of 84 months of data collection. In fact, compared with other published series on the use of HERS in trauma patients, this represents an important study period which, therefore, makes the results of the study credible. Furthermore, having compared the months before the introduction of the hybrid room with those immediately after, they tried to minimize the presence of possible environmental biases. In addition, the authors performed an effective and precise selection of the study cohort, taking great care in their exclusion criteria and selecting only patients that best fit the needs of this study. One more determining factor of this study underlined by the authors is that all the trauma team staff operating in the hybrid room had been successfully trained. They had received lessons and simulations in order to adequately learn the maneuvers and operations performed in the hybrid room to be able to derive the maximum performance from it. This factor, once again, highlights the importance of efficient and well-functioning staff and protocols; in fact, it is easy to see how the results in this study were much better than those recorded in article #2, and, certainly, this difference in preparation could also have had a decisive impact.

Data collection, as well as the choice of threshold values to delineate results, were all completed in a precise and reproducible way, observing the principles of damage control resuscitation, in surgery and interventional radiology, which contribute to making this paper consistent despite it being a monocentric, retrospectively designed study.

Cons: The study appears to have been conducted with care although the retrospective design and the study cohorts composed of consecutive patients without precise analysis of the remote or proximate pathological history are the principal limitations. Another limitation is the monocentric nature of the study; this could also positively or negatively affect the real level of performance of HERS both in terms of the work environment and operating staff.

Results, conclusion, and what it means

The take-home messages of this study, comparing the hybrid cohort with a cohort of patients who underwent general OR, are that the interval between OR arrival and hemorrhage control was significantly shorter in the hybrid cohort (49 vs. 60 minutes, $P=0.005$); the hybrid study cohort had significantly fewer red cell and plasma transfusions from 4-24 hours of arrival ($P=0.001$ and $P<0.001$, respectively); significantly

fewer infections and fewer ventilator days ($P=0.009$ and $P=0.011$) were revealed in the hybrid study cohort; and the in-hospital mortality was the same in the two groups ($P=0.579$). As previously mentioned, comparing this study to paper #2 makes it immediately clear how the preparation of trauma teams is fundamental in order to make the most of the diagnostic and therapeutic potential offered by HERS. Furthermore, it is once again demonstrated in “real-life medicine” that hybrid rooms bring innumerable advantages to patients, not only theoretically but, above all, in daily clinical practice; however, adequate preparation of the trauma team is necessary to be able to take advantage of these qualities. For example, in a period like the one we are currently living in, characterized by the spreading of the SARS-COV2 pandemic, the therapeutic advantages of the use of hybrid rooms can also bring logistical advantages through having a clear reduction in patient mobilization between departments that represents a huge advantage; regarding this, the results show lower infection rates, and this is only part of many data confirming how promising this new format of emergency medicine is. It should be noted that the result appears to be not in favor of HERS, since the in-hospital mortality rate compares to the group of patients who underwent general OR; however, it is in favor of this new technology because it is important to read the data counterclockwise: the patients had minor complications, minor infections, minor transfusions (also ensuring cost savings), but without differences in mortality rate.

Comments and future research

Certainly, the expense of the realization and management of HERS is not sustainable in all nosocomial structures, but in referral trauma centers, the adoption of this technology will become increasingly urgent if clinical studies continue to demonstrate its usefulness. This also requires a consequent need for adaptation and the training of trauma teams in order to avoid underperformance of hybrid rooms. On this premise, reporting from hospitals that already have these new protocols in use will obviously be of great help for all the EVTm community.

i Related important publications

Joseph B, Zeeshan M, Sakran JV, Hamidi M, Kulvatunyou N, Khan M, O’Keeffe T, Rhee P. Nationwide Analysis of Resuscitative Endovascular Balloon Occlusion of the Aorta in Civilian Trauma. *JAMA Surg.* 2019 Jun 1;154(6):500-508.

Coccolini F, Ceresoli M, McGreevy DT, Sadeghi M, Pirouzram A, Toivola A, Skoog P, Idoguchi K, Kon Y, Ishida T, Matsumura Y, Matsumoto J, Reva V, Maszkowski M, Fugazzola P, Tomasoni M, Cicuttin E, Ansaloni L, Zaghi C, Sibilla MG, Cremonini C, Bersztel A, Caragounis EC, Falkenberg M, Handolin L, Oosthuizen G, Szarka E, Manchev V, Wannatoop T, Chang SW, Kessel B, Hebron D, Shaked G, Bala M, Ordoñez CA, Hibert-Carius P, Chiarugi M, Nilsson KF, Larzon T, Gamberini E, Agnoletti V, Catena F, Hörer TM. Aortic balloon occlusion (REBOA) in pelvic ring injuries: preliminary results of the ABO Trauma Registry. *Updates Surg.* 2020 Jun;72(2):527-536.

ARTICLE NUMBER 4

Hybrid Emergency Room System (HERS) improves timeliness of angioembolization for pelvic fracture.

J Trauma Acute Care Surg. 2020 Feb;88(2):314-319.

Ito K, Nagao T, Tsunoyama T, Kono K, Tomonaga A, Nakazawa K, Chiba H, Kondo H, Sugawara T, Yamamoto M, Yokoyama T, Zako R, Suzuki A, Inui S, Miyake Y, Sakamoto T, Fujita T.

Abstract

Background: Timely angioembolization (AE) is known to improve outcomes of patients with hemorrhage resulting from pelvic fracture. The Hybrid Emergency Room System (HERS) is a novel trauma resuscitation room equipped with a computed tomography scanner, fluoroscopy equipment, and an operating room set-up. We hypothesized that the HERS would improve the timeliness of AE for pelvic fracture.

Methods: A retrospective medical record review of patients who underwent AE for pelvic fracture at our institution from April 2015 through December 2018 was conducted. Patients’ demographics, location of AE, Injury Severity Score, Revised Trauma Score, probability of survival by the trauma and injury severity score method (TRISS Ps), presence of interventional radiologists (IRs) upon patient arrival, time from arrival to AE, and in-hospital mortality were analyzed. These data were compared between patients who underwent AE in the HERS (HERS group) and in the regular angio-suite (Non-HERS group).

Results: Ninety-six patients met the inclusion criteria. The HERS group comprised 24 patients and the Non-HERS group 72 patients. IRs were more frequently present upon patient arrival in the HERS than Non-HERS group (IRs: 79% vs. 22%, $p<0.01$). The time from arrival to AE was shorter in the HERS than Non-HERS group (median 46 [range 5–75] vs. 103 [2–690] min, $p<0.01$). There were no differences in the rate of in-hospital mortality (13% vs. 15%, $p=0.52$) between the two groups. Survivors in the HERS group had a lower TRISS Ps (median 61% [range 1%–98%] vs. 93% [1%–99%], $p<0.01$) than survivors in the Non-HERS group.

Conclusion: The HERS improved the timeliness of AE for pelvic fracture. More severely injured patients were able to survive in the HERS. The new team building involving the addition of IRs to the traditional trauma resuscitation team will enhance the benefit of the HERS.

Article review and analysis

Aim of this study: The background from which this study started is two long-established concepts of the emergency field: timely angioembolization improves outcomes of patients with hemorrhage resulting from pelvic fracture and HERS reduces the time between diagnosis and treatment of patients with trauma lesions. The novelty of this

study was the focus on only one kind of treatment in this setting: angioembolization. In particular, researchers from the radiology and emergency department of the Tokyo school of medicine decided to investigate if the use of HERS could improve the timeliness of angioembolization in patients with an active hemorrhage as a consequence of pelvic fracture.

Methods

Pros: An important strength of this study is the algorithm for trauma patient care in the hybrid emergency room reported in Figure 2. The results of this study at Tokyo University derived from the application of this protocol in the arm of patients who underwent HERS. The scheme proposed in Figure 2 provides information that can be more certainly applied realistically to other hospitals that have recently installed HERS.

Cons: This study does show several limitations. The retrospective design is a limitation. In addition, the two main study samples (HERS and non-HERS groups) are not perfectly balanced because the non-HERS group is almost 3 times larger than the HERS group. Another factor to be mentioned is that the HERS group included patients who were in a worse clinical condition and with more major clinical signs of shock than in the non-HERS group. This discrepancy would have generated a bias relative to the selection of the two study groups. However, despite this possible bias against the group of patients treated in the hybrid room, almost all the parameters analyzed were statistically significant in favor of this group.

Results, conclusion, and what it means

One of the most important results of the study is the reduction of time to angioembolization in the HERS group. Patients treated in the hybrid room showed no difference in the rate of in-hospital mortality (13% vs. 15%, $p=0.52$) despite their worse clinical condition. It is likely that the faster execution of an angioembolization guaranteed the same results as the other group despite overcoming the limitations of worse clinical conditions.

The authors of this paper have clearly pointed out the importance of having a functioning trauma team prepared to face any unexpected event and who can maximize the potential of HERS.

Comments and future research

The results of this study (improvement of the timeliness of angioembolization for bleeding in pelvic fractures with the clinical consequence of enhancing the clinical conditions of severe patients) need to be confirmed by robust data from more methodologically accurate studies.

i Related important publications

Ito K, Nagao T, Nakazawa K, Kato A, Chiba H, Kondo H, Miyake Y, Sakamoto T, Fujita T. Simultaneous damage control surgery and endovascular procedures for patients with blunt trauma in the hybrid emergency room system: New multidisciplinary trauma team building. *J Trauma Acute Care Surg.* 2019 Jan;86(1):160-162.

Matsushima K, Piccinini A, Schellenberg M, Cheng V, Heindel P, Strumwasser A, Benjamin E, Inaba K, Demetriades D. Effect of door-to-angioembolization time on mortality in pelvic fracture: Every hour of delay counts. *J Trauma Acute Care Surg.* 2018 May;84(5):685-692.

Chou CH, Wu YT, Fu CY, Liao CH, Wang SY, Bajani F, Hsieh CH. Hemostasis as soon as possible? The role of the time to angioembolization in the management of pelvic fracture. *World J Emerg Surg.* 2019 Jun 13;14:28.

ARTICLE NUMBER 5

Hybrid emergency room shows maximum effect on trauma resuscitation when used in patients with higher severity.*J Trauma Acute Care Surg. 2021 Feb 1;90(2):232-239.**Umemura Y, Watanabe A, Kinoshita T, Morita N, Yamakawa K, Fujimi S.***Abstract**

Background: The hybrid emergency room (ER) system is a novel trauma workflow that uses angio-computed tomography equipment in a trauma resuscitation room. Although the hybrid ER system decreases time to start surgery and endovascular treatments and improves mortality, the optimal target benefitting from this system remained unclear. We aimed to identify a subset of trauma patients likely to receive the greatest benefits from the hybrid ER.

Methods: This retrospective cohort study was conducted in a tertiary hospital in Japan from August 2007 to January 2020. We consecutively included severe adult blunt trauma patients (Injury Severity Score [ISS], ≥ 16) and divided them into two groups: conventional group (August 2007 to July 2011) and hybrid ER (August 2011 to January 2020) group. We evaluated the association between the hybrid ER group and 28-day mortality using multivariable logistic regression analysis. The 28-day mortality trend during the study period was evaluated with restricted cubic spline analysis. To evaluate heterogeneity of effects within various patient severities, we evaluated whether the patients' ISS modified the effect of the hybrid ER on survival.

Results: Among 1,050 trauma patients, the conventional group comprised 360 patients and the hybrid ER group comprised 690 patients. Injury Severity Score and probability of survival (Ps) were not significantly different between the groups. Twenty-eight-day mortality was significantly lower in the hybrid ER group (Ps-adjusted odds ratio, 0.48; 95% confidence interval, 0.32-0.71; $p < 0.001$). Restricted cubic spline analysis revealed that Ps-adjusted 28-day mortality sharply decreased approximately 200 days after installation of the hybrid ER. Increase of survival probabilities according to the increase of ISS was significantly improved in hybrid ER group ($p = 0.014$). Because ISS increased to >25 , survival probabilities in the hybrid ER group were higher compared with those in the conventional group.

Conclusions: The hybrid ER may improve posttraumatic mortality, especially in patients with higher baseline severity.

Article review and analysis

Aim of this study: Many papers have demonstrated the usefulness of the hybrid ER system in decreasing the time from diagnosis and any kind of treatment, such as endovascular or surgical treatments in trauma patients. However, the optimal target for benefiting from this system remained unclear. This paper, therefore, aimed to identify

a subset of trauma patients that could most benefit from the innovative diagnostic and therapeutic approach offered by hybrid ER. This aim is a necessary step in order to facilitate the widespread use of this technique if the results are confirmed.

Methods

Pros: The main positive characteristic of this paper is that, to the best of our knowledge, it is the first study completely focused on the evaluation of the optimal target population for the hybrid ER. The population was composed of subjects enrolled over a long period (about ten years), resulting in a representative series of different kinds of trauma patients. Moreover, this team is a leader in the field since they were the first to introduce this new technology (hybrid OR).

The authors conducted a careful and exhaustive analysis dividing a population composed of 1050 severe blunt trauma patients into two main groups: Group 1, patients treated using a "conventional" approach (390 pts) and Group 2, patients managed in the hybrid OR (960 pts).

Another strength of the study is the consecutive enrollment of patients, which allows an exhaustive and very representative series of the different clinical scenarios.

The strategy used to identify the populations most benefiting from the use of hybrid OR is of great methodological value. In fact, the authors applied logistic regression models to identify the possible features and select patients most suitable for treatment in the hybrid ER, such as presence of contrast blush on CT versus its absence; ISS of ≥ 26 versus ≤ 25 ; undergoing emergency endovascular treatments versus did not undergo emergency endovascular treatments; and others.

The authors also completed a collection of the patients' clinical data in order to be able to clearly assess their status before or after the procedure. The assessment of 28-day mortality (the primary outcome of this study), and the evaluation of massive transfusion administered within the first 24 hours from hospital arrival, time from patient arrival in the trauma resuscitation room to the beginning of CT scanning, and bleeding control intervention correctly represented solid parameters of the effectiveness of the hybrid OR.

Cons: As mentioned by the authors, some limitations affected this study. First the single-center nature of this study exposes it to a selection bias, since the hospitalized patients may all present with similar characteristics, and consequently the efficiency demonstrated by the HR in this study may not prove as valid in other hospital settings or with other types of patients.

Secondly, the better results showed by the hybrid ER group, composed of patients that had been treated more recently than those in the conventional group, could be due not only to the use of the hybrid ER but also to an improvement in care from an anesthesiologic, resuscitation and surgical point of view. Furthermore, we do not know if there have been changes in the personnel operating in the ER and if an improvement of the whole emergency-team's performance may have occurred and positively influenced the

results for patients treated more recently compared to the ones treated earlier. Finally, the recent improvement of interventional radiology techniques, which over the years have led to the use of increasingly effective and safe materials, probably contributed and, therefore, should also be taken into account to justify the better performances achieved in the hybrid ER group. However, the above mentioned limitations affect almost all of the studies that are focused on these arguments because, for ethical reasons, it is not possible to design a randomized trial of patients treated with different approaches in the trauma setting. Therefore, this kind of study will be affected by methodological limitations, and the main aim is to achieve the most accurate approach as is methodologically possible.

Results, conclusion, and what it means

The rate of the 28-day mortality was significantly lower in the hybrid ER group than the conventional group (12.7% vs. 21.7%, $P < 0.001$). This result is in line with other studies focusing on the efficiency of HERS. The novelty of their results was the identification of an ISS cut-off that will be useful to stratify the patients. In fact, the increase of survival probabilities according to the increase of ISS was significantly improved in the hybrid ER group ($P = 0.014$). These data suggest that the most severe patients in terms of major ISS have the greatest benefits from the hybrid ER.

Another interesting result is that the greatest benefits in terms of 28-day mortality were recorded starting from 200 days after the installation of the hybrid ER. This data demonstrates, as in other previous published papers, the importance of developing a perfect ecosystem around HR to maximize its performance.

Another important result with high clinical implication that emerged from the study is the fact that the rate of patients who underwent massive transfusions of red blood cells and platelet concentrates were significantly decreased after the installation of the hybrid ER (11.7% vs. 22.2%, $P < 0.001$). This result may be justified by the fact that having an interventional radiology table immediately available to quickly perform embolization makes it possible to reduce the duration of bleedings and, consequently, the need for transfusions. These data also allow consideration of active bleeding patients as one of the sub-groups that most benefits from the use of hybrid ER. Another important aspect deriving from this result is that the reduction of the need for transfusions could also determine the reduction of hospitalization times and the overall management costs of each patient, showing consistent cost-effectiveness of HR compared to conventional treatments. The economic savings could partially reduce and compensate for the high building and operating costs of the hybrid ER.

The hybrid ER group achieved another important result compared to the conventional group concerning procedural times. In fact, a significantly shorter arrival time to CT was registered (10 vs. 26 minutes, $P < 0.001$), as was shorter times from arrival to emergency surgery (47 vs. 67.5 minutes, $P < 0.001$) and to bleeding control intervention (42 vs. 72 minutes, $P < 0.001$). These data support the clear advantages of having a

single room that simultaneously allows different types of treatment in the same place, without the need to move patients across various departments.

Comments and future research

Future prospective and multi-center studies are needed in order to equally compare the performances of conventional treatments and hybrid ER in the same types of patients. The development of a predictive model to select the most suitable patients for HR before, or at least simultaneously with, their hospitalization, based on the results of this study, would allow the planning of different prospective studies that are methodologically correct.

Related important publications

Kinoshita T, Moriwaki K, Hanaki N, Kitamura T, Yamakawa K, Fukuda T, Hunink MGM, Fujimi S. Cost-effectiveness of a hybrid emergency room system for severe trauma: a health technology assessment from the perspective of the third-party payer in Japan. *World J Emerg Surg.* 2021 Jan 7;16(1):2.

Jin H, Liu J. Application of the Hybrid Operating Room in Surgery: A Systematic Review. *J Invest Surg.* 2020 Nov 4;1:12.

CHAPTER 5.

Imaging with new generation CT for trauma and bleeding

Authors: *Francesca Iacobellis, Luigia Romano and Mariano Scaglione*

Introduction

The adoption of whole-body CT scanning for polytrauma patient assessment is commonly accepted in clinical practice thanks to the availability of new generation CT allowing the examination to be performed in a few minutes. The CT technological advances have led to new imaging approaches to trauma patients: from CT for stable or stabilized polytrauma patients to immediate total-body CT, to the most recent approach with a hybrid emergency room system.

Published studies recommend whole-body CT as a standard diagnostic method during the early resuscitation phase for patients with polytrauma as it seems to increase the probability of survival; however, exactly which patients could benefit from this approach remains a matter for debate. Furthermore, there is no consensus regarding the CT protocols to be utilized for trauma imaging amongst institutions and a variety of protocols can be found in the available literature, which differ in timing acquisition and number of phases. This may change the capability to detect, characterize and quantify the vascular injuries.

We hereby review the main publications concerning these points.

ARTICLE NUMBER 1

Emergency Bleeding Control Interventions After Immediate Total-Body CT Scans in Trauma Patients.*World J Surg.* 2019 Feb;43(2):490-496.*Treskes K, Saltzherr TP, Edwards MJR, Beuker BJA, Den Hartog D, Hohmann J, Luitse JS, Beenen LFM, Hollmann MW, Dijkgraaf MGW, Goslings JC; REACT-2 study group.***Abstract**

Background: Immediate total-body CT (iTBCT) is often used for screening of potential severely injured patients. Patients requiring emergency bleeding control interventions benefit from fast and optimal trauma screening. The aim of this study was to assess whether an initial trauma assessment with iTBCT is associated with lower mortality in patients requiring emergency bleeding control interventions.

Methods: In the REACT-2 trial, patients who sustained major trauma were randomized for iTBCT or for conventional imaging and selective CT scanning (standard workup; STWU) in five trauma centers. Patients who underwent emergency bleeding control interventions following their initial trauma assessment with iTBCT were compared for mortality and clinically relevant time intervals to patients that underwent the initial trauma assessment with the STWU.

Results: In the REACT-2 trial, 1083 patients were enrolled of which 172 (15.9%) underwent emergency bleeding control interventions following their initial trauma assessment. Within these 172 patients, 85 (49.4%) underwent iTBCT as primary diagnostic modality during the initial trauma assessment. In trauma patients requiring emergency bleeding control interventions, in-hospital mortality was 12.9% (95% CI 7.2–21.9%) in the iTBCT group compared to 24.1% (95% CI 16.3–34.2%) in the STWU group ($p = 0.059$). Time to bleeding control intervention was not reduced; 82 min (IQR 5–121) versus 98 min (IQR 62–147), $p = 0.108$.

Conclusions: Reduction in mortality in trauma patients requiring emergency bleeding control interventions by iTBCT could not be demonstrated in this study. However, a potentially clinically relevant absolute risk reduction of 11.2% (95% CI - 0.3 to 22.7%) in comparison with STWU was observed.

Article review and analysis

Aim of this study: The aim of this study was to assess whether an initial trauma assessment with immediate total-body CT is associated with lower mortality in patients requiring emergency bleeding control interventions.

Methods

Pros: The study analyzes a subcategory ($n=172$) of patients from the REACT-2 trial, which is an international, multicenter, randomized controlled trial. This design ensures that differences in trauma populations, trauma mechanisms and workflow in different parts of the world are considered.

Cons: There is heterogeneity of adopted CT protocols among different trauma centers, and heterogeneity of bleeding etiology and of treatment applied to stop the bleeding. The analysis presented in the study was unplanned at the design stage resulting in a lack of statistical power for the detection of the observed clinically relevant contrast between the mortality rates.

Results, conclusion, and what it means

In-hospital mortality was 12.9% (95% CI 7.2–21.9%) in the iTBCT group compared to 24.1% (95% CI 16.3–34.2%) in the STWU group (absolute risk reduction: 11.2%, 95% CI - 0.3 to 22.7%; $p = 0.059$). Time to diagnosis was reduced for patients who underwent iTBCT: 45 min (IQR 35–60) versus 57 min (IQR 43–85), $p = 0.009$. Time to bleeding control intervention was not significantly reduced: iTBCT 82 min (IQR 57–121) versus STWU 98 min (IQR 62–147), $p = 0.108$.

The analysis of the subgroup of patients with Injury Severity Score (ISS) ≥ 16 found in-hospital mortality was reduced after iTBCT compared to the STWU group: 13.3% (95% CI 7.2–23.0%) versus 27.8% (95% CI 18.7–39.1%), with an absolute risk reduction of 14.4% (95% CI 1.6–27.3%, $p = 0.030$). Time to diagnosis was reduced for patients who underwent iTBCT: 47 min (IQR 35–61) versus 57 min (IQR 42–83), $p = 0.033$. Time to bleeding control intervention was not significantly reduced: iTBCT 78 min (IQR 56–120) versus STWU 92 min (IQR 62–125), $p = 0.306$.

In both groups no differences were detected regarding percentage of complications and length of hospital stay.

The study results suggest a possible reduction in mortality in trauma patients with bleeding control interventions undergoing iTBCT, particularly in patients with ISS ≥ 16 , which is probably related to faster and exhaustive trauma workup. Indeed, knowing quickly and in detail the kind of patient injuries helps the decisions regarding the most appropriate treatment and the priority to treat in multiple injuries.

Comments and future research

Future research should focus on criteria to properly select trauma patients who could benefit from iTBCT in order to avoid potential overutilization of CT.

i Related important publications

Sierink JC, Saltzherr TP, Beenen LF, Luitse JS, Hollmann MW, Reitsma JB, Edwards MJ, Hohmann J, Beuker BJ, Patka P, Suliburk JW, Dijkgraaf MG, Goslings JC; REACT-2 study group. A multicenter, randomized controlled trial of immediate total-body CT scanning in trauma patients (REACT-2). *BMC Emerg Med.* 2012 Mar 30;12:4.

Treskes K, Saltzherr TP, Edwards MJR, Beuker BJA, Van Lieshout EMM, Hohmann J, Luitse JSK, Beenen LFM, Hollmann MW, Dijkgraaf MGW, Goslings JC; REACT-2 study group. Refining the criteria for immediate total-body CT after severe trauma. *Eur Radiol.* 2020 May;30(5):2955-2963.

Huber-Wagner S, Lefering R, Qvick LM, Körner M, Kay MV, Pfeifer KJ, Reiser M, Mutschler W, Kanz KG; Working Group on Polytrauma of the German Trauma Society. Effect of whole-body CT during trauma resuscitation on survival: a retrospective, multicentre study. *Lancet.* 2009 Apr 25;373(9673):1455-61.

ARTICLE NUMBER 2

The survival benefit of a novel trauma workflow that includes immediate whole-body computed tomography, surgery, and interventional radiology, all in one trauma resuscitation room: a retrospective historical control study.

Ann Surg. 2019; 269:370–6.

Kinoshita T, Yamakawa K, Matsuda H, Yoshikawa Y, Wada D, Hamasaki T, Ono K, Nakamori Y, Fujimi S.

Abstract

Objective: The aim of this study was to evaluate the impact of a novel trauma workflow, using an interventional radiology (IVR)–computed tomography (CT) system in severe trauma.

Background: In August 2011, we installed an IVR-CT system in our trauma resuscitation room. We named it the Hybrid emergency room (ER), as it enabled us to perform all examinations and treatments required for trauma in a single place.

Methods: This retrospective historical control study conducted in Japan included consecutive severe (injury severity score 16) blunt trauma patients. Patients were divided into 2 groups: Conventional (from August 2007 to July 2011) or Hybrid ER (from August 2011 to July 2015). We set the primary endpoint as 28-day mortality. The secondary endpoints included cause of death and time course from arrival to start of CT and surgery. Multivariable logistic regression analysis adjusted for clinically important variables was performed to evaluate the clinical outcomes.

Results: We included 696 patients: 360 in the Conventional group and 336 in the Hybrid ER group. The Hybrid ER group was significantly associated with decreased mortality [adjusted odds ratio (OR), 0.50 (95% confidence interval, 95% CI, 0.29–0.85); $P = 0.011$] and reduced deaths from exsanguination [0.17 (0.06–0.47); $P = 0.001$]. The time to CT initiation [Conventional 26 (21 to 32) minutes vs Hybrid ER 11 (8 to 16) minutes; $P < 0.0001$] and emergency procedure [68 (51 to 85) minutes vs 47 (37 to 57) minutes; $P < 0.0001$] were both shorter in the Hybrid ER group.

Conclusion: This novel trauma workflow, comprising immediate CT diagnosis and rapid bleeding control without patient transfer, as realized in the Hybrid ER, may improve mortality in severe trauma.

Article review and analysis

Aim of this study: The aim of the study is to evaluate if improving the access to CT and interventional radiology may contribute to reduced mortality in severe polytrauma patients.

Methods

Pros: The study evaluated the impact of a novel trauma workflow adopting the Hybrid ER. It is a well-designed study in which the authors examine a discrete number of severe trauma patients (n° 696) comparing those managed with hybrid ER with those conventionally treated.

Cons: Potential biases exist because of the retrospective study design. Only patients with severe trauma were included.

Results, conclusion, and what it means

Compared with the Conventional group, the 28-day mortality was significantly lower in the Hybrid ER group. The time intervals from arrival to the trauma resuscitation room to the beginning of the CT scanning and to the beginning of the emergency surgery were both shorter in the Hybrid ER group. The time to initiation of IVR, apart from direct surgery, was also significantly reduced in the Hybrid ER group.

The study demonstrates that the proposed workflow helps in reducing trauma patients mortality independently from the definition of bleeding etiology. This is related to the reduction of transportation time from trauma room to CT suite and then to the IVR room, and probably also to the increased availability of IVR.

Comments and future research

The proposed workflow may help in reducing mortality in severe poly-traumatized patients with ISS ≥ 16 ; however, it should have better defined the appropriate target for the treatment in the Hybrid ER and the effectiveness of the Hybrid ER system in patients with severe TBI.

i Related important publications

Kinoshita T, Moriwaki K, Hanaki N, Kitamura T, Yamakawa K, Fukuda T, Hunink MGM, Fujimi S. Cost-effectiveness of a hybrid emergency room system for severe trauma: a health technology assessment from the perspective of the third-party payer in Japan. *World J Emerg Surg.* 2021 Jan 7;16(1):2.

Umemura Y, Watanabe A, Kinoshita T, Morita N, Yamakawa K, Fujimi S. Hybrid emergency room shows maximum effect on trauma resuscitation when used in patients with higher severity. *J Trauma Acute Care Surg.* 2021 Feb 1;90(2):232-239.

ARTICLE NUMBER 3

Active hemorrhage and vascular injuries in splenic trauma: utility of the arterial phase in multidetector CT.

Radiology. 2014 Jan;270(1):99-106.

Uyeda JW, LeBedis CA, Penn DR, Soto JA, Anderson SW.

Abstract

Purpose: To determine whether the addition of arterial phase computed tomography (CT) to the standard combination of portal venous and delayed phase imaging increases sensitivity in the diagnosis of active hemorrhage and/or contained vascular injuries in patients with splenic trauma.

Materials and methods: The institutional review board approved this HIPAA-compliant retrospective study; the requirement to obtain informed consent was waived. The study included all patients aged 15 years and older who sustained a splenic injury from blunt or penetrating trauma and who underwent CT in the arterial and portal venous phases of image acquisition during a 74-month period (September 2005 to November 2011). CT scans were reviewed by three radiologists, and a consensus interpretation was made to classify the splenic injuries according to the American Association for the Surgery of Trauma splenic injury scale. One radiologist independently recorded the presence of contained vascular injuries or active hemorrhage and the phase or phases at which these lesions were seen. Clinical outcome was assessed by reviewing medical records. The relationship between imaging findings and clinical management was assessed with the Fisher exact test.

Results: One hundred forty-seven patients met the inclusion criteria; 32 patients (22%) had active hemorrhage and 22 (15%) had several contained vascular injuries. In 13 of the 22 patients with contained injuries, the vascular lesion was visualized only at the arterial phase of image acquisition; the other nine contained vascular injuries were seen at all phases. Surgery or embolization was performed in 11 of the 22 patients with contained vascular injury.

Conclusion: The arterial phase of image acquisition improves detection of traumatic contained splenic vascular injuries and should be considered to optimize detection of splenic injuries in trauma with CT.

Article review and analysis

Aim of this study: The aim was to investigate whether the addition of arterial phase CT to the standard combination of portal venous and delayed phase imaging increases sensitivity in the diagnosis of active hemorrhage and/or contained vascular injuries in patients with splenic trauma.

Methods

Pros: The study includes patients with blunt or penetrating trauma and compares the detected CT injuries with the patients' clinical outcome.

Cons: There is a lack of routine confirmation with conventional angiography of the vascular injuries diagnosed at CT. On examining the patient's outcome, patients undergoing surgery and/or embolization were assimilated without the possibility to distinguish patients who could benefit from endovascular treatment with splenic salvage and patients who underwent splenectomy.

Results, conclusion, and what it means

In the majority of patients with contained vascular injuries, these were visualized only at the arterial phase and were not seen at the portal venous or delayed phase. So, if the CT examination lacks the arterial phase, all these lesions are potentially missed and may increase in time leading to late organ rupture or overflow complications.

Regarding active hemorrhage, a significant difference in management (surgery and/or embolization vs conservative management) was detected between the patients with active hemorrhage and those without evidence of active hemorrhage at CT, whereas there was no significant difference in treatment (surgery and/or embolization vs conservative management) between patients in whom the active hemorrhage was seen at the arterial, portal venous, and delayed phases and those in whom hemorrhage was seen only at the portal venous and delayed phases. However, in this case, it would have been more interesting to distinguish the patients in whom the organ could be saved by undergoing endovascular embolization, and those in which the spleen had been surgically removed. Differences eventually detected between these two groups may demonstrate the use of distinguishing arterial from venous active bleeding.

In conclusion, the use of arterial phase imaging markedly increases the sensitivity of CT in the detection of contained vascular injuries in splenic trauma, whereas it does not increase the diagnosis of bleeding but, in our opinion, it helps in distinguishing the etiology and the amount of bleeding, thus orienting the management.

Comments and future research

Further studies should investigate how CT detection of arterial active bleeding could help in the management of patients by distinguishing the patients to undergo endovascular treatment with splenic salvage and patients to undergo emergency splenectomy.

i Related important publications

Iacobellis F, Scaglione M, Brilliantino A, Scuderi MG, Giurazza F, Grassi R, Noschese G, Niola R, Al Zuhir NYS, Romano L. The additional value of the arterial phase in the CT assessment of liver vascular injuries after high-energy blunt trauma. *Emerg Radiol*. 2019 Dec;26(6):647-654.

Melikian R, Goldberg S, Strife BJ, Halvorsen RA. Comparison of MDCT protocols in trauma patients with suspected splenic injury: superior results with protocol that includes arterial and portal venous phase imaging. *Diagn Interv Radiol*. 2016 Sep-Oct;22(5):395-9.

Boscak AR, Shanmuganathan K, Mirvis SE, Fleiter TR, Miller LA, Sliker CW, Steenburg SD, Alexander M. Optimizing trauma multidetector CT protocol for blunt splenic injury: need for arterial and portal venous phase scans. *Radiology*. 2013 Jul;268(1):79-88.

ARTICLE NUMBER 4

A review of split-bolus single-pass CT in the assessment of trauma patients.

*Emerg Radiol. 2018 Aug;25(4):367-374.
Jeavons C, Hacking C, Beenen LF, Gunn ML.*

Abstract

Purpose: The purpose of this study was to review and compare the image quality and radiation dose of split-bolus single-pass computed tomography (CT) in the assessment of trauma patients in comparison to standard multi-phase CT techniques.

Methods: An online electronic database was searched using the MESH terms “split-bolus”, “dual phase”, and “single pass”. Inclusion criteria required the research article to compare a split contrast bolus protocol in a single-pass scan in the assessment of trauma patients. Studies using split-bolus CT technique in non traumatic injury assessment were excluded. Six articles met the inclusion criteria.

Conclusions: Parenchymal and vascular image qualities, as well as subjective image quality assessments, were equal or superior in comparison to non-split-bolus multi-phase trauma CT protocols. Split-bolus single-pass CT decreased radiation exposure in all studies. Further research is required to determine the superior split-bolus protocol and the specificity and sensitivity of detecting blunt cerebrovascular injury screening, splenic parenchymal vascular lesions, and characterization of pelvic vascular extravasation.

Article review and analysis

Aim of this study: The article reviews and compares the image quality and radiation dose of split-bolus single-pass computed tomography (CT) in the assessment of trauma patients in comparison to a standard multi-phase CT technique.

Methods

Pros: The article clearly summarizes the results of six different studies on split-bolus single-pass CT, examining differences with a standard multi-phase protocol in image quality, radiation dose, and work flow efficiency.

Cons: The study is not designed as a systematic review. From this study, conclusions can be drawn only on the technical aspect of split-bolus protocols compared to a multiphasic protocol, but not in terms of diagnostic accuracy, especially for vascular injuries.

Results, conclusion, and what it means

All the studies investigating image quality for split-bolus single-pass CT found adequate quality with higher parenchymal enhancement and lower arterial enhancement

than with conventional CT protocol. The reason for the higher enhancement of parenchymal organs is related to the higher amount of administered contrast medium. The main issue concerns the identification and characterization of vascular injuries. Indeed, for their depiction, a greater contrast between arterial vessels and the parenchyma is needed, as well as a further subsequent venous phase to evaluate the stability or the presence of active bleeding, as this changes the patient management.

Comments and future research

The main limitation of the split-bolus technique remains the possible inadequate detection and characterization of vascular injuries, and the possible difficulties in distinguishing vascular injuries from pre-existing parenchymal findings.

The available literature still lacks studies that adequately explore this point.

i Related important publications

Leung V, Sastry A, Woo TD, Jones HR. Implementation of a split-bolus single-pass CT protocol at a UK major trauma centre to reduce excess radiation dose in trauma pan-CT. *Clin Radiol.* 2015 Oct;70(10):1110-5.

Stedman JM, Franklin JM, Nicholl H, Anderson EM, Moore NR. Splenic parenchymal heterogeneity at dual-bolus single-acquisition CT in polytrauma patients-6-months experience from Oxford, UK. *Emerg Radiol.* 2014 Jun;21(3):257-60.

Inaba K, Munera F, McKenney M, Schulman C, de Moya M, Rivas L, Pearce A, Cohn S. Visceral torso computed tomography for clearance of the thoracolumbar spine in trauma: a review of the literature. *J Trauma.* 2006 Apr;60(4):915-20.

CHAPTER 6.

REBOA in emergency trauma patients

Authors: *David Aranovich, Yaakov Daskal and Daniel Sheffer*

Introduction

Welcome to the world of trauma! REBOA was initially invented and intended for trauma patients. With accumulating experience, aortic balloon occlusion became a part of a more sophisticated hybrid approach and, with time, it has been converted into the EVTm concept. In addition, the important components of the EVTm concept, such as partial or intermittent REBOA, were also developed for trauma patients. Moreover, most of the basic animal research on various REBOA aspects and influences was also performed in trauma models. This may explain the large amount of existing, high-quality publications, which are highly recommended for reading. Despite substantial accumulated data, and numerous conferences, professional skepticism still exists among very skilled physicians. Paradoxically, most of the distrust comes from trauma surgeons while, probably, the most significant amount of publications are written by trauma experts. However, reviewing even the most “convincing” publications that did not justify REBOA’s use in trauma, which allows a different point of view on the problem. As always, truth is born in disputes. Therefore, we take this chapter as a challenge.

A meticulous search of relevant literature did not produce any double blind randomized or prospective controlled studies on this topic. Such designs are very restricted in the trauma sphere, mostly due to legal and ethical limitations. Currently, the best evidence we have is based on large retrospective studies, sometimes with prospectively collected data. Nevertheless, the success of various REBOA consequences evaluated in various excellent animal studies show that the sky is only the limit.

Here we present the five articles that, in our opinion, may serve as “milestones” of the EVTm concept progress in trauma.

ARTICLE NUMBER 1

The use of aortic balloon occlusion in traumatic shock: first report from the ABO trauma registry.

Eur J Trauma Emerg Surg. 2018 Aug;44(4):491-501.

Sadeghi M, Nilsson KF, Larzon T, Pirouzram A, Toivola A, Skoog P, Idoguchi K, Kon Y, Ishida T, Matsumura Y, Matsumoto J, Reva V, Maszkowski M, Bersztel A, Caragounis E, Falkenberg M, Handolin L, Kessel B, Hebron D, Coccolini F, Ansaloni L, Madurska MJ, Morrison JJ, Hörer TM.

Abstract

Purpose: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a technique for temporary stabilization of patients with non-compressible torso hemorrhage. This technique has been increasingly used worldwide during the past decade. Despite the good outcomes of translational studies, clinical studies are divided. The aim of this multicenter-international study was to capture REBOA-specific data and outcomes.

Methods: REBOA practicing centers were invited to join this online register, which was established in September 2014. REBOA cases were reported, both retrospective and prospective. Demographics, injury patterns, hemodynamic variables, REBOA-specific data, complications and 30-days mortality were reported.

Results: Ninety-six cases from 6 different countries were reported between 2011 and 2016. Mean age was 52 ± 22 years and 88% of the cases were blunt trauma with a median injury severity score (ISS) of 41 (IQR 29–50). In the majority of the cases, Zone I REBOA was used. Median systolic blood pressure before balloon inflation was 60 mmHg (IQR 40–80), which increased to 100 mmHg (IQR 80–128) after inflation. Continuous occlusion was applied in 52% of the patients, and 48% received non-continuous occlusion. Occlusion time longer than 60 min was reported as 38 and 14% in the non-continuous and continuous groups, respectively. Complications, such as extremity compartment syndrome ($n = 3$), were only noted in the continuous occlusion group. The 30-day mortality for non-continuous REBOA was 48%, and 64% for continuous occlusion.

Conclusions: This observational multicenter study presents results regarding continuous and non-continuous REBOA with favorable outcomes. However, further prospective studies are needed to be able to draw conclusions on morbidity and mortality.

Article review and analysis

Aim of this study: In the early 2010's, a group of REBOA researchers realized that future REBOA use depends on convincing data. Therefore, large efforts were made in the foundation of the international Aortic Balloon Occlusion registry. The aim of this study was to capture REBOA-specific data and outcomes. At the time of publication of this article, the data included 98 patients enrolled from six countries.

Methods

Pros: One of the most prominent effects shown in this article was the evidence that trauma surgeons are able to collaborate successfully. This study collected large data regarding multiple physiological and laboratory parameters in patients with hemorrhagic shock who were treated with REBOA placement. Specifically, the study examined the impact of continuous/intermittent aortic balloon occlusion on hemodynamic parameters. The complication rates and mortality were also reported.

Cons: This study has several limitations that must be highlighted. First, the retrospective design of this study must be taken into account, since all data were acquired via the use of a registry. In addition, despite the use of an international database, a relatively small number of patients were included. Another limitation that should be considered is that the trauma registry does not include data regarding specific clinical examination findings nor clear descriptions of clinical judgment and indications for surgery.

Results, conclusion, and what it means

The most significant impact of this study on our practice is that worldwide experience demonstrated favorable outcomes of REBOA in trauma and the safety of its use. Until the present time, and not just in this particular paper, we do not know why authors conclude that multiple organ failure is REBOA-related in patients with hemodynamic shock and multiple other problems. Due to these limitations, additional prospective studies on this topic are warranted. Nevertheless, in spite of its limitations, this article provided adequate legitimacy for REBOA use. To the best of our knowledge, since the publication of this study, many other trauma centers have joined the ABO registry in efforts to maximize the use of the database.

Comments and future research

Using cloud-computing services allows a collection of unlimited data in real time from operating room monitors, including 1-minute interval changes of all physiological parameters. Moreover, the timing and type of all interventions, such as fluid boluses, blood product resuscitation, changes in Fio_2 and vasopressor administration, may be recorded prospectively. We estimate that these advances will very soon be able to convert a significant amount of the retrospective trauma research into a prospective design and will bring investigators around the world together. As we stated initially, the sky is only the limit.

i Related important publications

Borger van der Burg BLS, van Dongen TTCF, Morrison JJ, Hedeman Joosten PPA, DuBose JJ, Hörer TM, Hoencamp R. A systematic review and meta-analysis of the use of resuscitative endovascular balloon occlusion of the aorta in the management of major exsanguination. *Eur J Trauma Emerg Surg*. 2018 Aug;44(4):535-550.

Aoki M, Abe T, Hagiwara S, Saitoh D, Oshima K. Resuscitative endovascular balloon occlusion of the aorta may contribute to improved survival. *Scand J Trauma Resusc Emerg Med*. 2020 Jun 30;28(1):62.

Moore LJ, Brenner M, Kozar RA, Pasley J, Wade CE, Baraniuk MS, Scalea T, Holcomb JB. Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage. *J Trauma Acute Care Surg*. 2015 Oct;79(4):523-30; discussion 530-2.

Bulger EM, Perina DG, Qasim Z, Beldowicz B, Brenner M, Guyette F, Rowe D, Kang CS, Gurney J, DuBose J, Joseph B, Lyon R, Kaups K, Friedman VE, Eastridge B, Stewart R. Clinical use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in civilian trauma systems in the USA, 2019: a joint statement from the American College of Surgeons Committee on Trauma, the American College of Emergency Physicians, the National Association of Emergency Medical Services Physicians and the National Association of Emergency Medical Technicians. *Trauma Surg Acute Care Open*. 2019 Sep 20;4(1):e000376

ARTICLE NUMBER 2

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is associated with improved survival in severely injured patients: A propensity score matching analysis.

Am J Surg. 2019 Dec;218(6):1162-1168.

Yamamoto R, Cestero RF, Suzuki M, Funabiki T, Sasaki J.

Abstract

Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a technique for temporary control of arterial hemorrhage. However, its effectiveness and clinical outcomes are unclear.

Methods: Using a nationwide database (2004-2016) in Japan, trauma patients with survival data were identified. Patients were divided between REBOA and non-REBOA groups, and a propensity score was developed using multivariate logistic regression. Survival to discharge was compared between the groups after propensity score matching.

Results: Among 82,371 patients included in this study, 385 were treated with REBOA. After propensity score matching, 117 pairs were selected. Survival to discharge was significantly higher among patients treated with REBOA than among those treated without REBOA (53 [45.3%] vs. 38 [32.5%]; odds ratio = 1.72; 95% CI = 1.01-2.93; p = 0.04).

Conclusions: REBOA use was associated with improved survival to discharge and should therefore be considered during the management of severely injured trauma patients.

Article review and analysis

Aim of this study: The use of REBOA in trauma settings has been debated since it was first introduced during the 1950's. The trauma community has been sizzling during the past decade and an increasing number of publications now discuss REBOA's indications, feasibility and effectiveness.

This article is one of the most prominent articles, originating from “the Country of the Rising Sun”. In Japan, the use of REBOA in clinical settings spread early, probably because the first commercial REBOA set was developed in Japan and was approved by the Japanese Ministry of Health in 2000. Despite an increasing amount of publications supporting REBOA use, there are several other important studies (including the large work by Peter Rhee published in “JAMA Surgery”) which have raised questions concerning the outcomes and safety of REBOA use. The article discussed here evaluates the feasibility of REBOA, using a multivariate propensity score.

Methods

Pros: The authors of this article created a multivariate propensity score and used the Japan Trauma Data Bank to compare outcomes of patients treated with REBOA and a

“non-REBOA” group. This is one of the largest studies on REBOA in trauma patients worldwide. The major advantage of the use of a propensity score is it eliminates the limitations of the study’s retrospective design and reduces the effects of confounding factors.

Cons: Among 82,371 patients found in the trauma registry, 385 were treated with REBOA; however, the propensity score used limited the comparison to only 117 pairs, making the conclusions of the article more ambiguous. The association between REBOA and improved survival might not be applicable in patients who were excluded during the final propensity model development.

It is not clear how the population of the “non-REBOA” group was treated. Despite the fact that both groups were statistically similar before the matching, there is no information comparing the incidence and types of interventions/surgeries between both groups after matching using the propensity score.

Results, conclusion, and what it means

This article was probably the first attempt to use robust statistical methods on a large nationwide trauma database to demonstrate that REBOA is independently associated with improved in-hospital survival in trauma patients, even though the REBOA group suffered from more severe injuries compared to the “non-REBOA” group (lower Glasgow Coma Scale [GCS], lower systolic blood pressures [BP] on arrival, and significantly higher ISS). Moreover, the authors clearly showed that REBOA was significantly associated with reduced mortality in patients who survived the first day of injury and the observed relationship was consistent regarding survival at 28 days.

The authors concluded that survival to hospital discharge was significantly higher among patients treated with REBOA compared to the “non-REBOA” group by approximately 15%. However, it is important to mention that REBOA is not a method to treat injuries, but a only “bridging technique” that allows for temporary hemorrhage control until other standard hemostasis procedures can be performed.

Comments and future research

This excellent article may lead to several future ideas. Today, the main debate regards the question of which patients will benefit the most from REBOA placement. Certainly, this would be interesting to perform even retrospectively, with similar multivariate propensity scores for patients with the same injury patterns. Moreover, the modified propensity score may be developed to chest, abdominal or pelvic injuries separately. Possible stratification for blunt versus penetrating injuries could better define the appropriate variables for such new scoring systems. The development of these scoring systems requires a larger database. There is no doubt that future collaboration efforts between international registries, such as the Japan Trauma Data Bank, ABO registry group, AAST and others, will provide the necessary information and enable the spread of EVTm.

i Related important publications

DuBose JJ, Scalea TM, Brenner M, Skiada D, Inaba K, Cannon J, Moore L, Holcomb J, Turay D, Arbabi CN, Kirkpatrick A, Xiao J, Skarupa D, Poulin N; AAST AORTA Study Group. The AAST prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: Data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). *J Trauma Acute Care Surg*. 2016 Sep;81(3):409-19.

Abe T, Uchida M, Nagata I, Saitoh D, Tamiya N. Resuscitative endovascular balloon occlusion of the aorta versus aortic cross clamping among patients with critical trauma: a nationwide cohort study in Japan. *Crit Care*. 2016 Dec 15;20(1):400.

Matsumoto S, Hayashida K, Akashi T, Jung K, Sekine K, Funabiki T, Moriya T. Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Severe Torso Trauma in Japan: A Descriptive Study. *World J Surg*. 2019 Jul;43(7):1700-1707.

Manzano Nunez R, Naranjo MP, Foianini E, Ferrada P, Rincon E, García-Perdomo HA, Burbano P, Herrera JP, García AF, Ordoñez CA. A meta-analysis of resuscitative endovascular balloon occlusion of the aorta (REBOA) or open aortic cross-clamping by resuscitative thoracotomy in non-compressible torso hemorrhage patients. *World J Emerg Surg*. 2017 Jul 14;12:30

ARTICLE NUMBER 3

Resuscitative Endovascular Balloon Occlusion of the Aorta and Resuscitative Thoracotomy in Select Patients with Hemorrhagic Shock: Early Results from the American Association for the Surgery of Trauma's Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery Registry.

J Am Coll Surg. 2018 May;226(5):730-740.

Brenner M, Inaba K, Aiolfi A, DuBose J, Fabian T, Bee T, Holcomb JB, Moore L, Skarupa D, Scalea TM; AAST AORTA Study Group.

Abstract

Background: Aortic occlusion is a potentially valuable tool for early resuscitation in patients nearing extremis or in arrest from severe hemorrhage.

Study design: The American Association for the Surgery of Trauma's Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery registry identified trauma patients without penetrating thoracic injury undergoing aortic occlusion at the level of the descending thoracic aorta (resuscitative thoracotomy [RT] or zone 1 resuscitative endovascular balloon occlusion of the aorta [REBOA]) in the emergency department (ED). Survival outcomes relative to the timing of CPR need and admission hemodynamic status were examined.

Results: Two hundred and eighty-five patients were included: 81.8% were males, with injury due to penetrating mechanisms in 41.4%; median age was 35.0 years (interquartile range 29 years) and median Injury Severity Score was 34.0 (interquartile range 18). Resuscitative thoracotomy was used in 71%, and zone 1 REBOA in 29%. Overall survival beyond the ED was 50% (RT 44%, REBOA 63%; $p = 0.004$) and survival to discharge was 5% (RT 2.5%, REBOA 9.6%; $p = 0.023$). Discharge Glasgow Coma Scale score was 15 in 85% of survivors. Prehospital CPR was required in 60% of patients with a survival beyond the ED of 37% and survival to discharge of 3% (all $p > 0.05$). Patients who did not require any CPR before had a survival beyond the ED of 70% (RT 48%, REBOA 93%; $p < 0.001$) and survival to discharge of 13% (RT 3.4%, REBOA 22.2%, $p = 0.048$). If aortic occlusion patients did not require CPR but presented with hypotension (systolic blood pressure <90 mmHg; 9% [65% RT; 35% REBOA]), they achieved survival beyond the ED in 65% ($p = 0.009$) and survival to discharge of 15% (RT 0%, REBOA 44%; $p = 0.008$).

Conclusions: Overall, REBOA can confer a survival benefit over RT, particularly in patients not requiring CPR. Considerable additional study is required to definitively recommend REBOA for specific subsets of injured patients.

Article review and analysis

Aim of this study: The "AORTA" multi-institutional database was started in 2013 to capture contemporary methods of aortic occlusion (AO) with the purpose of refining clinical protocols and future data collection. The results from this database demonstrated no difference in survival between resuscitative endovascular balloon occlusion of the aorta (REBOA) and resuscitative thoracotomy (RT). However, the study included all patients who received REBOA with highly variable causes of hemorrhage and physiological status at the time of intervention.

The purpose of this study was to investigate the use of REBOA and RT as a means of AO in a more selective group of patients. Data were collected prospectively; patients were enrolled from November 2013 to January 2017. In this study only patients undergoing AO in Zone 1 (distal thoracic aorta) in the emergency department (ED) were included. Patients who received REBOA in the operating room and patients who sustained penetrating thoracic injuries were excluded from analysis.

Methods

Pros: As has been mentioned as limitations of other works presented in this chapter, there is a lack of data regarding the physiological state of the patients during AO and, even more importantly, data following the AO is missing. This article elaborates on the time from initiation of AO procedure to successful AO, type and conduct of AO, resulting physiological response, post-AO laboratory changes, and subsequent outcomes. Additional procedures after AO were also recorded, as were resuscitation requirements.

A key difference in AORTA2 compared with AORTA1 is the inclusion criteria. By excluding penetrating thoracic injury as a cause of hemorrhage and/or traumatic arrest and enrolling only patients who received a Zone 1 REBOA in the ED, the patient population before AO became more homogenous, thus strengthening the conclusions. Moreover, the authors used a sub-analysis to isolate the patients who would gain most from REBOA. The injured patients who needed an AO were divided into 3 groups according to the need and timing of CPR, thus demonstrating no difference between REBOA and RT in patients who required CPR (pre-hospital or in-hospital pre-AO). However, patients with no need of CPR had significantly higher survival after transfer from the ED when treated with REBOA and higher survival to discharge.

Cons: While disassembling the multi-institutional database, one can notice that 94% of REBOA patients were enrolled at 2 early adopting institutions, and the remainder were from institutions that perform <10 REBOA placements per year.

Results, conclusion, and what it means

The presented data suggest that overall survival is higher in patients receiving REBOA. However, more detailed analysis demonstrates that the patients who might benefit most from REBOA are those who were in extremis but who did not require CPR before AO. As mentioned above, no difference in survival was seen in patients who required CPR before admission or before AO. With equivalent survival rates in this patient population, REBOA offers a less invasive and probably less morbidity-related option for AO than RT, with minimal exposure risk for medical providers.

Importantly, REBOA is a bridge for other trauma resuscitation and hemostasis procedures. This was demonstrated by REBOA patients receiving an additional intervention, such as exploratory laparotomy, craniotomy, preperitoneal packing or pelvic angioembolization.

Tolerance time of AO, particularly at Zone 1, remains unclear. In this study, patients who had no CPR before AO had higher survival rates with REBOA as compared with RT, with a mean of 60 minutes of AO in patients receiving REBOA compared to a mean of 20 minutes in RT patients. It appears that a longer duration of AO, up to approximately 60 minutes at Zone 1, is tolerated without affecting survival.

As in AORTA1, approximately half of all the REBOAs performed required a surgical exposure for CFA access. The inability to obtain percutaneous CFA access limits the spectrum of REBOA users. If CFA access is not achieved rapidly and properly, either by surgical exposure or percutaneously, then RT is a faster method of AO. These findings underscore the importance of placing a CFA arterial line at admission in any patient who might not adequately respond to resuscitation.

Comments and future research

This study demonstrated that AO of 60 minutes is feasible. It seems reasonable that a combination of total and partial AO will prolong the ability to provide proximal control without irreversible distal ischemia. Additional investigation is needed to determine the various systemic consequences of both approaches for aortic occlusion. For example, it will be very interesting to evaluate the degree of bowel ischemia in surviving patients as well as the incidence of abdominal/extremity compartment syndrome. Future animal studies can investigate the influence of aortic occlusion on muscle ischemia and resulting rhabdomyolysis, which may be, at least partially, responsible for acute kidney injury and worsening of metabolic acidosis in these patients.

i Related important publications

- DuBose JJ, Scalea TM, Brenner M, et al. The AAST Prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry: contemporary utilization and outcomes of aortic occlusion and REBOA. *J Trauma Acute Care Surg* 2016;81:409e419.
- Brenner M, Bulger EM, Perina DG, et al. Joint statement from the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP) regarding the clinical use of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA). *Trauma Surg Acute Care Open* 2018;3:e000154.
- Bekdache O, Paradis T, Shen YBH, Elbahrawy A, Grushka J, Deckelbaum D, Khwaja K, Fata P, Razek T, Beckett A. Resuscitative endovascular balloon occlusion of the aorta (REBOA): indications: advantages and challenges of implementation in traumatic non-compressible torso hemorrhage. *Trauma Surg Acute Care Open*. 2019 Apr 15;4(1):e000262.
- Brenner M, Teeter W, Hoehn M, Pasley J, Hu P, Yang S, Romagnoli A, Diaz J, Stein D, Scalea T. Use of Resuscitative Endovascular Balloon Occlusion of the Aorta for Proximal Aortic Control in Patients With Severe Hemorrhage and Arrest. *JAMA Surg*. 2018 Feb 1;153(2):130-135.

ARTICLE NUMBER 4

Nationwide Analysis of Resuscitative Endovascular Balloon Occlusion of the Aorta in Civilian Trauma.

JAMA Surg. 2019 Jun 1;154(6):500-508.

Joseph B, Zeeshan M, Sakran JV, Hamidi M, Kulvatunyong N, Khan M, O'Keeffe T, Rhee P.

Abstract

Importance: The need for improved methods of hemorrhage control and resuscitation has resulted in a reappraisal of resuscitative endovascular balloon occlusion of the aorta (REBOA). However, there is a paucity of data regarding the use of REBOA on a multi-institutional level in the United States.

Objective: To evaluate the outcomes in trauma patients after REBOA placement.

Design, setting, and participants: A case-control retrospective analysis was performed of the 2015-2016 American College of Surgeons Trauma Quality Improvement Program data set, a national multi-institutional database of trauma patients in the United States. A total of 593 818 adult trauma patients (aged ≥ 18 years) were analyzed and 420 patients were matched and included in the study; patients who were dead on arrival or were transferred from other facilities were excluded. Trauma patients who underwent REBOA placement in the ED were identified and matched with a similar cohort of patients (the no-REBOA group). Both groups were matched in a 1:2 ratio using propensity score matching for demographics, vital signs, mechanism of injury, injury severity score, head abbreviated injury scale score, each body region abbreviated injury scale score, pelvic fractures, lower extremity vascular injuries and fractures, and number and grades of intra-abdominal solid organ injuries.

Main outcomes and measures: Outcome measures were the rates of complications and mortality.

Results: Of 593 818 trauma patients, 420 patients (the REBOA group, 140 patients; 36 women and 104 men; mean [SD] age, 44 [20] years; the no-REBOA group, 280 patients; 77 women and 203 men; mean [SD] age, 43 [19] years) were matched and included in the analysis. Among the REBOA group, median injury severity score was 29 (interquartile range [IQR], 18-38) and 129 patients (92.1%) had a blunt mechanism of injury. There was no significant difference between groups in median 4-hour blood transfusion (REBOA: packed red blood cells, 6 U [IQR, 3-8 U]; platelets, 4 U [IQR, 3-9 U], and plasma, 3 U [IQR, 2-5 U]; and no-REBOA: packed red blood cells, 7 U [IQR, 3-9 U]; platelets, 4 U [IQR, 3-8 U], and plasma, 3 U [IQR, 2-6 U]) or 24-hour blood transfusion (REBOA: packed red blood cells, 9 U [IQR, 5-20 U]; platelets, 7 U [IQR, 3-13 U], and plasma, 9 U [IQR, 6-20 U]; and no-REBOA: packed red blood cells, 10 U [IQR, 4-21 U]; platelets, 8 U [IQR, 3-12 U], and plasma, 10 U [IQR, 7-20 U]), median hospital length of stay (REBOA, 8 days [IQR, 1-20 days]; and no-REBOA, 10 days [IQR, 5-22 days]), or median intensive care unit length of stay (REBOA, 5 days [IQR, 2-14

days]; and no-REBOA, 6 days [IQR, 3-15 days]). The mortality rate was higher in the REBOA group as compared with the no-REBOA group (50 [35.7%] vs 53 [18.9%]; $P = .01$). Patients who underwent REBOA placement were also more likely to develop acute kidney injury (15 [10.7%] vs 9 [3.2%]; $P = .02$) and more likely to undergo lower extremity amputation (5 [3.6%] vs 2 [0.7%]; $P = .04$).

Conclusions and relevance: Placement of REBOA in severely injured trauma patients was associated with a higher mortality rate compared with a similar cohort of patients with no placement of REBOA. Patients in the REBOA group also had higher rates of acute kidney injury and lower leg amputations. There is a need for a concerted effort to clearly define when and in which patient population REBOA has benefit.

Article review and analysis

Aim of this study: The purpose of REBOA is to provide temporary hemorrhage control in cases of severe non-compressible bleeding. At the time of publication of this article, there was still a lack of data regarding the effectiveness of this method in the treatment of trauma patients. In addition, the previously published studies in this field are observational and/or retrospective in design. These research methodologies are common in the field of trauma due to the logistical limitations of and ethical concerns in conducting a randomized study. The aim of this study was to evaluate the effectiveness of REBOA using a large ACS-TQIP database. In an effort to overcome the lack of randomization and the limitations of the retrospective design, this study was made by performing propensity score matching in order to compare the results of trauma patients with similar baseline characteristics who were treated with or without REBOA.

Methods

Pros: This is a multi-center study based on a large number of patients from the United States. The database includes multiple parameters (demographics, mechanism of injury, injury severity score [ISS], each body region abbreviated injury scale score [AIS], prehospital and ED vital signs, transfusion parameters, hospital length of stay [LOS], in-hospital complications, and mortality). Matching according to the different characteristics enables comparison of patients with similar demographic characteristics and identical injury severity and thus partially eliminates the built-in bias of a retrospective study design.

Cons: The main limitation of this study is the challenge in comparing the patients according to the criteria that do not necessarily adequately reflect the injury severity and the physiological conditions. For example, hemodynamic parameters, such as heart rate and blood pressure, according to the values obtained en-route to the trauma care facility, can reflect a momentary situation, while the subsequent hemodynamic status and the response to intravenous fluids, observed during resuscitation, are more significant in the prediction of survival.

Although, following the matching, there were no significant differences between the groups in the parameters used for comparison, this does not necessarily mean that the groups were identical. When looking at the prevalence of vascular injuries, there were no significant differences between the two groups (PV - 0.11). The prevalence of vascular injuries to the lower extremities or to the iliac vessels is essentially identical, while other vascular injuries were overrepresented in the REBOA group (27.1%) compared to the non-REBOA group (3.9%).

In addition, the study does not contain any information regarding the indications for REBOA use and the anatomical zones used for balloon inflation. In the group of non-survivors treated with REBOA, the median GCS was 3 and the AIS of the head injury was 2. As is well known, severe head injury is considered by many as a contraindication to REBOA. Thus, the argument can be made that, in these cases, it was not at all appropriate to perform REBOA.

Results, conclusion, and what it means

The authors of the study conclude that in the patients treated with REBOA, there was an over-prevalence of AKI, limb amputations and higher mortality. In addition, the time until definitive hemorrhage control intervention (angioembolization, laparotomy) was slightly longer in the REBOA group.

As noted above, in light of the inherent difficulties in performing proper matching, the validity of these conclusions can be questioned. Any increase in mortality, in the patients who received REBOA, was attributed to the first 24 hours of admission and there was no significant difference in later mortality. Is it likely that the REBOA itself caused mortality in the first few hours, while no difference in mortality was observed later on or, rather, does it indicate the injury severity among patients treated with REBOA?

As noted above, there was a delay of about 15 minutes in performing intervention (angioembolization or laparotomy) among patients treated with REBOA. It is uncertain whether the higher mortality could be attributed to such a short time interval. It is possible that, instead, it indicates the severity of injuries in this group of patients and reflects the need for more aggressive resuscitation until the definitive intervention can be performed.

High rates of serious complications, such as AKI and limb threatening ischemia, have been described in REBOA. However, assuming that this a lifesaving procedure, these complications are an unfortunate necessity. Moreover, until today, the literature lacks clear parameters, comparing different cause-related factors for such complications. It remains unclear whether deep hemorrhagic shock, massive musculoskeletal injuries or REBOA itself make a major contribution to the rate of these complications. Therefore, in our opinion, the authors' conclusions are still controversial.

Comments and future research

The use of matching in trauma research is a very beneficial tool to overcome the lack of randomization. Future research may include similar studies with better group matching and stratification of the injury patterns. Together with meticulous data collection regarding the resuscitation requirements, such research will provide a more adequate comparison between patients treated by these two approaches. Utilization of the common multicenter protocol, including standardization of the decision-making processes in application of REBOA in trauma patients, will probably provide the necessary information to define the best solution.

i Related important publications

Saito N, Matsumoto H, Yagi T, Hara Y, Hayashida K, Motomura T, Mashiko K, Iida H, Yokota H, Wagatsuma Y. Evaluation of the safety and feasibility of resuscitative endovascular balloon occlusion of the aorta. *J Trauma Acute Care Surg.* 2015 May;78(5):897-903.

Abe T, Uchida M, Nagata I, Saitoh D, Tamiya N. Resuscitative endovascular balloon occlusion of the aorta versus aortic cross clamping among patients with critical trauma: a nationwide cohort study in Japan. *Crit Care.* 2016 Dec 15;20(1):400. doi: 10.1186/s13054-016-1577-x. Erratum in: *Crit Care.* 2017 Feb 22;21(1):41.

Pieper A, Thony F, Brun J, Rodière M, Boussat B, Arvieux C, Tonetti J, Payen JF, Bouzat P. Resuscitative endovascular balloon occlusion of the aorta for pelvic blunt trauma and life-threatening hemorrhage: A 20-year experience in a Level I trauma center. *J Trauma Acute Care Surg.* 2018 Mar;84(3):449-453.

ARTICLE NUMBER 5

Titrate to equilibrate and not exsanguinate! Characterization and validation of a novel partial resuscitative endovascular balloon occlusion of the aorta catheter in normal and hemorrhagic shock conditions.

J Trauma Acute Care Surg. 2019 Nov;87(5):1015-1025.

Forte DM, Do WS, Weiss JB, Sheldon RR, Kuckelman JP, Eckert MJ, Martin MJ.

Abstract

Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a significant advancement in the control of noncompressible truncal hemorrhage. However, its ischemic burden and reperfusion injury following balloon deflation limits its utilization. Partial restoration of aortic flow during REBOA has the potential to balance hemorrhage control and ischemia. This study validates the mechanics, physiology, and optimal partial flow rates using a prototype partial REBOA (pREBOA) device.

Methods: Twenty-five swine underwent placement of aortic flow probes and zone 1 pREBOA. Experiment 1 (N = 5) animals were not injured and assessed the tested the catheters ability to titrate and control flow. Experiment 2 (N = 10) added 20% hemorrhage and either solid organ, or abdominal vascular injury to compare flow rate and rebleeding from injuries. Experiment 3 (N = 10) swine were similarly prepared, hemorrhaged, and underwent pREBOA at set partial flow rates for 2 hours followed by complete deflation for 30 minutes.

Results: Balloon volume at minimum flow (mean, 0.09 L/min) was 3.5 mL to 6.0 mL. Half maximal flow was achieved with 56.5% of maximum balloon inflation. Partial REBOA allowed very fine titration of flow rates. Rebleeding occurred at 0.45 L/min to 0.83 L/min. Distal flow of 0.7 L/min had 50% survival, 0.5 had 100% survival, and 0.3 L had 50% survival with mean end lactates of 9.6, 12.6, and 13.3, respectively. There was a trend toward hyperkalemia and hypocalcemia in nonsurvivors.

Conclusion: The pREBOA device demonstrated a high level of titratability for restoration of aortic flow. An optimal partial flow of 0.5 L/min was effective at hemorrhage control while limiting the burden of ischemic injury, and extending the tolerable duration of zone 1 occlusion. Aggressive calcium supplementation prior to and during partial occlusion and reperfusion may be warranted to prevent hyperkalemic arrest.

Article review and analysis

Aim of this study: This study aimed to evaluate the concept of partial restoration of blood flow (partial REBOA, pREBOA) and validate the hemodynamic parameters of its application in an animal model. Currently, there are no human data available on this technique, although some animal studies show promising results. One of the main problems with REBOA use is that the balloon occlusion time correlates with

poor outcome. In this work, the authors attempted to answer several unsolved questions. First, there was an initial effort to define the feasibility of titration of blood flow restoration. In addition, there was an assessment of risk-benefit of re-bleeding vs. perfusion-reperfusion injury.

The current commercially available devices are not designed for partial REBOA. Fine control of blood flow is not possible in the partially deflated balloon position with current catheters because the loss of full balloon apposition with the aortic wall results in rapid restoration of flow in spherically-shaped compliant balloons. The catheter used in the current study was especially designed for partial REBOA. The catheter tip carries a bilobed balloon that allows tight lumen occlusion by its non-compliant part, following which a fine-tuning of blood flow can be performed by the gradual deflation of the compliant part.

Methods

Pros: The swine animal model was used to conduct three sets of experiments.

The first experiment simulated the effect of controlled deflation of a pREBOA catheter placed in the thoracic aorta in a non-hemorrhaging animal.

The second experiment simulated resuscitation for initial hemorrhage control with 10 minutes of “balloon up” time to allow clot formation, and the effect of balloon deflation and gradual flow restoration on rebleeding. In this experiment, the animals were divided into solid organ injury and vascular injury groups.

The third experiment simulated partial aortic occlusion after 10 min of “balloon up” time in a hemorrhaging animal for a period of two hours at preset flow rates, followed by complete “balloon down” for 30 min.

The authors introduced a new type of occlusion balloon specially designed for partial flow restoration.

Cons: As with all animal model experiments, it is not always possible to correlate the trauma response to an injury performed in a controlled laboratory setting with a multitude of actual multi-trauma conditions. Such studies open a new horizon, validate the feasibility of the hypothesis, and serve as a basis for future human research. However, the conclusions from such studies cannot be directly implemented in clinical practice.

Results, conclusion, and what it means

First, this study presented a novel bilobed catheter that showed a high degree of blood flow control and an ability to titrate the flow across the balloon without abrupt fluctuations. The authors demonstrated that this newly designed catheter succeeded not only in aortic occlusion but also allowed control, titration and restoration of partial blood flow in the aorta.

Heart rate, distal aortic flow, proximal and distal pressure measurements through the inflation cycle, as well as the balloon deflation parameters, were described.

The reported values of flow and pressure, and the titration curves presented in the

study are undoubtedly influenced by the limitations of the animal model used in the experiments. However, this does not invalidate the results and the bilobed catheter is clearly capable of fine titration of flow.

The effect of rebleeding after balloon deflation was more pronounced in solid organ injury than in vascular injury. Rebleeding after major solid organ injury occurred at higher flow rates than that in vascular injuries. Due to the study's small sample size and the above-mentioned limitations, it is premature to draw any conclusions regarding the influence of the technique on the type of injury.

The effects of prolonged partial occlusion in a hemorrhaging animal at varying distal flow rates were evaluated. A survival advantage was shown in animals resuscitated at a partial flow of 0.5 L/h. This section of the study is significantly underpowered, but it may show broad trends to guide future research.

Based on the presented data, we conclude that the bilobed catheter design is capable of achieving gradual and controlled restoration of blood flow in partial REBOA settings. To the best of our knowledge, the catheters used in this study are not commercially available for human use. Given the inherent limitations of animal-based trauma research, the technique should be validated in clinical studies.

Comments and future research

The main role of REBOA is elevation of systemic blood pressure. However, the trauma literature lacks agreement regarding the optimal blood pressure in bleeding trauma patients, especially in those with concomitant head injuries. Moreover, no data exists regarding the expected blood pressure in patients undergoing aortic closure, either surgically or endovascularly. To the best of our knowledge, there are no predictive factors for the expected numbers. Any possibility to use "titrated" aortic occlusion, leaving the aorta open on the one hand, and providing partial distal flow on the other hand, opens a large spectrum and multiple directions for future research.

There is no doubt that such experiments should be performed first on animal models. For example, it may be very interesting to evaluate the association between blood pressure after REBOA (total, partial, titrated) and the accurate amount of blood loss. Similar research could be carried out with stratification according to the anatomic zone location. This information will also be very helpful for following future definition of the minimal adequate degree of aortic occlusion.

CHAPTER 7.

REBOA in emergency non-trauma patients

Authors: *Alexander Korin, Maya Paran and Mickey Dudkiewicz*

Introduction

Uncontrolled hemorrhage, specifically non-compressible bleeding, resulting from both trauma and non-trauma causes is a significant cause of death worldwide. Rapid control of such bleeding is challenging and thus exsanguination remains associated with high rates of mortality. In recent years, the use of endovascular occlusion of the aorta (REBOA) has been introduced and has gained popularity in the attempt to allow for better clinical outcomes in patients with uncontrolled hemorrhage from different causes. Although this method of hemorrhage control was initially invented for the treatment of trauma patients, it has since also been accepted for the achievement of bleeding control in non-trauma patients. The placement of REBOA in non-trauma patients with hemorrhagic shock is a promising approach for temporary bleeding control that is extremely challenging and was once thought to be bordering on the impossible. However, since this is a fairly new treatment option, studies researching the indications, clinical course, results, and possible complications of REBOA utilization in the treatment of non-trauma patients are relatively few. A thorough search of the literature regarding the use of REBOA in non-trauma causes of hemorrhage did not yield any randomized controlled or prospective studies. Currently, the evidence regarding this topic is limited to retrospective studies. We hereby review the latest and most relevant studies that have investigated the possible benefits and limitations of REBOA use in the treatment of non-trauma causes of uncontrolled hemorrhage.

ARTICLE NUMBER 1

Nontraumatic hemorrhage is controlled with REBOA in acute phase then mortality increases gradually by nonhemorrhagic causes: DIRECTIABO registry in Japan.

Eur J Trauma Emerg Surg. 2018;44:503–509.

Y. Matsumura, J. Matsumoto, K. Idoguchi, H. Kondo, T. Ishida, Y. Kon, K. Tomita, K. Ishida, T. Hirose, K. Umakoshi, T. Funabiki, DIRECT-IABO investigators.

Abstract

Purpose: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is now a feasible and less invasive resuscitation procedure. This study aimed to compare the clinical course of trauma and non-trauma patients undergoing REBOA.

Methods: Patient demographics, etiology, bleeding sites, hemodynamic response, length of critical care, and cause of death were recorded. Characteristics and outcomes were compared between non-trauma and trauma patients. Kaplan–Meier survival analysis was then conducted.

Results: Between August 2011 and December 2015, 142 (36 non-trauma; 106 trauma) cases were analyzed. Non-traumatic etiologies included gastrointestinal bleeding, obstetrics, and gynecology-derived events, visceral aneurysm, abdominal aortic aneurysm, and post-abdominal surgery. The abdomen was a common bleeding site (69%), followed by the pelvis or extra-pelvic retroperitoneum. None of the non-trauma patients had multiple bleeding sites, whereas 45% of trauma patients did ($P < 0.001$). No non-trauma patients required resuscitative thoracotomy compared with 28% of the trauma patients ($P < 0.001$). Non-trauma patients presented a lower 24-h mortality than trauma patients (19 vs. 51%, $P = 0.001$). The non-trauma cases demonstrated a gradual but prolonged increased mortality, whereas survival in trauma cases rapidly declined ($P = 0.009$) with similar hospital mortality (68 vs. 64%). Non-trauma patients who survived for 24 h had 0 ventilator-free days and 0 ICU-free days vs. a median of 19 and 12, respectively, for trauma patients ($P = 0.33$ and 0.39 , respectively). Non-hemorrhagic death was more common in non-trauma vs. trauma patients (83 vs. 33%, $P < 0.001$).

Conclusions: Non-traumatic hemorrhagic shock often resulted from a single bleeding site, and resulted in better 24-h survival than traumatic hemorrhage among Japanese patients who underwent REBOA. However, hospital mortality increased steadily in non-trauma patients affected by non-hemorrhagic causes after a longer period of critical care.

Article review and analysis

Aim of this study: The Japanese Society of Diagnostic and Interventional Radiology in Emergency, Critical Care and Trauma (DIRECT) is a multi-institutional registry in Japan. The objective of this registry was to investigate the use of REBOA in various

clinical situations throughout Japan. This study aimed to assess and compare the clinical course and results of REBOA use in trauma patients as compared with non-trauma patients with uncontrolled active bleeding.

Methods

Pros: An important strength of this study is the analysis of data regarding patients treated in 18 different medical centers. As this study assessed the clinical outcome not only in a single center with specific, unique abilities, it provides information that can be more certainly applied realistically to other hospitals.

Cons: The etiology of bleeding in the non-trauma group was highly variable. Therefore, this group of patients is very heterogeneous, which makes it difficult to assess the actual benefit of REBOA use in different indications. The authors attempted to better differentiate patients by subdividing the group into patients with emergency admission as opposed to patients with in-hospital onset of bleeding. The registry-based and retrospective design of this study is another important limitation of this study. Nevertheless, this is an important study and the first one to have compared the clinical outcome in trauma vs. non-trauma patients.

Results, conclusion, and what it means

The hemodynamic response to balloon inflation was similar in trauma and non-trauma patients. Importantly, all patients in the non-trauma group had a single bleeding site as opposed to only 45% in the trauma group, and the 24-hour mortality was significantly lower in the non-trauma group. In addition, non-hemorrhagic related death was more common in the non-trauma group. These results suggest that REBOA may possibly be even more useful in non-trauma scenarios than in the treatment of trauma patients for which this method was originally invented. Additionally, these results may also suggest that the utilization of REBOA in trauma patients with only a single source of bleeding may be more useful than in trauma patients with multi-bleeding sources. However, it is important to note that this study included non-trauma patients with a very wide variety of bleeding causes. Hence, it is difficult to deduct which causes of bleeding should be specific indications for REBOA use.

Comments and future research

Further studies are needed in order to better define indications for REBOA placement in patients with hemorrhagic shock and investigate the clinical outcome of these patients. Studies with a more homogenous population of patients and a single cause and type of hemorrhage may enable the creation of guidelines for REBOA use in non-trauma patients with uncontrolled bleeding. A small number of such studies have already been published and will be discussed in this chapter. It may also be very interesting to compare REBOA use in trauma patients with a single source of bleeding vs. trauma patients with concomitant bleeding from several different sources to further

evaluate the benefits of REBOA in specific situations. Another possible study might evaluate the adaptation of location of REBOA placement to different and particular sites of non-traumatic bleeding.

i Related important publications

Stannard A, Eliason JL, Rasmussen TE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for hemorrhagic shock. *J Trauma*. 2011 Dec;71(6):1869-72.

Brenner ML, Moore LJ, DuBose JJ, Tyson GH, McNutt MK, Albarado RP, Holcomb JB, Scalea TM, Rasmussen TE. A clinical series of resuscitative endovascular balloon occlusion of the aorta for hemorrhage control and resuscitation. *J Trauma Acute Care Surg*. 2013 Sep;75(3):506-11.

ARTICLE NUMBER 2

Resuscitative endovascular balloon occlusion of the aorta for uncontrollable nonvariceal upper gastrointestinal bleeding.

World J Emerg Surg. 2016;11:20

Sano H, Tsurukiri J, Hoshiai A, Oomura T, Tanaka Y, Ohta S.

Abstract

Background: Although resuscitative endovascular balloon occlusion of the aorta (REBOA) in various clinical settings was found to successfully elevate central blood pressure in hemorrhagic shock, this intervention is associated with high mortality and may represent a last-ditch option for trauma patients. We conducted a retrospective study of patients with nonvariceal upper gastrointestinal bleeding (UGIB) who underwent REBOA to identify the effectiveness of REBOA and reviewed published literatures.

Methods: REBOA were performed by trained acute care physicians in the emergency room and intensive care unit. The deployment of balloon catheters was positioned using ultrasonography guidance. Collected data included clinical characteristics, hemorrhagic severity, blood cultures, metabolic values, blood transfusions, REBOA-related complications and mortality. A literature search using PUBMED to include “aortic occlusion” and “gastrointestinal bleeding” was conducted.

Results: REBOA was attempted in eight patients among 140 patients with UGIB and median age was 66 years. Systolic blood pressure significantly increased after REBOA (66 ± 20 vs. 117 ± 45 mmHg, $p < 0.01$) and the total occlusion time of REBOA was 80 ± 48 min. Strong positive correlations were found between total occlusion time of REBOA and lactate concentration (Spearman's $r=0.77$), clinical Rockwall score (Spearman's $r=0.80$), and age (Spearman's $r=0.88$), respectively.

Conclusion: REBOA can be performed with a high degree of technical success and is effective at improving hemodynamic in patients with UGIB. Correlations between total occlusion time and high lactate levels, clinical Rockall score, and age may be important for successful use of REBOA.

Article review and analysis

Aim of this study: Upper gastrointestinal bleeding (UGIB) is one of the most common causes of massive bleeding in emergency surgery and hence presents one of the biggest challenges in the acute care setting. Such bleeding, if not quickly controlled, is associated with high mortality rates. REBOA presents a new treatment approach for patients with this type of bleeding and may enable sufficient “bridging time” for definitive bleeding source control. This study aimed to assess the effectiveness of REBOA use in patients with massive UGIB.

Methods

Pros: Other than a few case reports, this is the first study to report the results of REBOA use in a series of patients with UGIB. In addition, the authors report the influences of REBOA placement on multiple clinical and laboratory parameters, including SBP, heart rate, lactate, base excess, creatinine, and LDH, some of which are not regularly reported in other studies and are important in the understanding of the physiological impact of aortic balloon inflation.

Cons: All REBOA placements in this study were performed by or under the guidance of a single acute care physician who was specially trained in this technique. Thus, the study's results rely on a single person with specific expertise. The different levels of training and a variety of approaches must be taken into account when considering the real-world benefits and complications of a new technique. It is difficult to assess whether these results could be repeated and achieved in other hospitals where REBOA will be utilized by different physicians. Another limitation of this study is its small sample size, which warrants caution when applying the conclusions of the study in future practice. This study reports aortic occlusion in 8 patients with UGIB out of a total of 140 patients. It would have been interesting if a comparison between UGIB patients who were treated with and without REBOA placement had been made. Such a case-control study design could have provided important information on the benefit of REBOA use in this specific group of patients.

Results, conclusion, and what it means

This is the first case series to report on results of hemorrhage control using REBOA in patients with UGIB. This study has shown that REBOA use in patients with this specific cause of bleeding is feasible and enables adequate time to achieve definitive hemostasis by endoscopy/angioembolization/surgery.

Comments and future research

Prospective studies are needed in order to further evaluate the benefit and safety of REBOA use in patients with UGIB. However, before such studies may be performed, another interesting possibility is the assessment of how many patients with massive UGIB could have possibly benefited from REBOA utilization via a retrospective study design. For example, evaluation of UGIB related mortality may help identify potential candidates for REBOA in this unique population. As REBOA is a method for temporary hemorrhage control that needs to be eventually combined with definitive hemostasis, it may also be interesting for future studies to investigate and compare the clinical outcome of patients with UGIB undergoing REBOA and endoscopy as compared with REBOA and angioembolization or surgery with and without REBOA. Such studies may provide evidence for the benefits of different combinations of treatment methods.

i Related important publications

Morrison JJ, Galgon RE, Jansen JO, Cannon JW, Rasmussen TE, Eliason JL. A systematic review of the use of resuscitative endovascular balloon occlusion of the aorta in the management of hemorrhagic shock. *J Trauma Acute Care Surg.* 2016;80(2):324-34.

Karkos CD, Bruce IA, Lambert ME. Use of the intra-aortic balloon pump to stop gastrointestinal bleeding. *Ann Emerg Med.* 2001;38(3):328-31.

Shigesato S, Shimizu T, Kittaka T, Akimoto H. Intra-aortic balloon occlusion catheter for treating hemorrhagic shock after massive duodenal ulcer bleeding. *Am J Emerg Med.* 2015;33(3):473.e1-2.

ARTICLE NUMBER 3

Resuscitative endovascular balloon occlusion of the aorta for non-traumatic intra-abdominal hemorrhage.*Eur J Trauma Emerg Surg. 2019;45(4):713-718.**Hoehn MR, Hansraj NZ, Pasley AM, Brenner M, Cox SR, Pasley JD, Diaz JJ, Scalea T.***Abstract**

Background: Hemorrhagic shock is the second leading cause of death in blunt trauma and a significant cause of mortality in non-trauma patients. The increased use of resuscitative endovascular balloon occlusion of the aorta (REBOA) as a bridge to definitive control for massive hemorrhage has provided promising results in the trauma population. We describe an extension of this procedure to our hemodynamically unstable non-trauma patients.

Methods: This is a retrospective review of patients requiring REBOA for end stage non-traumatic abdominal hemorrhage from our tertiary care facility. After excluding patients with trauma, supradiaphragmatic bleed and thoracic/abdominal aortic aneurysms, demographics, etiology of bleed, REBOA placement specifics, complications and outcomes were reviewed.

Results: From August 2013 to August 2016, 11 patients were identified requiring REBOA placement for hemodynamic instability from non-traumatic abdominal hemorrhage. Average patient age was 54.9 (SD 15.2). Sixty-four percent suffered cardiac arrest prior to REBOA, with mean shock index of 1.29. Average time from diagnosis of shock ($\text{MAP} \leq 65$) or signs of bleeding to placement of REBOA was 177 min. The leading etiologies of hemorrhage were ruptured visceral aneurysm and massive upper gastrointestinal bleed. REBOA was placed by both acute care and vascular surgeons. The procedure was mainly completed in the operating room in 82% of the patients and at the bedside in 18%. One patient expired before operative repair. Definitive surgical control of the source of bleeding was obtained by open surgical approach ($n = 6$) and combined surgical and endovascular approach ($n = 4$). In-hospital survival was 64%. There were no local complications related to REBOA placement.

Conclusion: Similar to the trauma population, REBOA is an adjunctive technique for proximal control of bleeding as well as resuscitation in end stage non-traumatic intra-abdominal hemorrhage. We propose an algorithmic approach to REBOA use in this population and a larger prospective review is necessary to determine both the timing of REBOA placement and which non-traumatic patients may benefit from this technique.

Article review and analysis

Aim of this study: Uncontrolled non-compressible hemorrhage is one of the major problems in the field of emergency general surgery. REBOA utilization in such patients

is theoretically promising but not many studies have reported such use. This study aimed to assess the utility of REBOA placement in this population.

Methods

Pros: This is one of the only studies to suggest a practical algorithm for the decision concerning REBOA utilization and choice of REBOA placement location (zone) in non-trauma patients. This algorithm may serve as a basis for future decision-making when REBOA use will be implemented and utilized routinely in the field of non-trauma emergency general surgery.

Cons: This study included patients with a number of different sources of bleeding. Although all patients had an abdominal bleeding source, the etiologies of hemorrhage in patients included in this study are inherently different, and thus the impact of REBOA use in these patients is inevitably diverse. In addition, as with most studies in this field, this study is also based on a small group of patients.

Results, conclusion, and what it means

This is one of the important studies that have demonstrated the feasibility of REBOA use in patients with non-traumatic hemorrhagic shock. The mean age of patients in this study was 54.9 years which is significantly older than the population of patients in studies investigating the use of REBOA in trauma patients. It is reasonable to assume that such an older population may more commonly suffer from comorbidities, such as atherosclerosis and chronic kidney disease, which may affect the safety and feasibility of REBOA placement. Nonetheless, no direct REBOA-related complications were reported in this study. Hence, the demonstration of the safety of REBOA use in older patients is an important milestone in the development and progress of the use of this technique. Another important aspect of this result is the first report of REBOA use in several specific medical conditions in which REBOA utilization has been scarcely described in the past, including hemorrhagic necrotizing pancreatitis, iatrogenic liver laceration, renal artery bleed, and iliac artery hemorrhage.

Comments and future research

Larger studies that will also collect data regarding underlying comorbidities of non-trauma patients undergoing REBOA placement for hemorrhage control are needed in order to evaluate the specific results and implications of REBOA use in this population of patients. In addition, since randomized studies in this field are ethically challenging, it would be beneficial to retrospectively compare the results of patients with non-traumatic hemorrhagic shock who were treated with and without REBOA to assess the actual benefit of this technique. A large multicentric prospective observational data collection in patients treated with REBOA due to similar types of non-traumatic intra-abdominal bleeding may provide a significant contribution to existing knowledge.

i Related important publications

Weltz AS, Harris DG, O'Neill NA, O'Meara LB, Brenner ML, Diaz JJ. The use of resuscitative endovascular balloon occlusion of the aorta to control hemorrhagic shock during video-assisted retroperitoneal debridement or infected necrotizing pancreatitis. *Int J Surg Case Rep.* 2015;13:15-8.

Singh G, Nahm CB, Jamieson NB, Chua TC, Wong S, Thoo C, Mittal A, Gill AJ, Samra JS. Management of post-pancreatectomy haemorrhage using resuscitative endovascular balloon occlusion of the aorta. *Langenbecks Arch Surg.* 2019;404(2):253-255.

Morita R, Abo D, Soyama T, Yoshino Y, Yoshikawa T, Kimura T, Kudo K. Spontaneous rupture of the pancreatic arcade artery caused by neurofibromatosis type 1 successfully treated using emergency transcatheter arterial embolization, partial intra-aortic balloon occlusion, and stent graft placement: a case report and review of the literature. *CVIR Endovasc.* 2020;3(1):37.

ARTICLE NUMBER 4

REBOA Use in Nontrauma Emergency General Surgery: A Multi-institutional Experience.

J Surg Res. 2020;256:149-155.

Hatchimonji JS, Chipman AM, McGreevy DT, Hörer TM, Burruss S, Han S, Spalding MC, Fox CJ, Moore EE, Diaz JJ, Cannon JW.

Abstract

Background: The aim of this study was to determine the current utilization patterns of resuscitative endovascular balloon occlusion of aorta (REBOA) for hemorrhage control in nontrauma patients.

Methods: Data on REBOA use in nontrauma emergency general surgery patients from six centers, 2014-2019, was pooled for analysis. We performed descriptive analyses using Fisher's exact, Student's t, chi-squared, or Mann-Whitney U tests as appropriate.

Results: Thirty-seven patients with acute hemorrhage from nontrauma sources were identified. REBOA placement was primarily performed by trauma attendings (20/37, 54%) and vascular attendings (13/37, 35%). In seven patients (19%), balloons were positioned prophylactically but never inflated. In 24 (65%) of 37 patients, REBOA was placed in the operating room. 28/37 balloons (76%) were advanced to zone 1, 8/37 (22%) were advanced to zone 3, and there was one REBOA use in the inferior vena cava. Most common indications were gastrointestinal and peripartum bleeding. In the 30 cases of balloon inflation, 24 of 30 (80%) resulted in improved hemodynamics. Eleven of 30 patients (37%) died before discharge. One patient developed a distal embolism, but there were no reports of limb loss. Twelve patients (40% of all REBOA inflations and 63% of survivors) were discharged to home.

Conclusions: REBOA has been used in a range of acutely hemorrhaging emergency general surgery patients with low rates of access-related complications. Mortality is high in this patient population and further research is needed; however, appropriate patient selection and early use may improve survival in these life-threatening cases.

Article review and analysis

Aim of this study: The authors aimed to assess the possible application of REBOA in non-trauma causes of bleeding. Since exsanguination remains an important cause of death, even in the face of modern methods of hemorrhage control, REBOA is a promising technique that this study aimed to investigate by analyzing data from the different medical centers worldwide that routinely perform REBOA placement.

Methods

Pros: An important strength of this study is its multicentric design, which enables wider conclusions to be drawn. This is also the first study to test the relationship

between REBOA “volume” and mortality rate, aiming to assess the effect of experience with this technique and its success rate.

Cons: As with other studies in this field, this study also includes patients with a relatively wide range of bleeding etiologies. The heterogeneity of the studied group must be considered when interpreting the results of the study. The retrospective design of this study must also be taken into account.

Results, conclusion, and what it means

With 37 patients included, this is one of the largest existing studies on REBOA use in non-trauma patients. In addition, this study also first described the “prophylactic” insertion of REBOA, without inflation of the balloon. This is possibly a new approach that may be adopted in the future in high-risk procedures in which the expected risk of uncontrolled bleeding is high. This study reported comparison of mortality rates between hospitals with different volumes of REBOA use. The authors found that mortality rates were significantly lower in medical centers with a higher volume of REBOA use, which stresses the importance of appropriate experience and expertise when applying this innovative technique.

Comments and future research

Studies focusing on the investigation of the results of possibly preventive REBOA insertion are needed in order to evaluate the true value of this approach and its benefit. Since this study has shown the importance of experience in REBOA placement, another important aspect for future research is the design and assessment of training programs and investigation of the impact of the physicians’ learning curve on patients’ clinical outcomes. Promising future research, not limited to non-trauma patients, may better define the meaning of “high” vs. “low” volume of REBOA use.

Related important publications

Brenner M, Teeter W, Hoehn M, Pasley J, Hu P, Yang S, Romagnoli A, Diaz J, Stein D, Scalea T. Use of Resuscitative Endovascular Balloon Occlusion of the Aorta for Proximal Aortic Control in Patients With Severe Hemorrhage and Arrest. *JAMA Surg.* 2018;153(2):130-135.

McGreevy DT, Dogan E, Toivola A, Bilos L, Pirouzram A. Endovascular resuscitation with aortic balloon occlusion in non-trauma cases: first use of ER-REBOA in Europe. *J EMTM.* 2017;1:42e49

Reynolds CL, Celio AC, Bridges LC, et al. REBOA for the IVC? Resuscitative balloon occlusion of the inferior vena cava (REBOVC) to abate massive hemorrhage in retrohepatic vena cava injuries. *J Trauma Acute Care Surg.* 2017;83:1041e1046.

ARTICLE NUMBER 5

Resuscitative endovascular balloon occlusion of the aorta for uncontrolled haemorrhagic shock as an adjunct to haemostatic procedures in the acute care setting.

Scand J Trauma Resusc Emerg Med. 2016;24:13.

Tsurukiri J, Akamine I, Sato T, Sakurai M, Okumura E, Moriya M, Yamanaka H, Ohta S.

Abstract

Background: Haemorrhagic shock is a major cause of death in the acute care setting. Since 2009, our emergency department has used intra-aortic balloon occlusion (IABO) catheters for resuscitative endovascular balloon occlusion of the aorta (REBOA).

Methods: REBOA procedures were performed by one or two trained acute care physicians in the emergency room (ER) and intensive care unit (ICU). IABO catheters were positioned using ultrasonography. Collected data included clinical characteristics, haemorrhagic severity, blood cultures, metabolic values, blood transfusions, REBOA-related complications and mortality.

Results: Subjects comprised 25 patients (trauma, n = 16; non-trauma, n = 9) with a median age of 69 years and a median shock index of 1.4. REBOA was achieved in 22 patients, but failed in three elderly trauma patients. Systolic blood pressure significantly increased after REBOA (107 vs. 71 mmHg, p < 0.01). Five trauma patients (20 %) died in ER, and mortality rates within 24 h and 60 days were 20 % and 12 %, respectively. No REBOA-related complications were encountered. The total occlusion time of REBOA was significantly lesser in survivors than that in non-survivors (52 vs. 97 min, p < 0.01). Significantly positive correlations were found between total occlusion time of REBOA and shock index (Spearman’s r = 0.6) and lactate concentration (Spearman’s r = 0.7) in survivors.

Conclusion: REBOA can be performed in ER and ICU with a high degree of technical success. Furthermore, correlations between occlusion time and initial high lactate levels and shock index may be important because prolonged occlusion is associated with a poorer outcome.

Article review and analysis

Aim of this study: The study reports on the results of REBOA use in a single medical center, during a 5-year period, in an effort to characterize and evaluate the benefits and complications of this treatment option in a variety of different clinical scenarios.

Methods

Pros: A unique strength of this study is the relative homogeneity of the non-trauma cases included; 5 patients had gastric ulcers, 3 patients had duodenal ulcers and one patient had a pseudo-aneurysm due to pancreatic fistula. Another advantage of this study is the relatively long follow-up period of survival of within 2 months. Most studies in this field only report on survival rates at the ER, within 24 hours and only a few report survival rates within 30 days. The longer follow-up period in this study provides important information regarding the long-term results of REBOA use in patients with hemorrhagic shock. The authors have compared survivors and non-survivors based on several parameters, including SBP before and after REBOA, delta SBP, volume of blood transfusion required, and occlusion time. This is an important attempt to identify which parameters may predict survival in patients with uncontrolled bleeding undergoing REBOA placement. When performing this comparison, the authors have analyzed results separately for trauma and non-trauma patients. As previously shown in a number of studies, trauma and non-trauma patients with uncontrolled bleeding are inherently different and this separate comparison is therefore an important feature of this study.

Cons: When comparing the characteristics of survivors and non-survivors, survival was defined in this study as survival within 2 months. As successful hemorrhage control may be defined, for example, as 24-hour survival and not as survival within 2 months (which may be affected by many other various aspects in a patient's care), this form of analysis might limit the study's conclusions. In addition, as with other studies on this topic, this study is also based on retrospective data from a small group of only 9 non-trauma and 16 trauma patients. It is thus difficult to draw wide conclusions based on the authors' limited experience.

Results, conclusion, and what it means

Post REBOA inflation SBP was significantly higher in survivors as compared with non-survivors and may serve as a marker for successful REBOA response. However, in contrast to other studies in the field of REBOA use in both trauma and non-trauma patients, this study has found that delta SBP was not significantly higher in survivors compared with non-survivors. Another surprising and interesting result reported in this study is that no difference between survivors and non-survivors was found with regard to blood transfusion volume.

Comments and future research

Since REBOA use is becoming more prevalent, the number of non-trauma patients treated with REBOA placement will increase. This will allow the performance of future studies that will not include both trauma and non-trauma patients but rather only non-trauma patients. In this specific population, predicting which patients with hemorrhagic shock may benefit from REBOA use is an important challenge that needs to be

addressed in future research in order to be able to successfully choose where and when to use this technique. Furthermore, studies that investigate measures for real-time identification of successful REBOA response are needed. Using large "cloud-based" online computed database collection will enable the identification of the adequate timing of REBOA access/inflation/disinflation according to real-time physiological and laboratory parameters.

i Related important publications

Saito N, Matsumoto H, Yagi T, Hara Y, Hayashida K, Motomura T, et al. Evaluation of the safety and feasibility of resuscitative endovascular balloon occlusion of the aorta. *J Trauma Acute Care Surg.* 2015;78:897–903.

Ogura T, Lefor AT, Nakano M, Izawa Y, Morita H. Nonoperative management of hemodynamically unstable abdominal trauma patients with angioembolization and resuscitative endovascular balloon occlusion of the aorta. *J Trauma Acute Care Surg.* 2015;78:132–5.

CHAPTER 8.

REBOA in pelvic fractures

Authors: *Dan Hebron, Sivan Barkai and Nardin Zoubi*

Introduction

Pelvic hemorrhage, secondary to traumatic pelvic injury, still represents a great challenge to medical practitioners due to the majority of pelvic bleedings resulting from injury to the sacral plexus and pelvic bones, which are incompressible.

In patients with exsanguinating pelvic fractures, mortality and morbidity remain high, in spite of existing minimally invasive/open surgical techniques.

REBOA is a relatively new minimally invasive technique that was first introduced in 1948. Since then, the use of REBOA has evolved and today it is utilized in the treatment of severe trauma patients suffering from hemodynamic instability as a result of massive hemorrhage.

Currently, due to lack of experience, a limited database and few publications, REBOA is not utilized routinely in many medical centers worldwide.

In this chapter, we present and discuss several of the most notable studies published in recent years that have changed our perspective on the use of REBOA in the trauma field, specifically in pelvic injuries.

ARTICLE NUMBER 1

Pre-hospital Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for exsanguinating pelvic haemorrhage.

Resuscitation. 2019 Feb;135:6-13.

Lendrum R, Perkins Z, Chana M, Marsden M, Davenport R, Grier G, Sadek S, Davies G.

Abstract

Aim: To report the initial experience and outcomes of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an adjunct to pre-hospital resuscitation of patients with exsanguinating pelvic haemorrhage.

Methods: Descriptive case series of consecutive adult patients, treated with pre-hospital Zone III REBOA by a physician-led pre-hospital trauma service, between January 2014 and July 2018.

Results: REBOA was attempted in 19 trauma patients (13 successful, six failed attempts) and two non-trauma patients (both successful) with exsanguinating pelvic hemorrhage. Trauma patients were severely injured (median ISS 34, IQR: 27–43) and profoundly hypotensive (median systolic blood pressure [SBP] 57, IQR: 40–68 mmHg). REBOA significantly improved blood pressure (Pre-REBOA median SBP 57, IQR: 35–67 mmHg versus Post- REBOA SBP 114, IQR: 86–132 mmHg; Median of differences 66, 95% CI: 25–74 mmHg; $P < 0.001$). REBOA was associated with significantly lower risk of pre-hospital cardiac arrest (REBOA 0/13 [0%] versus no REBOA 3/6 [50%], $P = 0.021$) and death from exsanguination (REBOA 0/13 [0%] versus no REBOA 4/6 [67%], $P = 0.004$), when compared to patients with a failed attempt. Successful REBOA was associated with improved survival (REBOA 8/13 [62%] versus no REBOA 2/6 [33%]; $P = 0.350$). Distal arterial thrombus requiring thrombectomy was common in the REBOA group (10/13, 77%).

Conclusion: REBOA is a feasible pre-hospital resuscitation strategy for patients with exsanguinating pelvic hemorrhage. REBOA significantly improves blood pressure and may reduce the risk of pre-hospital hypovolemic cardiac arrest and early death due to exsanguination. Distal arterial thrombus formation is common, and should be actively managed.

Article review and analysis

Aim of this study: Recently, REBOA has been recognized as a treatment option in the acute care of unstable trauma patients. Nevertheless, there is still a lack of evidence regarding its use, such as the optimal timing, technique, and patient selection. This study aimed to assess the feasibility and outcome of pre-hospital REBOA use.

Methods

Pros: This study is the first prospective study to describe REBOA use in the field, prior to hospital admission. Since most published studies regarding REBOA use are based on retrospective data alone, the prospective design of this study is an important and unique strength. In addition, all teams completed an equal training and qualification program regarding REBOA insertion.

Cons: The small cohort, based on a single trauma medical center's experience, represents a limitation that restricts the power of evidence. Additionally, since all REBOA placements were performed in a single center, it isn't possible to apply these results to REBOA placement by different practitioners, with varying levels of skill. Moreover, the current study's results apply to REBOA Zone 3 alone.

Another limitation of this study is that the criteria for REBOA placement, as well as clinical or sonographic findings that supported hemodynamic instability attributed to pelvic trauma, were not stated.

This study does not report sufficient data regarding surgical/radiological findings that may point to the exact etiology of hemodynamic instability. This limits our ability to interpret the efficacy of REBOA, since the underlying injury is not specified. Another technical limitation is that, due to limited resources, a balloon type was used that is not suitable for proximal aortic occlusion.

Results, conclusion, and what it means

As previously stated, one of the strengths of this study is that it was the first to report utilization of REBOA as an emergency technique in the field. REBOA deployment had a significant impact on the improvement, and maintenance of SBP, and survival, with no reported pre-hospital cardiac arrest. Data also showed that patients who didn't undergo REBOA placement or had undergone failed attempts at REBOA insertion suffered from higher rates of prehospital deterioration and cardiac arrest. In addition, post-admission mortality in REBOA patients was attributed to other etiologies than exsanguinating hemorrhage. In 46% of REBOA patients, REBOA was associated with sufficient hemostasis without the need for further intervention.

The survival rate in the REBOA group was significantly higher than the reported survival rate for patients treated with thoracotomy in previous studies. This study indicates a higher survival rate for pre-hospital REBOA placement, versus in-hospital REBOA placement for pelvic trauma as reported in previous studies. REBOA complications include thrombus formation, unintentional SFA cannulation, REBOA malposition causing end-organ failure, and CFA dissection. These complications can be attributed, in part, to the suboptimal conditions in the field and other confounders that should be further investigated in future studies.

Comments and future research

Although current data shows promising results, further studies are needed to support REBOA use as a first-line resuscitative option in the field. Future studies may compare results of pre-hospital and in-hospital REBOA with regard to appropriate training of the treating teams, number of insertion attempts, complication rate and clinical outcome, as well as which patients would benefit specifically from pre-hospital REBOA. Another aspect that may be interesting to further evaluate is the feasibility and safety of transferring patients with an inflated balloon in place. Another interesting possibility is the foundation of a pre-hospital REBOA team that will be available not only for trauma patients but also for other scenarios in which patients may benefit from REBOA, such as non-traumatic cardiac arrest.

i Related important publications

Sadek S, Lockey DJ, Lendrum RA, Perkins Z, Price J, Davies GE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) in the pre-hospital setting: An additional resuscitation option for uncontrolled catastrophic haemorrhage. *Resuscitation*. 2016 Oct;107:135-8.

Pieper A, Thony F, Brun J, Rodière M, Boussat B, Arvieux C, Tonetti J, Payen JF, Bouzat P. Resuscitative endovascular balloon occlusion of the aorta for pelvic blunt trauma and life-threatening hemorrhage: A 20-year experience in a Level I trauma center. *J Trauma Acute Care Surg*. 2018 Mar;84(3):449-453.

ARTICLE NUMBER 2

Resuscitative Endovascular Balloon Occlusion of the Aorta vs Pre-Peritoneal Packing in Patients with Pelvic Fracture.

J Am Coll Surg. 2021 Jan;232(1):17-26.e2.

Asmar S, Bible L, Chehab M, Tang A, Khurram M, Douglas M, Castanon L, Kulvatunyou N, Joseph B.

Abstract

Background: Pelvic hemorrhage is potentially lethal despite homeostatic interventions such as pre-peritoneal packing (PP), resuscitative endovascular balloon occlusion of the aorta (REBOA), surgery, and/or angioembolization. REBOA may be used as an alternative/adjunct to PP for temporizing bleeding in patients with pelvic fractures. Our study aimed to compare the outcomes of REBOA and/or PP, as temporizing measures, in blunt pelvic fracture patients. We hypothesized that REBOA is associated with worsened outcomes.

Study design: We performed a 2017 review of the American College of Surgeons Trauma Quality Improvement Program (ACS-TQIP) and identified trauma patients with blunt pelvic fractures who underwent REBOA placement and/or PP before laparotomy and/or angioembolization. Propensity score matching was performed, adjusting for demographics, vitals, mechanism of injury, ISS, each body region-AIS, and pelvic fracture type. Outcomes were complication rates and mortality.

Results: A total of 156 patients (PP: 52; REBOA: 52; REBOA+PP: 52) were matched and included. Mean age was 43 ± 18 years, Injury Severity Score (ISS) was 28 (range 17-32), and 74% were males. Overall mortality was 42%. The 24-hour mortality (25% vs 14% vs 35%; $p = 0.042$), in-hospital mortality (44% vs 29% vs 54%; $p = 0.034$), and 4-hour pRBC units transfused (15 [9-23] vs 10 [4-19] vs 16 [9-27]; $p = 0.017$) were lower in the REBOA group. The REBOA group had faster times to both laparotomy ($p = 0.040$) and/or angioembolization ($p = 0.012$). There was no difference between the groups in acute kidney injury, lower limb amputations, or hospital and ICU length of stay among survivors.

Conclusions: REBOA is a less invasive procedure compared with PP and is associated with improved outcomes. Further clinical trials are needed to define the optimal patient who will benefit from REBOA.

Article review and analysis

Aim of this study: In the most recent guidelines and protocols, in addition to preperitoneal packing (PP), REBOA is listed as one of the formal modalities to be used for primary pelvic hemorrhage control until reaching angiography and/or laparotomy. This research compared REBOA and PP as temporary bleeding control measures in pelvic trauma, and their effect on morbidity, mortality and complication rate.

Methods

Pros: One of the main advantages of this research is the large database, collected from over 700 trauma centers with variable and diverse levels of expertise, and different treatment protocols. This large diversity and the conclusions reached are of significant value if REBOA is to be introduced in the future as a new technique. In addition, the propensity score that was applied limits potential bias.

Cons: The retrospective design of the research is a limitation of the study that needs to be noted. In addition, the study included patients with blunt pelvic trauma who were hospitalized during a single year, which resulted in a small sample size. Out of the 3 methods of hemorrhage control applied, the study doesn't specify the criteria on which the choice of treatment method was based. Information such as the type and size of REBOA used, duration of occlusion, and time to definitive bleeding control and sheath removal is lacking. In addition, information about other injuries and bleeding sources identified on laparotomy or angioembolization is only partially available. This information may be important in order to determine whether Zone 1 (rather than Zone 3) occlusion was of any added benefit. The research included patients who suffered from major isolated pelvic trauma. The extrapolation of REBOA use to trauma patients suffering from combined pelvic and extra pelvic injuries is, therefore, limited based on these results.

Results, conclusion, and what it means

This is the first large piece of research that has compared PP and REBOA, not only as separate treatment methods but also used concomitantly in exsanguinating pelvic hemorrhage.

The time factor plays an important role in the clinical course of these patients, affecting morbidity and mortality. Based on the reported results, REBOA proved to be the preferred minimally invasive technique that was applied in which hemorrhage control was successful. REBOA was associated with reduced blood transfusion requirement and enabled the achievement of hemodynamic stability, thus gaining time until definitive control was possible. In addition, REBOA was associated with lower mortality rates compared to PP (separately or combined), although patients treated with PP or PP+REBOA had higher Injury Severity Score (ISS) and more severe pelvic fracture injury. Therefore, higher mortality rates can be attributed to a more severe injury pattern. Regarding complications such as acute kidney injury (AKI), lower limb amputations and in hospital/ICU length of stay, no significant differences were found after the propensity score matching. However, the cause-effect relationship between REBOA/PP and these complications needs to be assessed more thoroughly since a significant percentage of patients suffering from major pelvic trauma experience deep hypovolemic shock which results in AKI. Similarly, lower limb vascular trauma can lead to lower limb amputation, regardless of REBOA use.

Comments and future research

Prospective studies are warranted in order to strengthen and prove the hypothesis that REBOA is a potential future tool for pelvic trauma hemorrhage control. The definition of indications for REBOA insertion should be set based on parameters such as HR, SBP, ISS, response to resuscitation, and body temperature.

In future research, further investigation of the advantages and disadvantages of REBOA is needed with an emphasis on important and useful information, such as different types and sizes of balloons, and time needed to insert and inflate the balloon. In addition, more specific data regarding which patients will benefit most from REBOA and the risk factors for REBOA-related complications is needed.

i Related important publications

Mikdad S, van Erp IAM, Moheb ME, Fawley J, Saillant N, King DR, Kaafarani HMA, Velmahos G, Mendoza AE. Pre-peritoneal pelvic packing for early hemorrhage control reduces mortality compared to resuscitative endovascular balloon occlusion of the aorta in severe blunt pelvic trauma patients: A nationwide analysis. *Injury*. 2020 Aug;51(8):1834-1839.

Do WS, Forte DM, Sheldon RR, Weiss JB, Barron MR, Sokol KK, Black GE, Hegge SR, Eckert MJ, Martin MJ. Preperitoneal balloon tamponade and resuscitative endovascular balloon occlusion of the aorta: Alternatives to open packing for pelvic fracture-associated hemorrhage. *J Trauma Acute Care Surg*. 2019 Jul;87(1):18-26.

ARTICLE NUMBER 3

Patterns and Outcomes of Zone 3 REBOA use in the Management of Severe Pelvic Fractures: Results from the AAST Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery Database.

J Trauma Acute Care Surg. 2021 Apr 1;90(4):659-665.

Harfouche M, Inaba K, Cannon J, Seamon M, Moore E, Scalea T, DuBose J.

Abstract

Background: Knowledge on practice patterns for aortic occlusion in the setting of severe pelvic fractures is limited. This study aimed to describe clinical outcomes based on number and types of interventions after Zone 3 REBOA deployment.

Methods: A retrospective review of the AAST AORTA multi-center registry was performed for patients who underwent Zone 3 aortic occlusion (AO) from 2013 to 2020. Patients with a blunt mechanism who survived beyond the Emergency Department (ED) were included. Interventions evaluated were preperitoneal pelvic packing (PP), angioembolization (AE), and external fixation of the pelvis (EF). Management approaches were compared against the primary outcome of mortality. Secondary outcomes included transfusion requirements, overall complications and acute kidney injury (AKI).

Results: Out of 207 patients who underwent Zone 3 AO, 160 (77.3%) fit the inclusion criteria. 60 (37.5%) underwent AO alone, 50 (31.3%) underwent a second hemostatic intervention and 49 (30.6%) underwent a third hemostatic intervention. Overall mortality was 37.7% (n=60). There were no differences in mortality based on any number or combination of interventions. On multivariable regression, only EF was associated with a mortality reduction (OR 0.22, $p=0.011$). Increasing number of interventions were associated with higher transfusion and complication rates. PP + AE was associated with increased AKI than PP or AE alone (73.3% v 29.5% and 28.6%, $p=0.005$), and AE was associated with increased AKI resulting in dialysis than PP alone (17.9% vs 6.8%, $p=0.036$).

Conclusion: Zone 3 REBOA can be used as a standalone hemorrhage control technique and as an adjunct in the management of severe pelvic fractures. The only additional intervention associated with a mortality reduction was external fixation. The benefit of increasing number of interventions must be weighed against more harm. Heterogeneity in practice patterns for REBOA use in pelvic fracture management underscores the need for an evidence base to standardize care.

Article review and analysis

Aim of this study: The integration of REBOA into trauma management has gained attention recently, specifically in patients who sustained major hemorrhagic pelvic injury. Along with other acceptable pelvic stabilization and hemodynamic control methods, such as preperitoneal packing, (PPP) angioembolization (AE), and external fixation (EF), surgeons are faced with a dilemma when deciding on the best management approach. This study compared patients who underwent REBOA placement alone vs. REBOA with subsequent interventions. Primary and secondary endpoints were morbidity, mortality, and complication rate.

Methods

Pros: Data was retrieved from the AORTA registry, a large multicentric trauma database in the US. This is the first study to assess the outcome of REBOA application in conjunction with other pelvic hemorrhage control methods.

Cons: Information regarding the indications for deployment of each method is missing. In addition, information concerning the order of PPP/AE/EF in the REBOA+1 or REBOA+2 groups, and the clinical or hemodynamic criteria that justified multiple invasive intervention, is also missing. Each intervention is time-consuming, which may delay the achievement of definitive hemorrhage control. The factor of time is also missing, including time to each intervention applied, number of attempts, time to laparotomy, etc., which may play a critical role in the decision-making process. Another disadvantage that needs to be considered is the limited power of evidence in retrospective studies, such as this study.

Results, conclusion, and what it means

This study shows that REBOA alone has a positive effect on hemodynamic stability and reduced mortality. Overall, mortality rate was 37%, which is similar to mortality rates reported in previous studies such as AAST. The beneficial effect of external fixation in reducing mortality rate was only observed when it was applied together with REBOA. However, PPP and AE were not associated with reduced mortality. This emphasizes the importance of pelvic stabilization techniques at an early stage to achieve adequate hemorrhage control, as described in previous studies. This study only compared overall mortality rates. Despite the conclusion noted above, no data was retrieved regarding mortality rate in the first 24-hours in which patients are expected to be most vulnerable due to hemodynamic instability. We assume that early morbidity and mortality may be affected by the early interventions, possible associated complications, and the overall/delayed mortality may be affected by complications related to the primary injuries. It is important to note that patients undergoing two or three interventions had higher AIS and ISS scores. Therefore, lack of survival benefit can be attributed to more severe injury, and exsanguinating hemorrhage that is difficult to control, rendering multiple interventions. In addition, undergoing multiple intervention necessitates higher RBC

transfusion volume, compared to the REBOA-only treatment group, which supports our previously mentioned assumption. Complication rate was noticed to be higher in the REBOA+1 and REBOA+2 groups. Acute kidney injury and need for urgent dialysis can be attributed to the fact that the patients underwent more invasive procedures along with a persistent state of hypovolemic shock. Nevertheless, the majority of these patients were very severely injured, and other complications such as ARDS, MOF, and sepsis may be attributed to hemodynamic instability, other injuries, and massive fluid resuscitation. Consequently, the necessity of multiple interventions is yet to be determined in order to decide which patients will benefit from REBOA. In addition, patients' baseline characteristics may increase mortality. These factors should be assessed and be taken into consideration in the future.

Comments and future research

Based on the data presented in this paper, REBOA alone or combined with other interventions may contribute to hemodynamic stability, bridging to definitive hemorrhage control. Although multiple interventions are available, a detailed treatment protocol that will be integrated into everyday trauma scenarios is necessary. Larger prospective studies are warranted in order to compare the outcome between REBOA vs. REBOA+EF in terms of morbidity and mortality. Future studies may emphasize the importance of time required for different interventions, time to definitive hemorrhage control, and the effect of different skill levels and training of the provider. Further studies could help stratify the outcome of REBOA or REBOA with additional interventions based on the patient's baseline characteristics and their proper stratification.

i Related important publications

Magee GA, Fox CJ, Moore EE. Resuscitative endovascular balloon occlusion of the aorta in pelvic ring fractures: The Denver Health protocol. *Injury*. 2020 Jan 31;50:1383(20)30072-3.

Coccolini F, Stahel PF, Montori G, Biffi W, Horer TM, Catena F, Kluger Y, Moore EE, Peitzman AB, Ivatury R, Coimbra R, Fraga GP, Pereira B, Rizoli S, Kirkpatrick A, Leppaniemi A, Manfredi R, Magnone S, Chiara O, Solaini L, Ceresoli M, Allievi N, Arvieux C, Velmahos G, Balogh Z, Naidoo N, Weber D, Abu-Zidan F, Sartelli M, Ansaloni L. Pelvic trauma: WSES classification and guidelines. *World J Emerg Surg*. 2017 Jan 18;12:5.

ARTICLE NUMBER 4

Preperitoneal balloon tamponade and resuscitative endovascular balloon occlusion of the aorta: Alternatives to open packing for pelvic fracture-associated hemorrhage.

J Trauma Acute Care Surg. 2019 Jul;87(1):18-26.

Do WS, Forte DM, Sheldon RR, Weiss JB, Barron MR, Sokol KK, Black GE, Hegge SR, Eckert MJ, Martin MJ.

Abstract

Background: The objective of this study was to compare the efficacy of preperitoneal balloon tamponade (PPB), resuscitative endovascular balloon occlusion of the aorta (REBOA), and open preperitoneal packing (OP) in a realistic animal model of pelvic fracture-associated hemorrhage.

Methods: Thirty-nine swine underwent creation of open-book pelvic fracture and iliac vascular injury. Animals were randomized to no intervention (n = 7), OP (n = 10), PPB (n = 9), zone 1 REBOA (n = 7), and zone 3 REBOA (n = 6) at a mean arterial pressure less than 40 mm Hg from uncontrolled hemorrhage. Primary outcome was survival at 1 hour. Secondary outcomes included survival in the immediate 10 m following intervention reversal, peak preperitoneal pressure (PP), blood loss, bleed rate, and peak lactate.

Results: Prior to injury, no difference was measured between groups for weight, hemodynamics, lactate, and hematocrit (all p = NS). The injury was uniformly lethal without intervention, with survival time (mean) of 5 m, peak PP of 14 mm Hg, blood loss of 960 g, bleed rate of 450 g/m, and peak lactate of 2.6 mmol/L. Survival time (m) was extended to 44 with OP, 60 with PPB, and 60 with REBOA (p < 0.01). Peak PP (mm Hg) was 19 with OP, 23 with PPB, 10 with zone 1 REBOA, and 6 with zone 3 REBOA (p < 0.05). Blood loss (g) was 850 with OP, 930 with PPB, 610 with zone 1 REBOA, and 370 with zone 3 REBOA (p < 0.01). Peak lactate (mmol/L) was 3.3 with OP, 4.3 with PPB, 13.4 with zone 1 REBOA, and 5.3 with zone 3 REBOA (p < 0.01). Only 33% of zone 1 REBOA animals survived the initial 10 m after balloon deflation, compared to 60% for OP, 67% for PPB, and 100% for zone 3 REBOA (p < 0.01).

Conclusion: Preperitoneal balloon tamponade and zone 3 REBOA are effective alternatives to OP in this animal model of lethal pelvic fracture-associated hemorrhage. Zone 1 REBOA extends survival time but with high mortality upon reversal.

Article review and analysis

Aim of this study: Thirty-nine swine underwent insertion of vascular dilators in the iliac vessels and creation of open book pelvic fracture by division of the pubic symphysis and placement of a 2.5 cm spacer between the cut edges, to mimic pelvic fracture-associated hemorrhage. All 4 interventional options (OP, PPB, Zone 1 REBOA and

Zone 3 REBOA) were prepositioned prior to bleeding start point so that they were ready to use when MAP reached 40 mm Hg. Measurements of total blood loss, bleeding rate, minimal pH, peak lactate level, IV fluid volume and peak preperitoneal pressure were obtained at 5, 30 and 60 minutes. HR and MAP were recorded every 10 seconds until 5 minutes, and then every minute until 10 minutes.

The primary outcome was survival at 1 hour. Secondary outcomes, apart from the measurements stated above, included survival in the immediate 10 minutes following intervention reversal.

In order to examine the latter secondary outcome, a subset of animals underwent removal of pelvic packing deflation of PPB and REBOA at 60 minutes after bleeding start point.

This study aimed to evaluate and compare the impact of each intervention (OP, PPB, Zone 1 REBOA and Zone 3 REBOA) on survival, hemodynamics, blood loss, and markers of ischemia-reperfusion after lethal pelvic fracture associated hemorrhage at 1 hour.

Methods

Pros: The swine model mimics pelvic fracture-associated hemorrhage well. Previous animal studies have been based on modeling of the bleeding alone, without creating a pelvic open book fracture that is thought to enlarge the pelvic space and potentially reduce the efficacy of balloon tamponade.

This study compares 4 different interventions, while previous works compared only two out of four interventions.

Cons: This study was performed in swine. Extrapolation of the results to humans, as in every animal model, is challenging. In addition, the sample size is small, which must also be taken into account. The interventions in this study were all prepared prior to the onset of bleeding, so that immediate hemostasis was carried out. This does not reflect the real-life management of patients, which includes lengthy efforts to create the space for PPB insertion or inserting the REBOA catheter. This study was limited only to the open book model; its impact on other pelvic fractures types, therefore, remains unclear.

Results, conclusion, and what it means

Mortality in the no intervention arm was 100%, showing that the swine model of pelvic fracture-related hemorrhage was indeed lethal, as expected in trauma patients arriving to the E.R. Mean survival time was 41.8±9.5 minutes with OP, 60 minutes with PPB, Zone 1 REBOA and Zone 3 REBOA. Following intervention reversal, only 33% of Zone 1 REBOA animals survived for 10 minutes, compared with 60% for OP, 67% for PPB and 100% for Zone 3 REBOA. The authors concluded that PPB and Zone 3 REBOA are effective alternatives to OP in pelvic fracture-associated hemorrhage. Of note is that the survival rate of the Zone 3 REBOA arm on reversal was 100%. This result could imply this intervention is superior to OP and PPB as a safe bridge to a definitive treatment.

Bleeding rate and IV fluid requirement were vastly reduced from controls to PPB or REBOA. However, Zone 1 REBOA was associated with significantly increased markers of ischemia-reperfusion injury, with no sequential benefit in survival rate compared to Zone 3 REBOA. Following euthanasia, autopsy revealed no evidence of ischemic bowel in any of the cases.

Comments and future research

The combination of the pelvic balloon occlusion with simultaneous REBOA use is not well established. Future human studies with large sample size are warranted to evaluate the feasibility of their simultaneous use. It will be very interesting to perform either animal or human studies on the combination of REBOA use with pelvic preperitoneal packing compared with concurrent REBOA and pelvic balloon tamponade. Such well-designed studies may provide crucial information regarding the impact of these different hybrid alternatives on various physiological and metabolic parameters and better define the best candidates for the specific treatments. In particular, the optimal size of balloons also remains unclear. Future research on patients with pelvic fractures other than open book fractures is also warranted.

Related important publications

Tran TL, Brasel KJ, Karmy-Jones R, Rowell S, Schreiber MA, Shatz DV, Albrecht RM, Cohen MJ, DeMoya MA, Biffl WL, Moore EE, Namias N. Western Trauma Association Critical Decisions in Trauma: Management of pelvic fracture with hemodynamic instability-2016 updates. *J Trauma Acute Care Surg.* 2016 Dec;81(6):1171-1174.

Reva VA, Hörer TM, Makhnovskiy AI, Sokhranov MV, Samokhvalov IM, DuBose JJ. Field and en route resuscitative endovascular occlusion of the aorta: A feasible military reality? *J Trauma Acute Care Surg.* 2017 Jul;83(1 Suppl 1):S170-S176.

Pieper A, Thony F, Brun J, Rodière M, Boussat B, Arvieux C, Tonetti J, Payen JF, Bouzat P. Resuscitative endovascular balloon occlusion of the aorta for pelvic blunt trauma and life-threatening hemorrhage: A 20-year experience in a Level I trauma center. *J Trauma Acute Care Surg.* 2018 Mar;84(3):449-453.

ARTICLE NUMBER 5

Pre-peritoneal pelvic packing for early hemorrhage control reduces mortality compared to resuscitative endovascular balloon occlusion of the aorta in severe blunt pelvic trauma patients: A nationwide analysis.

Injury. 2020 Aug;51(8):1834-1839.

Mikdad S, van Erp IAM, Moheb ME, Fawley J, Saillant N, King DR, Kaafarani HMA, Velmahos G, Mendoza AE.

Abstract

Background: Early hemorrhage control after severe blunt pelvic trauma is lifesaving. The aim of this study is to compare the efficacy and outcomes of pre-peritoneal packing (PPP) and Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) with a subsequent hemorrhage control procedure to control life-threatening pelvic hemorrhage in trauma patients.

Methods: A 3-year (2015-2017) retrospective analysis of the Trauma Quality Improvement Program (TQIP) was performed. All blunt trauma patients (aged ≥ 15 years) who underwent PPP or Zone 3 REBOA placement were included while deaths on arrival and transfers were excluded. Patients were matched on clinical characteristics using propensity score matching (PSM). Univariate analysis was performed to compare mortality, time to procedure, time in ED, transfusion requirements, complications rates, and ICU and hospital length of stay (LOS) amongst patient groups.

Results: Of 420 trauma patients, 307 underwent PPP and 113 REBOA. Patients had similar hemodynamics and ISS upon presentation, but PPP patients had a higher GCS ($P = 0.037$) and more blunt kidney injuries ($P = 0.015$). After PSM, 206 trauma patients were included in the analysis. There were no significant differences in blood transfusion, LOS, or major complications. Time to REBOA was shorter than time to PPP (52 vs 77.5 min; $P < 0.001$) with longer time in ED (65 vs 51 min; $p = 0.023$). The 24-hour (32.4 vs 17.7%; $P = 0.23$) and in-hospital mortality (52.0 vs 37.3%; $P = 0.048$) were higher after REBOA.

Conclusion: PPP is associated with improved survival compared to REBOA placement. Delay in definitive hemorrhage control may provide a potential explanation, but causation remains unresolved. This data suggests that early PPP may offer a benefit over REBOA in the setting of hemorrhage after blunt pelvic trauma. Further, large, multi-institutional studies are warranted to support these findings.

Article review and analysis

Aim of this study: The treatment of patients with bleeding due to pelvic fractures has evolved and changed greatly in recent years. Since pelvic preperitoneal packing was introduced in the late 1990s, it has gained popularity worldwide. REBOA is a relatively

new technique, which has been reported to be effective for temporary hemorrhage control in patients with pelvic fractures. This study aimed to compare these two techniques.

Methods

Pros: An important strength of this study is the matching of patients in both study groups with regard to variables that were significantly different between the two groups, including vital signs in the ED, ISS, AIS, and intra-abdominal solid organ injuries. This matching enables a comparison of the two groups, without injury severity influencing the results, and thus assists in evaluating the true clinical outcome of the two management options. In addition, this is a national multicentric study. As such, its results are not based on a single center's abilities but rather enables evaluation of the real-world results of the two examined techniques.

Cons: An important limitation of this study that must be recognized is that 68.6% of patients in the REBOA group were also treated with PPP. It is not clearly stated why these patients were treated with both techniques. Hence, when assessing the results of the patients in the REBOA group, it must be noted that more than half of the patients in this group were actually treated with both techniques. The authors also report no access to information regarding the clinical judgement and indications for performing either PPP or REBOA, or the clinical events leading to proceeding with PPP after the deployment of REBOA. In addition, the collected data regarding mortality did not include cause of death but only rates of 24-hour and in-hospital mortality. Moreover, this is a retrospective study including 102 patients in each of the two study groups. Thus, it is subject to the well-known limitations of such a study design.

Results, conclusion, and what it means

This study has found both 24-hour and in-hospital mortality rates to be higher in the REBOA group (32.4% vs 17.7% $p=0.023$, 52% vs. 37.3%, $p=0.048$, respectively). No difference in complication rate was reported. Of note, is that even after the propensity score matching was carried out as mentioned above, patients in the REBOA group had higher rates of a completely disrupted posterior pelvic arch (30.4% vs. 15.7%), although no p-value was reported for this difference between the groups. This difference between the two groups must be taken into account when considering the results of this study. The time to a definitive hemorrhage control procedure was longer for PPP (77.5 minutes vs 52 minutes), which should be considered as an advantage of REBOA. In 68% of the patients in the REBOA group, REBOA was placed in the ER, while all PPP were performed in the OR. This difference may be responsible for the longer time REBOA patients spent in the ED (65 minutes vs. 51 minutes).

The median HR and BP of patients enrolled in this study were not reported and nor was their correlation with the intervention's efficacy. The authors report that about 59% of patients in both groups had HR > 100 bpm and about 33% in both groups had SBP < 90 mmHg, which means half of the patients had near normal HR and two thirds had a near normal BP.

Comments and future research

It is already agreed that most of the patients had pelvic bleeding, originating from the venous source. However, hemodynamic instability was mostly associated with arterial hemorrhage. Therefore, the adaptation of the optimal treatment remains very challenging. The real rate of patients who do not respond to PPP remains unclear. Similarly, REBOA response rates in patients with pelvic fractures is still underinvestigated. Future studies, especially prospective ones, could provide these much needed answers. In addition, further studies may investigate the risk factors and/or reasons for patients not responding to the methods of treatment. It will be interesting to compare different types of pelvic fractures (e.g. anterior fractures, open book fractures, sacral fractures, etc.) in order to examine the possible relationship between specific fracture types and the success rate of different treatment methods. Such studies could provide important information regarding which patients could benefit from which approach.

i Related important publications

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CHAPTER 9.

REBOA in obstetric catastrophes

Authors: *Liron Vardi David, Rawan Daher and Ilan Bruchim*

Introduction

One of the leading causes of antepartum and postpartum hemorrhage is abnormally adherent placenta, with a prevalence of approximately 1 in 500 pregnancies¹. The two major risk factors for morbidly adherent placenta (MAP) (are placenta previa and prior cesarean delivery, in which the risk increases with the number of previous cesarean deliveries. Owing to the rapid increase in the cesarean delivery rate in the past two decades, the prevalence of MAP has also increased, leading to an increase in associated abnormal obstetric hemorrhage, and maternal morbidity and mortality².

Antenatal diagnosis of MAP has led to an improvement in the management of pregnancies complicated by abnormally adherent placenta through planning the time of delivery with a multi-disciplinary experienced team, including obstetricians, gynecologists, urologists, vascular surgeons, interventional radiologists and intensive care unit expertise. Hysterectomy remains the most commonly performed procedure to control massive obstetric hemorrhage, especially in the setting of placenta accreta, although the main disadvantage of hysterectomy is its permanent effect on fertility.³

In the past few decades, more focus has been on conservative surgical approaches to control intraoperative bleeding and decrease the rate of hysterectomy, including uterine artery embolization and balloon occlusion of major pelvic vessels. However, due to the numerous collateral vessels supplying the uterus, the efficacy of these approaches is limited. Furthermore, it is associated with postoperative complications such as infection, pain secondary to ischemia, hematoma, and bladder injury.²⁻⁴

Experience over the past years suggests that REBOA is a safe and effective intervention

to avoid catastrophic hemorrhage related to MAP. The use of abdominal aortic occlusion for MAP has been suggested since 1995⁵, and case reports describe the use in other obstetric and gynecological emergencies, such as amniotic fluid emboli, uterine rupture and ruptured ectopic pregnancy⁶⁻⁸. While the traditional role of REBOA has been for unstable patients with life-threatening hemorrhage, it is also applicable for other clinical scenarios, such as MAP, for decreasing excessive blood loss⁹. Thorough research of the literature regarding the use of REBOA in obstetric emergencies yielded mostly results on the use of prophylactic abdominal aortic balloon occlusion for MAP and also retrospective studies, case series, and case reports on its use in the emergent setting, and other obstetric indications.

In this chapter we present 5 articles on the use of REBOA in both prophylactic and emergent settings for the management of PPH, which in our opinion best describes the different aspects of this subject.

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ARTICLE NUMBER 1

Fluoroscopy-free Resuscitative Endovascular Balloon Occlusion of the Aorta) REBOA (for controlling life-threatening postpartum hemorrhage.

PLoS One 2017 .Mar;(3)12;29 e0174520.

Knut Haakon Stensaeth , Edmund Sovik , Ingrid Natasha Ylva Haig, Erna Skomedal, Arve Jorgensen

Abstract

Background: Severe postpartum hemorrhage occurs in 1/1000 women giving birth. This condition is often dramatic and may be life-threatening. Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) has been introduced as a possible treatment for hemorrhagic shock. We present a series of fluoroscopy-free REBOA for controlling life-threatening postpartum hemorrhage.

Methods: In 2008 an 'aortic occlusion kit' was assembled and used in three Norwegian university hospitals. The on-call interventional radiologist (IR) was contacted with a response time < 30 minutes in case of life-threatening postpartum hemorrhage (PPH). Demographics and characteristics were collected from the medical records.

Results: This retrospective study includes 36 patients treated with fluoroscopy-free REBOA for controlling severe PPH in the years 2008-2015. The REBOA success rate was 100% and no patients died from REBOA related complications. Uterine artery embolization was performed in 17 (47%) patients and a hysterectomy in 16 (44%) patients. There was a strong negative correlation between uterine artery embolization and hysterectomy ($\rho = -0.50$, $P = 0.002$).

Although, short (11cm) introducer length was strongly associated with iliac artery thrombus formation ($\rho = 0.50$, $P = 0.002$).

Conclusions: The current study indicates the clinical safety and feasibility of REBOA in life-threatening PPH. Also, REBOA can be used in an emergency situation without the use of fluoroscopy with a high degree of technical success. Safety implementation of REBOA must be established, especially through limited aortic balloon occlusion time and a thorough balloon deflation regime.

Article review and analysis

Aim of this study: In recent years, REBOA has been used as a novel treatment for hemorrhagic shock, although there is limited data in the literature concerning the use of REBOA in PPH. Fluoroscopy-free REBOA has been used in Norway in three major university hospitals since 2008. The authors describe the experience in Norway of the use of fluoroscopy-free REBOA for the treatment of PPH in an emergent lifesaving setting, where fluoroscopy is not available.

Methods

Pros: An important strength is that it is a multicenter study that stems from 3 major university hospitals in Norway over a 7-year period, which results in the largest case series for the use of REBOA in an emergent lifesaving situation of obstetric catastrophe. Most related information on the emergent use of REBOA in the literature comes only from case reports. This study enables the assessment of the use of REBOA and related complications in the acute setting of obstetric indications.

Cons: Although it is the largest study for the emergent use of REBOA for PPH, the study sample is limited (n=36). Furthermore, the study is retrospective with the known limitations and biases related to this kind of study. Of note is that there is no clear definition of the indication to use REBOA for hemodynamically unstable severe PPH and lack of division for different bleeding etiologies. With the difficulty of conducting a randomized control trial (RCT) or using propensity scores in the acute setting, the lack of a control group does not allow any additional conclusions to be made.

Results, conclusion, and what it means

With a study population of 36 patients, it is the largest study on the use of REBOA in emergent lifesaving PPH. The use of REBOA resulted in the achievement of hemodynamic stability with no major complications. There were 6 cases with procedure-related complications, mostly local thrombus formation (iliac and femoral arteries) related to a shorter introducer length, and one case of aortic tear, with successful treatment and complete recovery, but with no fatalities. These findings point to the safety of this procedure, even in the acute setting, without fluoroscopy use and with a high degree of success. By achieving hemodynamic stability, REBOA use has enabled additional time in cases of hemorrhagic shock due to PPH. The additional time allows assessment and hemorrhage control, for example with uterotonics and uterine artery embolization, with a potential for uterine and reproduction function preservation. In the present study there was limited occlusion time (mean of 33 ± 6 min) with short balloon deflations every 10-15 minutes and re-inflation, which allows reperfusion to the extremities, and resulted in no ischemic complications. In addition, repetitive balloon deflations allow assessment of hemorrhage control during the procedure.

Comments and future research

This is the largest study regarding the use of REBOA for obstetric emergencies and describes the applicability in this setting with the possibility of decreasing maternal morbidity and mortality. However, this is a retrospective study with a limited cohort and without a control group. There is a need to conduct larger multicenter trials that will determine the effectiveness and safety of REBOA in the emergent setting.

i Related important publications

Harma M, Harma M, Kunt AS, Andac MH, Demir N. Balloon occlusion of the descending aorta in the treatment of severe post-partum haemorrhage. *Aust N Z J Obstet Gynaecol.* 2004 Apr;44(2):170-1.

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ARTICLE NUMBER 2

Clinical evaluation of prophylactic abdominal aortic balloon occlusion in patients with placenta accreta: a systematic review and meta-analysis.

BMC Pregnancy Childbirth. 2019 Jan 15;19(1):30.

Chen L, Wang X, Wang H, Li Q, Shan N, Qi H.

Abstract

Background: Severe obstetric hemorrhage caused by placenta accreta results in significant maternal morbidity and mortality. As a new technology, abdominal aortic balloon occlusion (AABO) is becoming an important treatment for patients with placenta accrete. To evaluate the safety and efficacy of AABO, a systematic review and a meta-analysis of previous studies was conducted.

Methods: A three-check subset was used, including placenta accrete (placenta previa, percreta, increta, etc.), balloon, and aortic (aortas, aorta, etc.) to form a retrieval formula and searched in MEDLINE, EMBASE, the Cochrane Library, clinicaltrials.gov and Web of Science. All articles regarding placenta previa or placenta accrete and including the use of abdominal aortic balloon occlusion were included in this screening. Two researchers selected articles and extracted data independently. Finally, the Newcastle-Ottawa Quality Assessment Scale was used for quality assessments.

Results: 776 articles were retrieved and eventually 11 clinical studies were included. Meta-analysis showed that AABO significantly reduced the blood loss volume (MD – 1480 ml, 95% CI -1806 to – 1154 ml, $P < 0.001$) and blood transfusion volume (MD – 1125 ml, 95% CI -1264 to – 987 ml, $P < 0.001$). Similarly, obvious reductions in the hysterectomy rate (OR 0.30, 95% CI 0.19 to 0.48, $P < 0.001$), hospitalization duration and operative time (MD – 29.23 min, 95% CI -46.04 to – 12.42 min, $P < 0.001$) were observed in the AABO group.

Conclusion: The prophylactic use of AABO in patients with placenta accrete is safe and effective.

Article review and analysis

Aim of this study: The increasing incidence of cesarean section has led to a rise in cases with adherent placenta and its related significant complications, including maternal morbidity and mortality. The increased need for developing fertility-preserving strategies has led to the development of conservative approaches that will decrease the rate of hysterectomy. One of the new strategies that has been studied increasingly in recent years is the use of prophylactic abdominal aortic balloon occlusion. Few studies have been published about the use of this approach to control obstetric hemorrhage related to adherent placenta, and little is known about its efficacy and complications.

The aim of this study was to perform a systematic review and meta-analysis all relevant

studies for evaluation of the safety and efficacy of AABO. As far as we are aware, this is the first systemic review of this issue.

Methods

Pros: This is the first systematic review and meta-analysis aimed at evaluating the efficacy and safety of AABO during removal of the placenta at the time of cesarean section in women with placenta accreta. This is a relatively large study (776 patients) with 463 patients in the study group and 268 in the control group.

This analysis provides an actual comparison between women who underwent AABO and the control group in terms of outcome, including blood loss rate, blood transfusion rate, hysterectomy rate, operation time and length of postoperative hospitalization.

Cons: Although it is a systematic review and meta-analysis, the number of articles included in the analysis is still relatively low. Furthermore, there was heterogeneity in the information provided in the different studies, for example: only 7 articles included information about intraoperative blood loss and operative time. There is also a lack of information about the location and degree of depth in placenta implantation, which could have a great impact on the outcome and complication rates. Moreover, there was no uniform standard for the duration of balloon occlusion; the mean time ranged from 18 to 36.95 minutes with a maximum occlusion time of 80 minutes. These are important data and could have a significant impact on the outcome and complications of the procedure.

Results, conclusion, and what it means

The main aim of the meta-analysis and systematic review is to evaluate the use of prophylactic abdominal aortic balloon occlusion in patients with placenta accreta. The findings of this study showed significant benefits of the use of prophylactic AABO in patient with placenta accreta. The blood loss is significantly decreased with the use of AABO prior to the surgery compared to no AABO, as has been analyzed in 7 studies. Women who underwent AABO required less blood transfusion compared to women who did not; this was statistically significant in 6 studies. The rate of hysterectomy was significantly lower in the AABO group compared to the control group, as has been reported from all the studies. Regarding the operative time and post-operative hospitalization, both were observed to be significantly lower in women who underwent prophylactic AABO compared to the control group. Moreover, AABO was associated with 0 cases of disseminated intravascular coagulopathy, a devastating complication of massive hemorrhage (DIC), compared to 8 cases of DIC and 12 cases of hemorrhagic shock in the control group, as observed in 4 articles.

Importantly there was no reported morbidity of the newborn related to the AABO and no differences of the APGAR score between the two groups.

The results from this large meta-analysis provide evidence that AABO is a safe and effective treatment approach in women with abnormally adherent placenta.

This new technology proved to have a beneficial effect by decreasing bleeding and transfusion requirement during and after the surgery, and reducing the need for hysterectomy, an important consideration in planning the surgery for women who desire fertility preservation.

Comments and future research

This is the first and largest systematic review and meta-analysis that has evaluated the efficacy and safety of prophylactic AABO in the setting of placenta accreta. It provides evidence that the technique is promising in the prevention of massive obstetric hemorrhage in cases of placenta accreta and its related morbidity and mortality.

However, further larger studies are needed to provide solid evidence regarding the safety and efficacy of AABO compared to other interventions in patients with placenta accreta and in emergency obstetric emergencies.

i Related important publications

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ARTICLE NUMBER 3

Pregnancies Outcome After Balloon Occlusion of the Infrarenal Abdominal Aorta During Caesarean in 230 Patients with Placenta Praevia Accreta.

Cardiovasc Intervent Radiol. 2016 Nov;39(11):1573-1579.

Wu Q, Liu Z, Zhao X, Liu C, Wang Y, Chu Q, Wang X, Chen Z.

Abstract

Purpose: To explore the efficacy and safety of prophylactic temporary balloon occlusion of the infrarenal abdominal aorta during cesarean for the management of patients with placenta praevia accreta.

Methods: Two hundred and sixty-eight cases of placenta praevia accreta from January 2012 to June 2015 were retrospectively reviewed. Group A included two hundred and thirty patients who underwent prophylactic temporary balloon occlusion of infrarenal abdominal aorta followed by cesarean section. Group B included thirty-eight patients who underwent cesarean without endovascular intervention. The parameters that were compared between the two groups included operating room time, estimated blood loss, blood transfusion volume, PT (prothrombin time) during operation, days in the intensive care unit, and total hospital days.

Results: The operating room time, estimated blood loss, PT, the incidence of hysterectomy, blood transfusion volume, postpartum hemorrhage, and days in the intensive care unit were lower in group A than in group B, with statistical significance ($P < 0.05$). There was no significant difference in the Apgar scores of the neonates and the incidences of thrombosis in lower limbs between the two groups ($P > 0.05$). No patient in the group with prophylactic temporary balloon occlusion of the infrarenal abdominal aorta undergone a hysterectomy, while in three patients in group B hysterectomy was performed because of uncontrollable hemorrhage.

Conclusions: The results of this study indicate that prophylactic temporary balloon occlusion of infrarenal abdominal aorta followed by cesarean section is safe and effective to control intraoperative blood loss and greatly decreases the risk of hysterectomy in patients with placenta praevia accreta.

Article review and analysis

Aim of this study: With limited data in the literature on the use of prophylactic temporary occlusion of the infrarenal aorta for the treatment of morbidly adherent placenta (MAP), this study aims to report the efficacy and safety of this surgical treatment, with a retrospective analysis of 268 cases of placenta previa accreta, 230 of them treated with prophylactic infra-renal abdominal aortic balloon occlusion.

Methods

Pros: This study includes the largest sample size for the prophylactic use of aortic balloon occlusion in cases of MAP, evaluates the efficacy and safety of this method, and provides the basis of additional studies on this subject.

Cons: The control group in the study (Group B, $n=38$) is significantly smaller than the intervention group (Group A, $n=230$), and includes patients who are in an emergent state, which is problematic to compare with an elective cesarean section receiving prophylactic treatment. The majority of the patients in this study had placenta inccreta and perccreta rather than accreta, which is the most common subtype of MAP, in both the control and intervention groups, which may affect the generalization of the results. As with other studies in this field, it is a retrospective study with its important drawbacks.

Results, conclusion, and what it means

Previously, few studies with only a small cohort reported the use of infra-renal abdominal aorta occlusion with the majority eventually treated with hysterectomy. In the present study, all patients in group A were treated successfully without requiring cesarean hysterectomy, compared with 3 hysterectomies from group B for uncontrollable bleeding. In addition, the median estimated blood loss was significantly lower in group A (921 ± 199 ml) than in group B (2790 ± 335 ml). Group A required less median blood transfusion volume (422 ± 58 ml) compared with group B (1580 ± 67 ml), with statistical significance. This suggests that prophylactic intra-renal balloon occlusion offers better hemostatic results than other treatment options.

Group A had significantly shorter operating times (64.1 ± 5.1 Vs. 92.1 ± 9.7), less admission to the ICU, and shorter postoperative stay compared with group B. Fetal outcome was similar for 1 and 5 minutes Apgar scores (>8 in all delivered fetuses) and birth weight. No maternal or neonatal mortality was observed in this study. While the main complications for infrarenal balloon occlusion of the aorta are distal ischemia, reperfusion injury, thrombosis, and embolization of the lower extremities, only two patients in group A had vein thrombosis of the lower limb and subsequently recovered with conservative treatment. Therefore, the results of this study suggest that it might be possible to avoid these complications with a short balloon inflation time (under 30 minutes in all patients). Regarding fetal safety, fetal radiation doses were smaller than for prophylactic internal iliac artery balloon occlusion, with doses considered negligible for radiation-induced abnormality (5.1 ± 3.0 mGy on average).

Comments and future research

This is a promising study on the possible efficacy of the use of REBOA in the prophylactic management of MAP, with easy placement and few complications. However, more extensive studies with a larger and comparable control group are needed, preferably as an RCT or prospective trial to better evaluate the efficacy of the prophylactic

treatment of REBOA for MAP, and the possible complications of this method compared with traditional treatments.

Related important publications

Chen M, Xie L. Clinical evaluation of balloon occlusion of the lower abdominal aorta in patients with placenta previa and previous cesarean section: A retrospective study on 43 cases. *Int J Surg.* 2016 Oct;34:6-9.

Cui S, Zhi Y, Cheng G, Zhang K, Zhang L, Shen L. Retrospective analysis of placenta previa with abnormal placentation with and without prophylactic use of abdominal aorta balloon occlusion. *Int J Gynaecol Obstet.* 2017 Jun;137(3):265-270.

ARTICLE NUMBER 4

Prophylactic balloon occlusion of internal iliac arteries, common iliac arteries and infrarenal abdominal aorta in pregnancies complicated by placenta accreta: a retrospective cohort study.

Eur Radiol. 2018 Dec;28(12):4959-4967.

Li K, Zou Y, Sun J, Wen H.

Abstract

Objectives: To evaluate the efficacy of prophylactic balloon occlusion (PBO), and to compare hemostatic effects and perioperative outcomes of PBO of the internal iliac arteries (IIA), common iliac arteries (CIA), and infrarenal abdominal aorta (IAA) in patients with placenta accreta.

Methods: One hundred and ninety-nine patients with placenta accreta were retrospectively reviewed, 112 patients who underwent PBO, and 87 patients without endovascular intervention that classified as the control group. The PBO group was divided into IIA (n = 37), CIA (n = 42) and IAA (n = 33) subgroups.

Results: Patients in the PBO group had decreased estimated blood loss (EBL) and blood transfusion volume (BTv), (1550 mL vs 3500 mL), (500 mL vs 2100 mL), respectively. There were also improved other perioperative outcomes in other parameters including shorter operation time and less hysterectomy rate.

As to comparison among subgroups, patients had decreased EBL and BTv, (1000-1025 vs 2900 mL and 200 vs 1200 mL, respectively) as well as improved other perioperative outcomes in CIA and IAA subgroups compared to the IIA subgroup. Further validation by multivariate analysis revealed that PBO of IIA (vs others) could independently predict more EBL.

Conclusions: PBO reduces intraoperative blood loss and improves other perioperative outcomes in patients with placenta accreta. Moreover, PBO of the CIA and IAA is more effective compared to PBO of IIA.

Article review and analysis

Aim of this study: The principle of using prophylactic balloon occlusion in the setting of placenta accreta is to significantly reduce blood flow to the uterus, thus decreasing life-threatening hemorrhage and the need for transfusion, and subsequently improving maternal and fetal outcomes. Only a few studies revealed evidence regarding the efficacy of PBO in patients with placenta accreta; however, the sample size of these studies was limited. The current study aimed to assess the efficacy of PBO in a larger study population and to provide a comparison between subgroups of PBO, including IIA, CIA, IAA in terms of efficacy, safety, and perioperative outcomes.

Methods

Pros: The current study included a relatively large study population with patients that were treated with prophylactic balloon occlusion (PBO) compared to a control group without intravascular intervention.

All the patients were treated in a single university medical center in China, with the same analysis system for all data. All patients in both the study group and the control group had a confirmed diagnosis of placenta accreta as demonstrated by histopathology or cesarean macroscopic finding. All patients had planned cesarean delivery, excluding emergent operations that could have biased the outcome.

Another major advantage of this study is that it includes analysis for primary intraoperative outcome and secondary perioperative and postoperative outcomes of the different PBO subgroups and control group. Furthermore, the study included a subgroup analysis that compared the outcome between the subgroups of PBO (IIA, CIA, IAA) according to the balloon occlusion method and provides the efficacy of these different PBO techniques.

Cons: This is a retrospective study which, therefore, may introduce selection bias or information bias. The data that was extracted from the medical records may be inaccurate and subject to biases.

The insertion of a balloon catheter in the study group was performed by three different interventional radiologists, and differences regarding the application technique and related outcome and complication could not be ruled out, although all were highly experienced (range of 12-15 years of experience) and the technique was described as uniform.

Results, conclusion, and what it means

Patients with placenta accreta who underwent PBO had decreased EBL and BTv, with $P < 0.001$ for both outcomes. The estimated blood loss in the study group was 1550 mL compared with 3500 mL in the control group. Moreover, patients treated with PBO had significantly better secondary outcomes, including shorter operation time and a lower rate of hysterectomy compared to the control group. Furthermore, fewer patients required ICU admission in the PBO group, and the length of hospital stay was shorter compared to the control group.

For the subgroup analysis, in a comparison of primary and secondary outcomes among women who underwent IIA, CIA, IAA, the estimated blood loss was less in the CIA and IAA groups compared to IIA. Moreover, the blood transfusion volume was less in CIA and IAA compared to IIA with statistical significance, $P < 0.001$. There was no difference between CIA and IAA in terms of EBL and BTv.

Regarding secondary outcomes, patients who underwent CIA or IAA had shorter operation duration, lower hysterectomy rate, shorter length of postoperative stay, less radiation dose, and shorter interventional operation duration compared to patients who underwent IIA occlusion.

Comments and future research

This study provides evidence that PBO was associated with less blood loss and lower transfusion volume, as well as improved perioperative outcome. Furthermore, the use of PBO is suggested to be negatively correlated with estimated blood loss, and that placenta depth is an independent predictive risk for estimated blood loss in women with invasive placentation. Furthermore, PBO of the CIA and IAA were negatively associated with estimated blood loss while PBO of IIA was positively associated with estimated blood loss.

A possible explanation for the advantage of CIA and IAA occlusion over IIA occlusion is that the first two routes lead to obstruction of the collateral flow from the external iliac artery and femoral arteries, thus leading to better effect on hemostasis by decreasing hemorrhage and improving the outcome.

Further prospective studies are needed to emphasize these results and encourage clinicians to choose these procedures when planning the management of pregnant women with placenta accreta.

i Related important publications

Tan YL, Suharjono H, Lau NL, Voon HY. Prophylactic bilateral internal iliac artery balloon occlusion in the management of placenta accreta: A 36-month review. *Med J Malaysia*. 2016 Jun;71(3):111-6.

Minas V, Gul N, Shaw E, Mwenenchanya S. Prophylactic balloon occlusion of the common iliac arteries for the management of suspected placenta accreta/percreta: conclusions from a short case series. *Arch Gynecol Obstet*. 2015 Feb;291(2):461-5.

Tan CH, Tay KH, Sheah K, Kwek K, Wong K, Tan HK, Tan BS. Perioperative endovascular internal iliac artery occlusion balloon placement in management of placenta accreta. *AJR Am J Roentgenol*. 2007 Nov;189(5):1158-63.

Salim R, Chulski A, Romano S, Garini G, Rudin M, Shalev E. Precesarean Prophylactic Balloon Catheters for Suspected Placenta Accreta: A Randomized Controlled Trial. *Obstet Gynecol*. 2015 Nov;126(5):1022-1028.

ARTICLE NUMBER 5

Risk of vascular complications in prophylactic compared to emergent resuscitative endovascular balloon occlusion of the aorta (REBOA) in the management of placenta accreta spectrum.

J Matern Fetal Neonatal Med. 2020 Aug 11:1-4.

Whittington JR, Pagan ME, Nevil BD, Kalkwarf KJ, Sharawi NE, Hughes DS, Sandlin AT.

Abstract

Objective: To compare prophylactic and emergent resuscitative endovascular balloon occlusion of the aorta (REBOA) catheter placement in the management of placenta accreta spectrum (PAS).

Study design: A retrospective chart review of all patients with PAS (January 2018 to January 2020) at a single tertiary center who underwent prophylactic or emergent REBOA for cesarean hysterectomy for PAS.

Results: A total of 16 pregnant patients with PAS underwent percutaneous REBOA placement by acute care surgeons in collaboration with a multi-disciplinary PAS team. The REBOA catheter was placed prophylactically in 11 cases and emergently in 5 cases. No complications occurred in the prophylactic placement group. In the emergent placement group, 3 of 4 surviving patients had vascular access site complications requiring intervention.

Conclusion: A multidisciplinary approach for the management of PAS utilizing REBOA is feasible in the setting of both planned and emergent cesarean hysterectomy and can improve the control of acute hemorrhage. The risk for vascular access site complications related to REBOA catheter placement is higher in the emergent setting compared to prophylactic placement.

Article review and analysis

Aim of this study: In the past years, REBOA has been introduced as a novel treatment modality for the treatment of morbidly adherent placenta (MAP). The present study compares the risk of vascular complications in the prophylactic and emergent REBOA catheter placement during cesarean hysterectomy for the management of MAP.

Methods

Pros: The major advantage of this study is the comparison between the two scenarios of both prophylactic and emergent placement of the REBOA catheter. The existing data in the literature is scarce and the current study is the largest case series conducting such a comparison. This comparison might emphasize the importance of planning the surgery for patients with MAP, and allow the provision of evidence-based information to patients regarding treatment with REBOA in both scenarios.

Cons: This is a retrospective study with a very limited sample size (5 emergent cases and 11 prophylactic cases). Statistical analysis was not conducted in this study and the results were only descriptive, possibly due to the low number of cases. It is therefore difficult to draw wide conclusions based on this small sample. The small sample also decreases the generalizability of this study to other patient populations and institutes.

Results, conclusion, and what it means

Between the years 2018 and 2020, 16 patients received percutaneous REBOA catheter placement at a tertiary medical center. In 11 cases of prophylactic REBOA placement, there were no vascular complications, similar to previous studies with a complication rate of 0.6% to 4.4%. In 5 emergent cases, there was one maternal death due to placental abruption and disseminated coagulopathy, with no relation to the REBOA placement. Three of the four surviving patients in the emergent group had vascular complications related to REBOA catheter placement requiring intervention with thrombectomy and repair by vascular surgery, recovered with no residual complications. This study had a higher complication rate for emergent REBOA placement than previously described in the study by Stensaeth et al. The complication rate might be associated with hypotension related to hemorrhage in addition to the hyper-coagulable state in pregnancy or manipulation of the patient's pelvic anatomy in an attempt to achieve hemorrhage control and possible distortion of the pelvic vessels. The estimated blood loss was greater in the emergent group compared to the prophylactic group (median of 5 L vs. 2 L) and required more packed RBC units (median of 8 vs. 1 units); however, statistical analysis was not conducted in the study.

Comments and future research

REBOA is a possible treatment modality for obstetric emergencies and may be used in a prophylactic or emergent setting. Currently, there is almost no data in the literature comparing the emergent versus prophylactic treatment with REBOA for MAP. There is a need for larger prospective randomized multicenter trials comparing both scenarios relating to both the efficacy and the safety of this procedure. Additional information will allow evidence-based treatment selection and planning for patients with MAP, with a better understanding of potential complications.

i Related important publications

Greer JW, Flanagan C, Bhavaraju A, Davis B, Kimbrough MK, Privratsky A, Robertson R, Taylor JR, Sexton KW, Beck WC. Right external iliac artery thrombus following the use of resuscitative endovascular balloon occlusion of the aorta for placenta accreta. *J Surg Case Rep.* 2018 Nov 13;2018(11):rjy313.

CHAPTER 10.

Embolization of traumatic bleeding

Authors: Viktor Reva and Marta Madurska

Introduction

Around 155 years ago, the greatest Russian surgeon Nikolay Pirogov wrote: "A new era for surgery will come when we manage to stop the flow in a major artery quickly and surely without its exploration and ligation". The father of Russian surgery, who routinely explored major vessels in his Saint Petersburg practice as well as in austere combat environments, predicted a paradigm shift that has now become a reality. Angioembolization has become a standard method of controlling many bleeding vessels. Traumatic injury of arterial branches supplying abdominal organs, hypogastric/pelvic arteries, deep femoral, gluteal and lumbar arteries are just some indications for endovascular treatment using embolization techniques. In optimal settings, and with skilled hands, a straightforward embolization procedure can be performed within 20 minutes, once vascular access is obtained. Unstable hemodynamic status is no longer an absolute contraindication for embolization as demonstrated by a growing evidence base. While REBOA can temporarily stabilize a trauma patient, arterial embolization can make this patient a survivor. With rapid technological advances, there is a proliferation of improved devices and embolization agents, each with a different profile and varying levels of controllability for permanent and temporary vessel occlusion. This widens the window of opportunity for trauma care as demonstrated by a growing number of endovascular and embolization training events aimed at emergency and trauma surgeons. With similarities to laparoscopic surgery having been adopted by general surgeons, angioembolization is becoming another tool in the armory of a trauma surgeon to control hemorrhage and ultimately save lives.

This chapter aims to explore a few notable articles pooled by the idea of minimally invasive embolization, and may help extend the horizons of EVT and stimulate further research into methods of hemorrhage control in trauma.

ARTICLE NUMBER 1

Effect of door-to-angioembolization time on mortality in pelvic fracture: Every hour of delay counts.*J Trauma Acute Care Surg.* 2018 May;84(5):685–92.

Matsushima K, Piccinini A, Schellenberg M, Cheng V, Heindel P, Strumwasser A, Benjamin E, Inaba K, Demetriades D

Abstract

Introduction: Angioembolization (AE) is widely used for hemorrhagic control in patients with pelvic fracture. The latest version of the Resources for Optimal Care of the Injured Patient issued by the American College of Surgeons Committee on Trauma requires interventional radiologists to be available within 30 minutes to perform an emergency AE. However, the impact of time-to-AE on patient outcomes remains unknown. We hypothesized that a longer time-to-AE would be significantly associated with increased mortality in patients with pelvic fracture.

Methods: This is a 2-year retrospective cohort study using the American College of Surgeons Trauma Quality Improvement Program database from January 2013 to December 2014. We included adult patients (age ≥ 18 years) with blunt pelvic fracture who underwent pelvic AE within 4 hours of hospital admission. Patients who required any hemorrhage control surgery for associated injuries within 4 hours were excluded. Hierarchical logistic regression was performed to evaluate the impact of time-to-AE on in-hospital and 24-hour mortality.

Results: A total of 181 patients were included for analysis. The median age was 54 years (interquartile range, 38–68) and 69.6% were male. The median injury severity score was 34 (interquartile range, 27–43). Overall in-hospital mortality rate was 21.0%. The median packed red blood cell transfusions within 4 and 24 hours after admission were 4 and 6 units, respectively. After adjusting for other covariates in a hierarchical logistic regression model, a longer time-to-pelvic AE was significantly associated with increased in-hospital mortality (odds ratio, 1.79 for each hour; 95% confidence interval, 1.11–2.91; $p = 0.018$).

Conclusion: The current study showed an increased risk of in-hospital mortality related to a prolonged time-to-AE for hemorrhagic control following pelvic fractures. Our results suggest that all trauma centers should allocate resources to minimize delays in performing pelvic AE.

Level of evidence: Therapeutic/care management, level IV.

Article review and analysis

Aim of this study: Hemorrhage resulting from unstable pelvic fracture is a multidisciplinary problem which brings together multiple specialties, including: trauma,

orthopedic and vascular surgery, urology and, most recently, interventional radiology and endovascular surgery.

Although arterial injury accounts for only about 10–15% of all cases of hemorrhage associated with pelvic trauma, at least 50–70% of hemodynamically unstable pelvic fractures are arterial in nature.

Measures including pelvic binders and external fixators, or even preperitoneal packing, have been demonstrated to reduce arterial bleeding but are unable to stop it completely. A variety of techniques have been described to address arterial vascular injury in pelvic trauma. The surgical approach involves vascular exploration and ligation of the specific injured artery or bilateral internal iliac artery (IIA) ligation. The endovascular approach involves permanent or temporary selective and non-selective IIA embolization and is becoming the first line intervention in many trauma centers; however, optimal timing for the procedure is still unknown. Dr. Matsushima's study sheds some light on when angioembolization should best be performed.

Methods

Pros: This study utilizes a subset of the National Trauma Data Bank (ACS TQIP) consisting of trauma-related data from more than 700 Level 1 and Level 2 trauma centers across the United States. The authors managed to enroll 181 severely injured patients who met the inclusion criteria and divided them into four groups according to door-to-angiography time (first angiography or trans-arterial angioembolization (TAE)): < 1 hour (10.5%), 1–2 hours (19.9%), 2–3 hours (43.6%) and 3–4 hours (26.0%). Patients who received angioembolization more than 4 hours after arrival to hospital, had purely diagnostic procedures, or those who had damage control surgery within 4 hours, were excluded from the analysis. Thus, the authors obtained a relatively homogeneous cohort of patients and performed correct statistical analysis to evaluate the risk of mortality if TAE is delayed.

Cons: The study is limited by a two-year period and is retrospective in nature. Being a multicenter study, different institutional resuscitation protocols may not be accounted for, and exact door-to-embolization time is sometimes difficult to control. For example, non-selective aortography may be performed within a minute after vascular access is achieved, but bilateral selective cannulation of each hypogastric artery followed by injection of appropriate embolizing agent might be time-consuming. Type of embolization agent, laterality of the embolization, and procedure-related complications were not recorded in this study. Unfortunately, the study design did not allow for separation of those deaths which occurred a few days/weeks after trauma, so some late deaths could also be considered hemorrhage-related and affected by door-to-embolization time. Moreover, as endovascular interventions > 4 hours were excluded from analysis, it is impossible to say whether the delayed TAEs performed in many centers worldwide (reaching 5 hours and more, even in top trauma centers) are at all worthwhile.

Results, conclusion, and what it means

Based on the results, the authors draw a powerful conclusion that every hour of delay before pelvic TAE counts and is associated with an increased risk of in-hospital death by 80% (odds ratio 1.79 for each hour, 95% CI, 1.11–2.91, $p=0.018$). No deaths occurred in the <1 hour group within the first 24 hours (non-significant compared to 11%, 8%, 11% in the 1–2, 2–3, and 3–4 hours groups). Only one in-hospital death occurred in the <1 hour group (5%) compared to 17–25% for the other groups. These findings provide a basis for upgrading local and regional trauma systems to satisfy the current needs of polytrauma patients being appropriately treated, regardless of time of day, and therefore even when access to interventional service provision can be restricted. The conventional sequential protocol: external fixator followed by pelvic packing before angioembolization, does not meet modern requirements and barely supports the well-proven doctrine “treat first what kills first”. This article confirms “the golden hour” policy and highlights the dogma of achieving hemorrhage control within 60 minutes. If the primary focus of trauma care is lifesaving hemorrhage control, and with TAE being a proven method of hemorrhage control, then access to interventional resources should be available on a 24/7 basis. There are a few ways of improving embolization availability in acute trauma settings: 1) establish a 24/7 radiology service: an angio suite and IR personnel; 2) train surgeons to perform basic endovascular maneuvers, e.g., arterial access, REBOA, and simple embolization, typically in a “semi-hybrid” operation room using a high-quality C-arm and a sliding radiolucent operating table; 3) implement new protocols with hybrid techniques combining open exposure of the iliac arteries and direct injection of embolization substances, e.g., diluted gelatin powder or sliced gelatin sponge (Figure 1). The latter method has potential advantages over classical TAE, but without the obstacles of obtaining percutaneous arterial access and needing the manipulation of wires and catheters inside the arterial tree, which is of relevance to rare users and non-specialists in interventional radiology.

Comments and future research

Pelvic TAE offers a great opportunity to control the most difficult and most dangerous fracture-related hemorrhages. The article discussed here demonstrates benefits of early embolization and supports other studies which demonstrate survival benefit in early arterial access. However, other management techniques of fracture-related hemorrhage are developing: preperitoneal pelvic packing, minimally invasive emergent sacro-iliac joint screw fixation, etc. Evidence from prospective controlled trials is required to define optimal lines of intervention in the management of polytraumatized patients with various injury characteristics. Can embolization be the next prioritized intervention after pelvic binder application in non- and transient responders? If so, are the currently used pelvic belts appropriate for transfemoral interventions or will they interfere with vascular access in the groin (Figure 2)? Moreover, groin access for TAE may be compromised by the trauma itself, or access to the target vessel from the groin may be challenging for anatomical reasons. Difficulties in vascular access from the

groin may be avoided by a transradial approach – a concept which is further explored in another paper discussed in this chapter.

Pelvic trauma remains among the most challenging, and pelvic bleeding is difficult to control with high mortality and morbidity, which highlights the need for high-quality data. Future studies are needed to find answers to these questions.

i Related important publications

- Katsura M, Yamazaki S, Fukuma S, Matsushima K, Yamashiro T, Fukuhara S. Comparison between laparotomy first versus angiographic embolization first in patients with pelvic fracture and hemoperitoneum: a nationwide observational study from the Japan Trauma Data Bank. *Scand J Trauma Resusc Emerg Med.* 2013;21:82.
- Tanizaki S, Maeda S, Matano H, Sera M, Nagai H, Ishida H. Time to pelvic embolization for hemodynamically unstable pelvic fractures may affect the survival for delays up to 60 min. *Injury.* 2014;45:738–741.
- Tesoriero RB, Bruns BR, Narayan M, Dubose J, Guliani SS, Brenner ML, Boswell S, Stein DM, Scalea TM. Angiographic embolization for hemorrhage following pelvic fracture: is it “time” for a paradigm shift? *J Trauma Acute Care Surg.* 2017;82:18–26.
- Coccolini F, Stahel PF, Montori G, Biffi W, Hörer TM, Catena F, Kluger Y, Moore EE, Peitzman AB, Ivatury R, Coimbra R, Fraga GP, Pereira B, Rizoli S, Kirkpatrick A, Leppaniemi A, Manfredi R, Magnone S, Chiara O, Solaini L, Ceresoli M, Allievi N, Arvieux C, Velmahos G, Balogh Z, Naidoo N, Weber D, Abu-Zidan F, Sartelli M, Ansaloni L. Pelvic trauma: WSES classification and guidelines. *World J Emerg Surg.* 2017 Jan 18;12:5. doi: 10.1186/s13017-017-0117-6.eCollection 2017.
- Parry JA, Smith WR, Moore EE, Burlew CC, Mauffrey C. The past, present, and future management of hemodynamic instability in patients with unstable pelvic ring injuries. *Injury.* 2020 Feb 22 S0020-1383(20)30176-5. doi: 10.1016/j.injury.2020.02.101
- Tran TLN, Brasel KJ, Karmy-Jones R, Rowell S, Schreiber MA, Shatz DV, Albrecht RM, Cohen MJ, DeMoya MA, Biffi WL, Moore EE, Namias N. Western Trauma Association Critical Decisions in Trauma: Management of pelvic fracture with hemodynamic instability – 2016 updates. *J. Trauma Acute Care Surg.* 2016 Dec;81(6):1171–1174

ARTICLE NUMBER 2

Simultaneous damage control surgery and endovascular procedures for patients with blunt trauma in the hybrid emergency room system: New multidisciplinary trauma team building.

J Trauma Acute Care Surg. 2019 Jan;86(1):160–2.

Ito K, Nagao T, Nakazawa K, Kato A, Chiba H, Kondo H, Miyake Y, Sakamoto T, Fujita T

Abstract

No abstract available. Published as a case report.

Article review and analysis

Aim of this study: This study reports the experience of a single Japanese trauma center equipped with the hybrid emergency room system (HERS) and describes the potential of modern endovascular techniques in trauma management based on a clinical case of severe polytrauma. The authors wanted to demonstrate that EVTm is an essential part of polytrauma protocols and that damage control surgery is no longer the only player in the arena of severe trauma.

Methods

Pros: The authors describe a 24-year-old female who had fallen from the height of a six-story building and suffered severe multiple injuries: traumatic brain injury, multiple rib fractures with bilateral lung contusions, left hemopneumothorax, grade II splenic injury, grade III liver and bilateral kidney injury, open-book pelvic fracture, as well as right femur and calcaneus fractures. The ISS was 48 with a probability of survival of 9%. The patient arrived severely shocked (blood pressure less than 60 mm Hg, heart rate 133 bpm), acidotic (pH 7.14; lactate 5.16 mmol/L) and coagulopathic (INR 2.92) upon admission. The ATLS and massive transfusion protocol were implemented followed by immediate whole body CT scan (WBCT) using a scanner located in the middle of the HERS. Once catastrophic chest injuries were excluded and FAST had demonstrated a moderate amount of free fluid in the abdomen, the team prepared for a hybrid procedure. Within 10 minutes of arrival, bilateral femoral arterial access was achieved (8-Fr, 5-Fr in right and left groins, respectively), and Zone I REBOA was performed. A laparotomy was carried out immediately on the spot and demonstrated 2-3 liters of blood intraperitoneally; a splenectomy was completed 5 minutes later. A left liver lobe laceration and Zone II and III non-expanding retroperitoneal hematomas were packed giving way to TAE lasting 53 minutes in total. As soon as contrast extravasation was evident in the right IIA, right sacral arteries and 4th lumbar artery, they were embolized with gelatin sponge particles. On completion of an angiogram, another bleeder was recognized in the left IIA that was embolized with a mixture of

N-butyl-2-cyanoacrylate (NBCA) and lipiodol. Finally, the injured middle sacral artery was embolized with NBCA via a microcatheter. During the TAE procedures, REBOA was in place for a total of 55 minutes, including intermittent and partial occlusion. Within 90 minutes of arrival, all interventions were completed. The patient was stabilized, later underwent planned second- and third-look laparotomies followed by definitive abdominal closure on day 6 and discharge on day 69 without surgical site infection or other in-hospital complications.

Cons: The study describes only one case without underlying evidence. The proposed algorithm “beyond ATLS” when WBCT is literally included in the primary survey replacing X-ray imaging and, in some cases, ultrasound, is unique and should be followed with caution. Currently, it is not the “one size fits all” strategy and works only for highly developed trauma systems with HERS and 24/7 access to interventional radiology services.

Results, conclusion, and what it means

On behalf of more than ten integrated HERS units across Japan, the authors were able to demonstrate how polytrauma patients are currently treated, and how they will be treated in the future. Despite being a single case report, through the publication of this article the editors have accepted that this management setup is the future of trauma care. Five arteries were embolized within 50 minutes, and no clear answer as to how to control these bleeders without EVTm exists. Is it justified to initiate TAE in a critically unstable patient? From this Japanese experience the answer is ‘Yes’. It should be observed from the PRESTO point of view. PRESTO stands for Prompt and Rapid Endovascular Strategies in Traumatic Occasions and is the term proposed by Junichi Matsumoto (Tokyo). The idea is “start soon and finish sooner”, where TAE, early trauma team (including IR) activation, WBCT, focused assessment of the scans, form the basis of the strategy. Non-selective, fast (< 10 minutes per bleeder) TAE to stop hemorrhage and prevent death is the main goal. A coagulation system-free method of embolization (NBCA) is preferred compared to others, since it works even in severe coagulopathy. The key requirement for this system is appropriate set-up, team members who are mentally and technically prepared (the Japanese DIRECT course is one of the first in the world to start teaching non-IR specialists how to perform endovascular procedures), and the trauma team works as the “pit-stop” in Formula-1. During scientific conferences, we admire reports demonstrating the work of trauma teams in HERS and the successful treatment of patients having a probability of survival close to zero. In the Japanese HERS clinical portfolio there are cases when dying polytrauma patients are treated, even without laparotomy – by TAE of liver, splenic and pelvic bleeders, simultaneously with craniotomy, etc. This published case, however, demonstrates a reasonable balance between damage control surgery, endovascular damage control (or damage control interventional radiology), and damage control resuscitation (6 units of packed red blood cells, 8 units of plasma, 5 units of platelets). All this was carried out within 90 golden minutes and the patient survived! REBOA here plays the role of a bridging

technique – for temporary stabilization and hemorrhage control – which buys time for definitive hemorrhage cessation. Precise choice of tools is of importance: from the very beginning the surgeons knew that a 8-Fr sheath is required for REBOA and a 5-Fr sheath for TAE. In the era of 7-Fr balloon catheters it is perfect, but this might change soon. Once the 4-Fr REBOA catheter (COBRA-OS, Front Line Medical Tech, Canada) becomes commercially available, bilateral 5-Fr access for both REBOA and TAE may become the primary access option of choice.

The authors also emphasize the necessity of rapid patient transport directly to HERS, bypassing the emergency department, following the Code Red protocol for a severely injured patient. Despite the reported success of this case, the same authors (in an earlier study) found increased rates of infectious complications compared to those treated in the OR, which warrants additional investigation. Interestingly, in the majority of trauma centers across Russia, shocked patients are directed immediately to a trauma operation theater, bypassing the emergency department, and no increased risk of complications has been registered.

Comments and future research

The study discussed here is provocative and provides little in terms of evidence. The role of HERS is being investigated and some good quality papers have already demonstrated a clear survival benefit compared to conventional emergency treatment (including IR). Future prospective studies are, however, warranted to confirm the effectiveness, reliability and safety of very rapid implementation of endovascular techniques (e.g., TAE) in the Code Red protocol and which may even be included into future editions of the ATLS protocol.

i Related important publications

Matsumoto J, Lohman BD, Morimoto K, Ichinose Y, Hattori T, Taira Y. Damage control interventional radiology (DCIR) in prompt and rapid endovascular strategies in trauma occasions (PRESTO): A new paradigm. *Diagn Interv Imaging*. Jul-Aug 2015;96(7-8):687-91.

Kinoshita T, Yamakawa K, Matsuda H, Yoshikawa Y, Wada D, Hamasaki T, Ono K, Nakamori Y, Fujimi S. The survival benefit of a novel trauma workflow that includes immediate whole-body computed tomography, surgery, and interventional radiology, all in one trauma resuscitation room: a retrospective historical control study. *Ann Surg*. 2019 Feb;269(2):370-376.

ARTICLE NUMBER 3

Endovascular adjuncts for hybrid liver surgery.

J Trauma Acute Care Surg. 2020 Sep;83(3):e51-e54.

Belyayev L, Herrold JA, Ko A, Kundi R, DuBose JJ, Scalea TM, Morrison JJ

Abstract

This review paper has no abstract.

Article review and analysis

Aim of this study: Liver trauma resulting in hemorrhage can be complex and carries a high risk of mortality and morbidity in patients who do not respond to liver packing and require open repair, the use of which is dependent on highly variable anatomy. Endovascular control of bleeding may provide a good alternative; however, due to logistical issues with the need for specialist resources, this approach has been generally underutilized in unstable patients until now. This paper is purely a technique review which describes the concept of hybrid endovascular-open surgery approaches to liver trauma, with particular focus on hemorrhage control. The most interesting part of this article is a description of a technique of portal venous embolization – an area that has previously remained tabula rasa for endovascular interventions in trauma.

Methods

Pros: Liver trauma is generally complex and involves access to deep structures. Currently adopted management strategies carry a significant burden of morbidity and mortality. The strategies described in this paper show novel creative techniques which may offer an alternative to solely an open surgical approach. The techniques are described in a straightforward manner, with a broad focus on hemorrhage control dependent on three main hepatic vascular territories. The authors also describe basic equipment and technology needs in terms of typical endovascular sheaths/catheters that are needed as well as operating room set-up. The description of basic aberrant anatomy with high impact on the procedural success is also useful.

Cons: This paper does not provide any scientific evidence and is purely a description of methods based on a single-center experience. It must be highlighted that the strategies described in this work require a significant amount of specific resources in terms of training and 24/7 access to hybrid and endovascular tools. Not every unit has these capabilities.

Results, conclusion, and what it means

Hybrid strategies are described for the control of three types of liver injury related hemorrhage: arterial bleeding, portal venous bleeding and hepatic venous bleeding. The arterial bleeding control by selective coil embolization described here can

be approached in a purely endovascular or hybrid setting and is performed using a radial artery approach, which is described in more depth in the next section of this chapter. The methods for arterial embolization highlight the need for arteriography prior to selective embolization due to a relatively high incidence of aberrant anatomy. Moreover, there is a recognized need to avoid unnecessary embolization due to risks of hepatic necrosis, abscess or bile leak. The hybrid method for control of portal venous bleeding presented here utilizes access of the inferior mesenteric vein (IMV) during laparotomy, which cannot be performed in a purely endovascular setting. The “trans-inferior mesenteric venous embolization” (TIMVE) procedure describes a relatively straightforward access to the portal and splenic vein via the IMV, which can be obtained using a steerable catheter. Following a portal venogram and identification of specific bleeding branches, a selective coil embolization can be performed. This new technique may have a significant impact on the future of trauma surgery when all the potential sources of bleeding can be controlled by endovascular or “semi-endo” interventions. In our laboratory in St. Petersburg, we investigated the possibility of trans-splenic venous embolization (via the splenic vein) in a porcine model of liver hemorrhage. Our findings were further reinforced by human anatomical studies which confirmed the feasibility of “transiliocolic venous embolization”, which we have termed TICVE, where the ileocolic vein may be accessed via a small incision in the McBurney’s point. TICVE precludes the need for laparotomy and potentially allows control of all possible sources of liver-related hemorrhage via the hepatic artery, IVC and portal vein. The Pringle maneuver, thus, can also be performed from inside. Retrohepatic caval bleeding can be particularly catastrophic and difficult due to the anatomic location. The endovascular approach to IVC control with a Bridge occlusion balloon, with a REBOA as standby in the event of sudden loss of cardiac output, seems less complex than conventional open approaches and may present an attractive alternative to retro hepatic control of bleeding. It is highlighted that the bridge balloon should be used for control, followed by an open approach to repair via venorrhaphy, since endovascular stenting of hepatic veins carries a high risk of thrombosis and is not feasible in trauma patients in whom anticoagulation is contraindicated.

Comments and future research

The techniques described here are novel and poorly reported in the literature apart from a few separate case reports; however, they open new horizons for investigators to define whether a totally endovascular approach to liver bleeders is feasible, effective and safe. Will transportal venous embolization be the next gamechanger in trauma surgery and an option of choice in severe liver injuries? This is the question for the coming few years of translational and clinical research.

i Related important publications

- Adnan SM, Romagnoli AN, Madurska MJ, Dubose JJ, Scalea TM, Morrison JJ. Safety and efficacy of radial access in trauma in 65 trauma endovascular cases. *J Vasc Surg.* 2020;71(5):1564–1571.
- Carver D, Kirkpatrick AW, D’Amours S, Hameed SM, Beveridge J, Ball CG. A prospective evaluation of the utility of a hybrid operating suite for severely injured patients: overstated or underutilized? *Ann Surg.* 2020; 271(5):958–961.
- Mohan B, Bhoday HS, Aslam N, Kaur H, Chhabra S, Sood N, Wander G. Hepatic vascular injury: clinical profile, endovascular management and outcomes. *Indian Heart J.* 2013;65(1):59–65.
- Bui TD, Mills JL. Control of inferior vena cava injury using percutaneous balloon catheter occlusion. *Vasc Endovascular Surg.* 2009;43(5):490–493.
- Reynolds CL, Celio AC, Bridges LC, Mosquera C, O’Connell B, Bard MR, Dela’O CM, Toschlog EA. REBOA for the IVC? Resuscitative balloon occlusion of the inferior vena cava (REBOVC) to abate massive hemorrhage in retrohepatic vena cava injuries. *J Trauma Acute Care Surg.* 2017;83(6):1041–1046.

ARTICLE NUMBER 4

A comparison of transradial and transfemoral access for splenic angio-embolisation in trauma: a single centre experience.

Eur J Vasc Endovasc Surg. 2020 Mar;59(3):472-479.

Sakib M. Adnan, Anna N. Romagnoli, James R. Martinson, Marta J. Madurska, Joseph J. Dubose, Thomas M. Scalea, Jonathan J. Morrison

Abstract

Objective: The study compared transradial access (TRA) and transfemoral access (TFA) for splenic angio-embolisation (SAE), with a focus on technical success, intra-operative adjuncts, and complications.

Methods: This was a retrospective comparative study of all trauma patients undergoing SAE by TRA or TFA between February 2015 and February 2019 at a single institution. The medical records were queried for procedural and post-operative data, with comparisons made based on access site. Continuous variables were compared using a two tailed t test and categorical variables were compared using a chi square test.

Results: Over a four year period, there were 47 cases of SAE via TRA and 127 via TFA. Technical success was 95.7% during TRA and 98.4% during TFA ($p = 0.30$). Technical failures were a result of failed splenic artery cannulation after successful radial or femoral access. Time to splenic cannulation was shorter in the TRA group (19 min vs. 30 min; $p = 0.008$). Two or fewer catheters were used during TRA, whereas more than two catheters were needed during TFA ($p < 0.001$). There were no statistically significant differences in procedure length, fluoroscopy time, radiation dose, or contrast volume between groups. Nine patients (5.2%) developed access related complications, all in the TFA group ($p = 0.12$). Mortality rate was 2.3% ($n = 4$), with no statistical significance between groups ($p = 0.71$).

Conclusion: While TFA is the conventional strategy for SAE, TRA is a safe and efficacious modality for SAE in trauma patients. Although larger studies are needed to establish the full efficacy of TRA for SAE at the multi-institutional level, this single centre study demonstrates the legitimacy of an alternative means for SAE in the trauma population.

Article review and analysis

Aim of this study: Endovascular therapies are gaining momentum in the management of trauma patients with some procedures becoming a mainstay in select patients. Selective splenic angioembolization (SAE) is one such procedure that has become a standard in many centers in the non-operative management of hemodynamically stable patients with moderate-to-high grade splenic injury. Transfemoral vascular access (TFA) is the standard approach for SAE but carries a risk of morbidity and can be

compromised in trauma patients by concomitant groin injury or placement of devices used to aid resuscitation. Transradial access (TRA) has been well adopted by interventional cardiologists and proven to be a safe approach but is poorly described in visceral interventions. This paper aims to compare transfemoral access vs radial access in terms of technical success, complications and intraoperative factors, such as procedure time and contrast use.

Methods

Pros: The paper describes a novel approach for the trauma population which can serve as a really useful alternative to the current practice standards, especially in the event of compromised groin access in trauma patients who may have concomitant injuries to their femoral vasculature or may have indwelling lines and catheters precluding further access. The cohort comes from a well-established large center with a high volume of patients and spans 4 years. This paper describes well the procedural steps, key tools and technical aspects of TRA and TFA, which may not be apparent to most practitioners without prior experience in this type of approach. This also involves the optimal operating room configuration, which is key to procedural success.

Cons: The authors describe a retrospective analysis based on patient documentation – this carries an inherent risk related to documentation error and bias resulting from omitting complications which may not have been documented or not noticed early enough. The paper describes the experience from a single center thus carrying a risk of patient selection and operator bias as well as procedural and care standards that may not be applicable in other centers. The sample size, particularly for TRA, is small and follow up time is short. Patients with post TRA radial artery thrombosis are often asymptomatic and not routinely surveyed for this following their SAE. Hence radial artery occlusion rates may have been mis-represented in this study. The paper focuses solely on splenic embolization and does not take into account other visceral or non-visceral organ management, i.e., liver, pelvic fractures, renal injury etc. This is important to consider when interpreting the findings.

Results, conclusion, and what it means:

This early report of a novel approach in SAE provides some promising data. The technical success of SAE was comparable between the TRA and TFA groups ($p = 0.30$) signifying feasibility for the radial approach for SAE. There were two technical failures in each group requiring conversion to the opposite approach. Neither of these were due to specifically vascular access site issues, but rather due to difficulties cannulating the target vessel. Celiac axis cannulation can be a particularly troublesome aspect of the whole procedure, especially when approached retrograde via TFA, in fact both of the TFA failure cases were due to this. Interestingly the technical failures in the TRA approach were specifically due to the lack of adequately long catheters that could reach the celiac axis in unusually tall patients (190 cm) when advanced from the radial artery. It could be argued that technical failures in TRA were due to device limitations rather than the practical or technical anatomical approach. Time to splenic cannulation in

TRA was found to be about 2/3 of that in TFA (19 min vs. 30 min; $p = 0.008$) and is an important finding that may play a significant role in the development of this approach in the endovascular management of trauma patients with injuries other than spleen. The overall mortality rate was 2.3% and similar in both groups ($p = 0.71$). The lack of reported major access site complications in the TRA group compared to 5.2% in the TFA group is a promising finding and supports larger studies in a non-trauma population, since pseudoaneurysms and acute limb ischemia are a particular fear in patients undergoing IR procedures. However, the small sample size of TRA patients in this group may be the reason for the lack of reported complications in radial approach and should be considered when interpreting this work. Interestingly the access site did not affect total procedural length, fluoroscopy time or dose, nor the amount of contrast given. However, TRA resulted in the use of less catheters (two or less) vs more than two in the TFA ($p < 0.001$), which can be an important finding highlighting the potential saving in procedural complexity and resources.

Comments and future research

The TRA approach described here may be a good alternative in trauma, especially for patients who have limited groin access due to injury, indwelling catheters, or body habitus. Further research should be carried out, ideally on a larger population and in the form of a prospective randomized trial to truly appreciate the complication rates and procedural time in multi-institutional settings.

Related important publications

Crichton JCI, Naidoo K, Yet B, Brundage SI, Perkins Z. The role of splenic angioembolization as an adjunct to nonoperative management of blunt splenic injuries: a systematic review and meta-analysis. *J Trauma Acute Care Surg* 2017;83:934e43.

Jolly SS, Yusuf S, Cairns J, Niemelä K, Xavier D, Widimsky P, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomized, parallel group, multicenter trial. *Lancet* 2011;377:1409e20.

Posham R, Biederman DM, Patel RS, Kim E, Tabori NE, Nowaowski FS, et al. Transradial approach for noncoronary interventions: a single-center review of safety and feasibility in the first 1,500 cases. *J Vasc Interv Radiol* 2016;27:159e66.

Meertens MM, Ng E, Loh SEK, Samuel M, Mees BME, Choong AMTL. Transradial approach for aortoiliac and femoropopliteal interventions: a systematic review and meta-analysis. *J Endovasc Ther* 2018;25:599e607.

Morrison JJ, Madurska MJ, Romagnoli A, Ottochian M, Adnan S, Teeter W, et al. A surgical endovascular trauma service increases case volume and decreases time to hemostasis. *Ann Surg* 2019;270:612e9.

ARTICLE NUMBER 5

Splenic artery embolization versus splenectomy: Analysis for early in-hospital infectious complications and outcomes.

J Trauma Acute Care Surg. 2017 Sep;83(3):356-360.

Aiolfi A, Inaba K, Strumwasser A, Matsushima K, Grabo D, Benjamin E, Lam L, Demetriades D

Abstract

Background: Splenic artery embolization (SAE) has gained increasing acceptance as an important adjunct in the treatment of splenic injuries. Residual immunologic function of the spleen after embolization and its consequences on early infectious complications still remain intensely debated. The purpose of this study was to compare SAE and splenectomy (SP) in terms of early in-hospital infectious complications and outcomes.

Methods: Two-year retrospective Trauma Quality Improvement Program database prognostic study. Patients with grade IV to V splenic injury requiring SAE or SP were included in the final analysis. Examined variables were demographics, mechanism of injury, Abbreviated Injury Scale (AIS), Injury Severity Score, Organ Injury Scale, admission vital signs, blood transfusion in the first 24 hours, early infectious complications, and outcomes. Multivariate analysis adjusted for patient and injury-related variables was used to identify independent predictors for infectious complication and mortality.

Results: During the study period, 4,063 patients with a grade IV to V splenic injury managed with SAE or SP were included in the study. SAE was performed in 461 (11.3%) patients. The early infectious complication rate was 23.1% in the SP group and 11.7% in the SAE group ($p < 0.001$). Stepwise logistic regression analysis identified age 65 years or older, Glasgow Coma Scale (GCS) score less than 9, Head AIS score of 3 or greater, SP, and blood transfusion in the first 24 hours as independent predictors for early infectious complications. The unadjusted overall mortality was 12.7% in the SP group and 5.4% in the SAE group ($p < 0.001$). Age 65 years or older, GCS score less than 9, hypotension, head AIS score of 3 or greater, and blood transfusion in the first 24 hours were independent risk factor for mortality. SP was not an independent risk factor in terms of mortality. Subgroup analysis in patients with isolated splenic injury showed age 65 years or older, GCS score less than 9, and blood transfusion in the first 24 hours as independent factors associated with early infection.

Conclusion: Our study supports the effectiveness of SAE in hemodynamically stable patients with a grade IV to V splenic injury. SP is associated with an increased risk of early infectious complications but is not an independent risk for mortality.

Article review and analysis

Aim of this study: Splenic artery embolization (SAE) has become the standard management for hemodynamically stable patients with high grade splenic injury, with splenectomy remaining the treatment of choice for unstable patients who do not respond to initial resuscitation. Although its role has been recognized as non-vital, the spleen plays a major role in antibacterial and antifungal immune reactions. While late post-splenectomy infection is rare, early infections can be more common and the impact of spleen preserving SAE on the early infection rate has yet to be elucidated. This paper sets out to compare early in-hospital infections, mortality and hospital-related outcomes in patients treated with SAE and splenectomy (SP).

Methods

Pros: This is a retrospective multi-center observational study. The study population is large. The multi-center nature of the study allowed the authors to analyze patients with a variety of injuries while avoiding operator bias or confounding related to specific institutional management protocols. Albeit a registry, the Trauma Quality Improvement Program (TQIP), which is the source of the data presented here, is considered high quality. It is expected that postoperative infections would be more common in “sicker” patients with higher injury burden and those predisposed to infection from any etiology due to co-morbidities and other underlying factors. The authors have made appropriate attempts to account for these possible confounders by adjusting for patient and injury-related variables. Moreover, the authors also performed a subgroup analysis on those cases with isolated splenic injuries with the aim of reducing bias related to polytrauma and trauma heterogeneity.

Cons: The study is a retrospective analysis without blinding or randomization. This carries an intrinsic risk of bias that cannot be avoided in a retrospective analysis. Although the registry source of this data is considered relatively high quality, it is still vulnerable to documentation errors. The “early infection” definition is limited to hospital stay and may miss those who developed signs of infection following hospital discharge. There is no standardized follow up of these patients, which may have identified complications that may not have presented during the initial hospital stay. This is a multicenter study. Access to surgical or interventional radiology facilities may differ in various centers, moreover specific arterial embolization techniques may also differ from one institution to another, which can have an impact on outcomes.

Results, conclusion, and what it means

Overall analysis demonstrated that SP is related to worse outcomes with increased mortality 12.7% vs 5.4%, $p < 0.001$, increased hospital and ICU length of stay ($p < 0.001$), as well as increased overall complications – 26% vs 14.7% for SAE, $p < 0.001$, and increased in-hospital infection rate – 23.1% vs 11.7% for SAE, $p < 0.001$, with specifically increased rates of pneumonia and systemic sepsis compared to SAE.

Interestingly, when assessing for predictors for increased in-hospital infections and mortality, SP was found to be an independent factor for infection but not mortality. When analyzing isolated splenic injury, SP was not identified as an independent factor for either complications or mortality. This study supports other literature findings of reduced infective complications and the relative safety of SAE in hemodynamically stable patients with injured spleens. However, it is still impossible to tell whether the reduced infective complication rates in SAE are due to preserved spleen function or lack of invasive open surgical intervention, which in itself carries a significant risk of surgical site and post-operative infection. This question remains unanswered especially given the finding that the SP was not an independent predictor of infection in isolated splenic injury patients.

Comments and future research

A prospective trial design with a larger number of patients and standardized embolization protocols would be ideal in elucidating outcomes following SAE and SP. Moreover, a microbiological and immunological analysis, including specific infective etiology with more detailed and longer follow up, would hopefully evaluate the role of residual function in preserved spleen in SAE patients. Four trials are currently registered on Clinicaltrials.gov that specifically focus on splenic embolization in trauma patients. While three ongoing trials are designed to investigate technical outcomes related to embolization, one study, which has completed recruitment, is aimed specifically at assessing splenic function and will hopefully shed more light on this issue.

Related important publications

- Demetriades D, Scalea TM, Degiannis E, Barmparas G, Konstantinidis A, Massahis J, Inaba K. Blunt splenic trauma: splenectomy increases early infectious complications: a prospective multicenter study. *J Trauma Acute Care Surg.* 2012;72:229–234.
- Gauer JM, Gerber-Paulet S, Seiler C, Schweizer WP. Twenty years of splenic preservation in trauma: lower early infection rate than in splenectomy. *World J Surg.* 2008;32:2730–2735.
- Olthof DC, Lammers AJ, van Leeuwen EM, Hoekstra JB, ten Berge IJ, Goslings JC. Antibody response to a T-cell-independent antigen is preserved after splenic artery embolization for trauma. *Clin Vaccine Immunol.* 2014;21:1500–1504.
- Scarborough JE, Ingraham AM, Liepert AE, Jung HS, O'Rourke AP, Agarwal SK. Nonoperative management is as effective as immediate splenectomy for adult patients with high-grade blunt splenic injury. *J Am Coll Surg.* 2016;223:249–258.
- Pachter HL, Guth AA, Hofstetter SR, Spencer FC. Changing patterns in the management of splenic trauma: the impact of nonoperative management. *Ann Surg.* 1998;227:708–717.

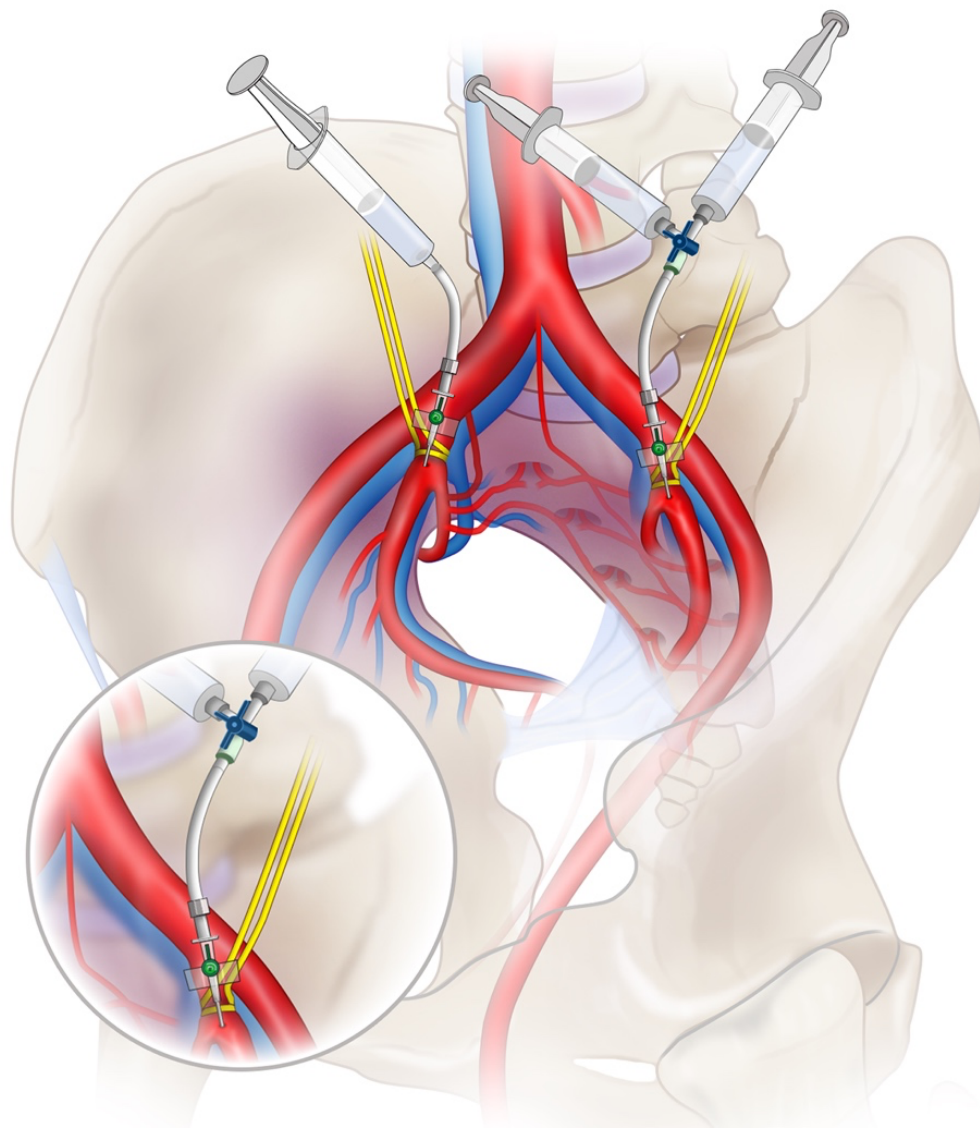


Figure 1. A schematic illustration of a hybrid damage control technique of direct internal iliac artery embolization – “direct artery puncture embolization” (DAPE). Performed under direct vision during laparotomy or preperitoneal pelvic packing. Proximal control is provided by a temporary application of vessel loops (yellow) followed by a slow injection of sliced gelatin sponge. No fluoroscopy is required, providing a quick alternative to conventional mono- or bilateral IIA embolization. (Courtesy of Viktor Reva, illustrated by Yulia Grebneva).

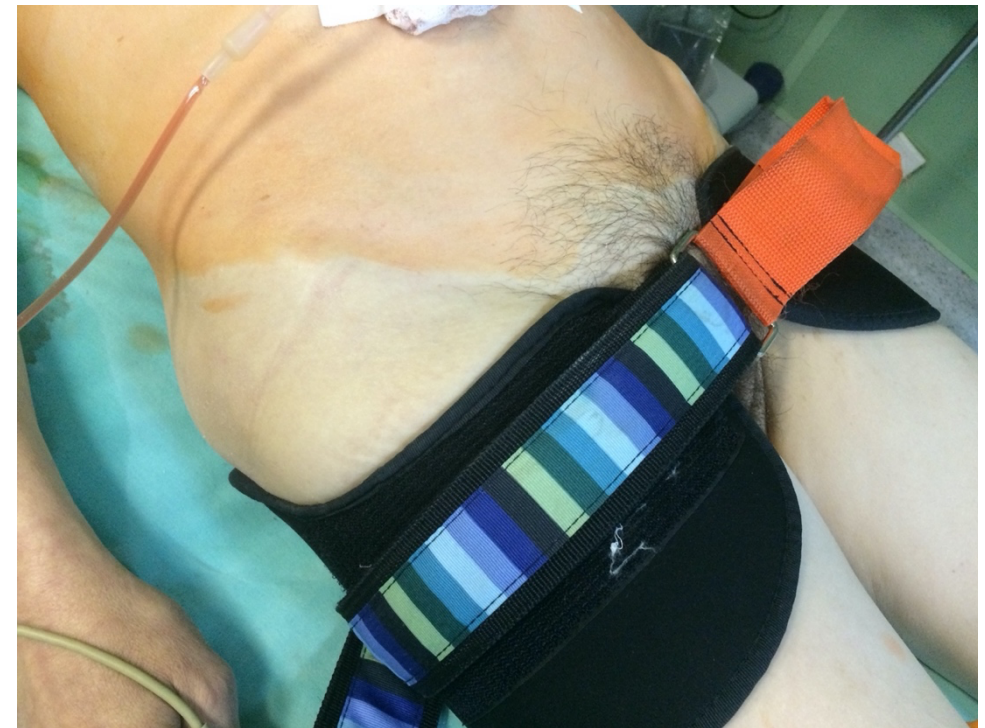


Figure 2. A pelvic belt with bilateral notches, designed specifically to provide access to both femoral regions during acute phase interventions, e.g. vascular access, REBOA, etc. (Courtesy of Viktor Reva).

CHAPTER 11.

Endovascular management of blunt aortic trauma

Authors: *Maysam Shehab and Simone Fajer*

Introduction

The FDA approved the first thoracic endovascular aortic repair (TEVAR) in 2005. Since the first TEVAR, there has been an increase in its use and it has emerged as an attractive treatment option for a wide range of thoracic aortic pathology, including blunt aortic thoracic injury (BATI).

Current data suggests that in comparison to open repair (OR), TEVAR may reduce early death, short term morbidity and hospital stay.

In addition, access and device-related complications are rare in contemporary practice due to the continued advancement of endovascular technology. The current SVS guidelines for BATI management provide the evidence-based course of treatment guidelines.

There are many challenges and controversies in the subject of trauma management, including:

1) non-operative management of grade II injury; 2) systemic heparinization /pulse therapy with BATI and other injuries, especially brain injury; 3) ideal timing of BATI treatment; 4) coverage of left subclavian artery (LSA); 5) optimal stent graft for pediatric patients; and finally 6) the long term durability of endovascular devices and long term complications.

We review here some of the most relevant studies that have been performed and some of the challenges mentioned above.

ARTICLE NUMBER 1

Durability of Endovascular Repair in Blunt Traumatic Thoracic Aortic Injury: Long-Term Outcome from Four Tertiary Referral Centers.

Eur J Vasc Endovasc Surg (2015) 50, 460e465.

Steuer J, Björck M, Sonesson B, Resch T, Dias N, Hultgren R, Tunesi R, Wanhainen A, Lachat M, Pfammatter T.

Abstract

Objectives: To analyze the early and long-term survival and re-intervention rate in patients undergoing TEVAR for blunt traumatic thoracic aortic injury.

Methods: This was a consecutive case series. Between the years 2001 and 2010, a total of 74 patients underwent TEVAR for blunt traumatic thoracic aortic injury at four tertiary referral centers, three in Sweden and one in Switzerland. The median age of the patients was 41 years, and 16% were women. Demographic, procedural, and outcome data were collected and reviewed retrospectively. The patients were followed up during 2013-2014.

Results: Early (30 day) mortality was 9% (7 patients), with only two cases directly related to the aortic injury; in hospital mortality was 14% as three patients died during the primary hospital admission within the first 6 months. Most patients had sustained severe injuries to other organ systems, and among all in hospital deaths brain injury was the predominant cause. Five year survival in the whole group was 81%. Re-intervention was needed in 16% (12 patients) during the first year, half of them within the first month. Only one patient underwent re-intervention more than 1 year after the initial procedure. Infolding and partial stentgraft collapse was the reason for the secondary procedure in five of the 13 patients; in three it occurred within 3 weeks of the acute TEVAR.

Conclusion: TEVAR allows rapid and effective therapy in trauma patients with blunt aortic injury. The outcome is dependent on the severity of the concomitant injuries. The treatment is durable during the first decade after the procedure, but even longer follow up is needed to determine the impact of TEVAR in young patients on the degenerative changes that take place in the aging aorta.

Article review and analysis

Aim of this study: Endovascular approaches have slowly replaced open surgical repair for the management of blunt thoracic aortic injuries.

This study aim to analyze the long term outcome of TEVAR in patients with traumatic aortic injury; the primary endpoints were survival and reintervention rate.

Methods

Pros: The long term (10 years) follow up is very important due to the very young average age of thoracic blunt trauma injury patients. The study was not extended beyond 2010 to allow follow up for all the patients. All patients were evaluated by CTA before discharge and at 1 month, after 3-6 months, and at 12 months, and annually thereafter. The characteristics of the 13 patients who underwent re-intervention after TEVAR were detailed as follows: gender, age, trauma mechanism, aortic injury type, stent graft type, indication for reintervention, time to reintervention, operation. Moreover, there is a descriptive list of characteristics of the seven patients who died within 30 days of TEVAR and the cause of death.

Cons: This study has several limitations. This is a retrospective study. The number of patients is small (74). Long-term survival was followed in 69 patients (5 lost to follow-up). The endovascular devices implanted were old models whereas nowadays the industry offers new and modified devices. Even though long-term device-related adverse events seem to be rare, little is known about aortic remodeling and the long-term effect over decades.

Results, conclusion, and what it means

The findings of this study support other related publications. The reason for early death in patients undergoing TEVAR is, in most cases, unrelated to the aortic injury. In patients surviving the trauma and the primary hospitalization, long-term survival is excellent, and the need for reintervention is very rare after one year. In recent years, TEVAR has emerged as the preferred treatment for patients with blunt traumatic thoracic aortic injury. The most significant finding of this study was the favorable outcome of TEVAR in blunt thoracic aorta injury. Early mortality (30 days) was 9%, but only two of seven deaths were directly attributed to the aortic injury. The optimal timing of TEVAR in patients with concomitant brain injury is poorly defined due to the use of systemic heparinization in TEVAR. Patients sustaining blunt traumatic thoracic aortic injury are young (median age in this study was 41 years). This is consistent with other studies (age range 30-45 years, predominantly male). This poses several technical challenges since young patients tend to have a more acute curvature of the aortic arch (bird beak configuration).

This study was published in 2015. Since 2015, many modifications have evolved in thoracic stent grafts, i.e., smaller diameter stent grafts. Assessment of the long-term durability of TEVAR in young patients and the long-term follow-up make this study important, in comparison with other studies which had shorter follow-up time.

Based on the authors' experience and a review of the literature, the incidence of complications is higher during the first year. The need for endovascular reintervention and the occurrence of aortic-related deaths are much lower after the first year, suggesting the use of a more infrequent follow up regimen over time.

Comments and future research

Larger case numbers with longer follow up are recommended.

i Related important publications

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ARTICLE NUMBER 2

Functional Assessment and Evaluation of Outcome After Endovascular Therapy With Coverage of the Left Subclavian Artery in Case of Blunt Thoracic Aortic Injury.

Ann Vasc Surg. 2017 Apr;40:98-104.

Gombert A, Kotelis D, Griepker UM, Fraedrich G, Klocker J, Glodny B, Jacobs MJ, Greiner A, Grommes J.

Abstract

Background: Patients suffering blunt thoracic aortic injury (BTAI) can be treated by use of thoracic endovascular aortic repair (TEVAR). In this setting, the coverage of the left subclavian artery (LSA) is frequently necessary. Nevertheless, the functionality of the upper left extremity after TEVAR had been rarely analyzed. Thus, this study intends to underline the safety of TEVAR as well as to determine the functionality of the left arm after coverage of the LSA.

Methods: All patients suffering from BTAI treated by endovascular means in 3 centers (Aachen [Germany], Maastricht [Netherlands], and Innsbruck [Austria]) between 1996 and 2009 were retrospectively analyzed. The safety of the procedure had been assessed by the morbidity and mortality rate. The mid-term functional status of the upper left extremity was evaluated by using the DASH score (disabilities of the arm shoulder and hand).

Results: Forty-six patients (40 male, 6 female), mean age 39.4 ± 16.9 years suffered from BTAI caused by traffic accident ($n = 31$ [67.39%]), by skiing injury ($n = 8$ [17.39%]), and by fall ($n = 7$ [15.21%]). All patients underwent TEVAR, the technical success rate was 100%; 1 carotid-carotid subclavian bypass implantation was necessary. LSA coverage was performed in 76% (35/46) of the cases. Total complication rate was 17.3% (8/46); the endoleak rate was 8.6% (4/46) ($2 \times Ib$, $1 \times IIa$, $1 \times IV$). Further complications were bypass and endograft occlusion. The postoperative mortality rate was 6% (3/46), the DASH score was completed in 65% (30/46). The study population reached a mean value of 17 ± 20 , which is comparable to a nonharmed reference group (10.10 ± 14.68). A significant correlation between the DASH score and patients age could be demonstrated (2-sided P value: 0.0213).

Conclusion: Endovascular therapy of BTAI revealed a good primary success rate. An adequate mid-term functional status of the upper left extremity could be assessed in comparison to a nonharmed reference group.

Article review and analysis

Aim of this study: The aim of this study was to analyze the influence of LSA coverage on the functionality of the left arm.

Methods

Pros: This is a multicenter study, which included 46 patients suffering from BTAI, treated in 3 different European university hospitals between 1996 and 2009. The imaging protocol was the same in all hospitals; the treatment decision was based on the SVS 2011 guidelines. Revascularization of LSA via carotid subclavian bypass was performed if necessary. The CTA follow-up protocol was similar in all hospitals – before discharge, at 6 months and thereafter annually. Systemic blood pressure between two arms was performed after 6 months, and systemic analysis of the data was performed. The DASH score (disability of the arm, shoulder and hand) questionnaire is a standardized tool that was used in order to assess the function of the arm and quality of life (QOL). It was sent to all patients in 2014.

Cons: This study examined the effect of LSA coverage on the left arm; however, it did not evaluate the perioperative stroke incidence following TEVAR with LSA coverage. The number of participants is small, although when comparing this study with other studies concerning BTAI, the number of patients and the time frame are acceptable. There was no short term (<6 months) assessment of the arm function. The result of the DASH questionnaire was evaluated in just 65% of patients.

The time frame of 14.9 years between an injury causing BTAI and the DASH score assessment may question the validity of the results; however, since the DASH score evaluates permanent dysfunctions of the upper arm, this limitation can be eliminated. Moreover, the CTA protocol did not routinely include neck and brain vessels. Since 80% of the cases were performed as an emergency treatment, no evaluation of the circle of Willis or left vertebral dominance was performed before treatment.

Results, conclusion, and what it means

BTAI was treated in all cases by endovascular means via femoral artery access. The primary technical success was 100%. A hybrid procedure was applied in one case due to problematic landing zone (LT CCA and LT SCA proximity). The mean follow up was 2.2 + 3.4 years (0.5-14). LSA was covered in 76% (35/46). No neurological complications, such as stroke or paraplegia, were observed. No procedural-related death could be assessed. One case of subclavian steal syndrome (vertigo) was treated conservatively. The DASH score assessment was compared in those with and without LSA coverage. Patients with additional injury to the left upper arm were also taken into consideration. No significant difference was observed between the groups. In the existing literature, as well as in this study, coverage of LSA showed low incidence of complications in the follow up and revascularization of LSA seemed to be dispensable in the majority of these patients.

Comments and future research

A prospective larger case number study comparing emergent TEVAR with non-covered LSA (also including: fenestration, branched, chimney techniques) versus covered LSA is required.

i Related important publications

Skripochnik E, Novikov D, Bilfinger TJ, Loh SA. Short-term results of left subclavian artery salvage in blunt thoracic aortic injury with short proximal landing zones. *J Vasc Surg.* 2018 Oct;68(4):985-990.

McBride CL, Dubose JJ, Miller CC 3rd, Perlick AP, Charlton-Ouw KM, Estrera AL, Safi HJ, Azizzadeh A. Intentional left subclavian artery coverage during thoracic endovascular aortic repair for traumatic aortic injury. *J Vasc Surg.* 2015 Jan;61(1):73-9.

ARTICLE NUMBER 3

The role of heparin in endovascular repair of blunt thoracic aortic injury.*J Vasc Surg* 2019 .Dec.1809-1815;(6)70;

Kenel-Pierre S, Ramos Duran E, Abi-Chaker A, Melendez F, Alghamdi H, Bornak A, Lopez AJ, Rey J.

Abstract

Objective: Early diagnosis and treatment are essential to improve survival of patients with blunt thoracic aortic injury (BTAI). Often, aortic surgical intervention may be delayed because of increased risk of bleeding with heparin, particularly in polytrauma victims. We believe that surgical delay may be remedied by proceeding without heparinization. This study reviewed the outcome of patients subjected to thoracic endovascular aortic repair (TEVAR) under full, low-dose, and no intraoperative systemic heparinization.

Methods: There were 77 cases of confirmed BTAI identified and retrospectively analyzed at a high-volume urban trauma center during a period of 15 years (March 2003-September 2017). Patients were stratified into three groups on the basis of the intraoperative use of heparin during TEVAR, as follows: full heparin (FH), low-dose heparin (LH), and no heparin (NH). Baseline characteristics including the patients' demographics, diagnostic laboratory data and imaging studies, operative reports, post-operative complications, embolic and bleeding outcomes, and mortality data were reviewed.

Results: Of the 77 total patients who underwent TEVAR for BTAI, 42 patients received full-dose heparinization, 18 received low-dose heparin, and 17 had no use of systemic heparin. There was no significant difference in age, sex, body mass index, or smoking history. The most common mechanism of injury was motor vehicle collision. Grade 3 (pseudoaneurysm) was the predominant type of BTAI (FH, 69.0%; LH, 61.1%; NH, 76.5%; $P = .23$). The mean interval between admission and repair was three times longer in the FH group than in the NH group (FH, 2.33 days; NH, 0.76 day; $P = .091$). The mean time in the intensive care unit was shorter in the NH group vs the FH group (15 days vs 26.21 days; $P = .025$). Thromboembolic and bleeding outcomes and mortality rates were comparable in all three groups; 57 patients continued follow-up for a mean time of 30.99 months.

Conclusion: Our study shows no statistically significant difference in outcomes between the heparinized and nonheparinized groups. The primary benefit of the NH group is seen in time to repair. Although not statistically significant, the mean time to repair was three times longer in the FH group. Patients in the NH group also benefited from prompt intervention and treatment. Therefore, intraoperative heparinization in critically ill patients with BTAI undergoing TEVAR remains at the surgeon's discretion,

although the lack of heparinization appears to be a safe and potentially faster alternative, particularly in the polytrauma patient.

Article review and analysis

Aim of this study: This study reviews the outcome of patients with BTAI who were treated with TEVAR and full, low dose and no intraoperative systemic heparin.

Methods

Pros: This study reviewed the experience of a high volume trauma center over a period of 15 years (2003-2017) with regard to heparinization and compared the outcome.

The study suggests that small dose or no intraoperative heparinization in critically ill patients (multi-trauma and particularly head injury) with BTAI undergoing TEVAR appears to be a safe alternative.

TEVAR is a relatively quick procedure and the risk of a thrombotic event is small.

Cons: The most significant limitation of this study is that it is a retrospective review, and therefore not all the data are available. Moreover, the time frame of the study is long and endovascular technology has evolved rapidly over this time period; however, this further supports the study results. The sample size is not sufficiently large.

Results, conclusion, and what it means

A total of 77 patients underwent TEVAR for BTAI.

Motor vehicle crash was the most prominent cause of injury and the most common injury grade was grade 3 pseudoaneurysm.

Patients in the NH group demonstrated a higher overall ISS; however, this was not statistically significant. Concomitant injuries, such as intra cranial hemorrhage (ICH) and solid organ injury (SOI), were noted and compared, and a higher incidence in the LH and NH groups was seen, although this finding was not statistically significant. 42 patients (54%) received full heparin, 18 patients (23%) low dose heparin and 17 (22%) did not receive heparin. Heparinized saline flushes of endograft sheath were carried out in all groups.

The study endpoints are as follows:

1. Thromboembolic complications:
There was only one report and it was in the LH group, the patient developed an embolic stroke due to atrial fibrillation. Lower extremity perfusion was assessed clinically in the post-operative admission. Ankle-Brachial Index (ABI) was not routinely obtained.
2. Bleeding complications defined as excess blood loss and the need for blood transfusion/surgical intervention:
This was reported in the 3 groups. There was no statistically significant difference in the outcome of the full heparinization, low dose heparin and no systemic heparin groups.

The take home message from this study is that a lack of heparinization appears to be safe and that we can consider this option in critically ill patients with BTAI undergoing TEVAR.

Comments and future research

This study addresses an important dilemma with regard to trauma patients and systemic heparinization, but it is based on a small number of patients and therefore a larger case number study is recommended.

i Related important publications

Makaloski V, Widenka H, Schönhoff F, Spanos K, Wyss TR, Schmidli J. Efficacy and Safety of Heparinization before Deployment of Endograft for Blunt Traumatic Aortic Injury in Severely Injured Patients. *Ann Vasc Surg.* 2021 Feb 5;50:890-5096(21)00150-3.

ARTICLE NUMBER 4

National Trends of Thoracic Endovascular Aortic Repair versus Open Thoracic Aortic Repair in Pediatric Blunt Thoracic Aortic Injury.

Ann Vasc Surg. 2019 Aug;59:150-157.

Hasjim BJ, Grigorian A, Barrios C Jr, Schubl S, Nahmias J, Gabriel V, Spencer D, Donayre C.

Abstract

Background: Blunt thoracic aortic injury (BTAI) occurs in <1% of all trauma admissions. Thoracic endovascular aortic repair (TEVAR) has become the preferred treatment modality in adult patients with BTAI, but its use in pediatrics is currently not supported by device manufacturers and lacks United States Food and Drug Administration approval. We hypothesized that there would also be an increased use of TEVAR in the pediatric population, thus conferring a lower risk of mortality compared with open thoracic aortic repair (OTAR).

Methods: The National Trauma Data Bank (2007-2015) was queried for patients ≤17 years with BTAI. The primary outcomes were the incidences of TEVAR and OTAR. Secondary outcome was risk of mortality in those undergoing intervention. A multi-variable logistic regression model was used to determine the risk of mortality in OTAR versus TEVAR.

Results: We identified 650 pediatric BTAI patients with 159 (24.5%) undergoing intervention. Of these, 124 underwent TEVAR (78.0%) and 35 (22.0%) underwent OTAR. The rate of TEVAR steadily increased from 2007 to 2015 (15.4% vs. 27.1%, $P < 0.001$). Patients receiving OTAR and TEVAR had a similar injury severity score and rate of hypotension on admission ($P > 0.05$). Compared with OTAR, TEVAR patients had a higher rate of any traumatic brain injury (TBI) (63.7% vs. 37.1%, $P = 0.005$) and shorter hospital and intensive care unit length of stay (LOS) (16.4 vs. 21.4 days, $P = 0.02$; 10.1 vs. 12.2 days, $P = 0.01$). TEVAR and OTAR, even when stratified by ≤14 years and 15-17 years, had no difference in risk for mortality (odds ratio 1.20, confidence interval 0.29-5.01, $P = 0.80$).

Conclusion: The rate of TEVAR in pediatric BTAI nearly doubled from 2007 to 2015. Compared with OTAR, TEVAR was associated with a shorter hospital LOS despite a higher rate of TBI. There was no difference in risk for mortality between TEVAR and OTAR. Longitudinal studies to determine the long-term efficacy and complication rates, including reintervention, development of endoleak, and/or need for further operations, are needed as this technology is being rapidly adopted for pediatric trauma patients.

Article review and analysis

Aim of this study: The long-term safety and effectiveness of TEVAR in patients younger than 18 years has not been established. This study compares the outcomes of pediatric patients with BTAI undergoing TEVAR versus those with BTAI undergoing OTAR.

Methods

Pros: The large number of patients in this study is a strength. This retrospective study identified 650 pediatric BTAI patients between 2007-2015 with 159 (24.5%) requiring operative repair (open/endo).

It provides information about the morbidity/mortality in the short term.

Cons: The time frame of the study is 2007-2015; however, since then smaller diameter, lower profile thoracic devices, and hydrophilic delivery sheaths have granted endovascular access to small caliber vessels such as those seen in the pediatric population.

Patients treated with TEVAR or OTAR for BTAI were not stratified based on where they were treated, for example, at suburban, urban, teaching, nonteaching, pediatric, or adult trauma centers.

This study lacks important information, such as the specific TEVAR procedure (e.g., size of device, oversize, coverage of the left subclavian artery, types of grafts), information about the patient's anatomy (e.g., diameter of arteries, distance from left subclavian, maximum descending thoracic artery diameter) and procedure-related complications.

There was also no outpatient follow-up data.

This study does not provide answers regarding the long term prognosis in children.

Results, conclusion, and what it means

The use of TEVAR to manage BTAI in the pediatric population has nearly doubled between 2007 and 2015, from 15.4% in 2007 to its peak of 27.1% in 2015. Comparatively, the incidence of OTAR has steadily declined from 14.1% to 2.4% from 2007 to 2015.

Compared to patients undergoing OTAR, those treated with TEVAR had a shorter mean hospital LOS (16.4 vs. 21.4 days, $P = 0.02$) and ICU LOS (10.1 vs. 12.2 days, $P = 0.01$). There was no difference in the rates of mortality (5.5% vs. 8.6%, $P = 0.56$) or in-hospital complications, which included blood transfusions, AKI, ARDS, unplanned intubation, pneumonia, and cerebrovascular accident ($P > 0.05$). None of the patients undergoing TEVAR or OTAR had paraplegia.

When stratified by age, patients ≤ 14 years and 15–17 years, TEVAR and OTAR had no significant differences in mortality risk.

Comments and future research

In order to assess the long term outcomes of TEVAR on the pediatric population, additional research is necessary. Even retrospective research that has both large pediatric

patient numbers and important details regarding the anatomical and endovascular treatment technical details on the one hand, and long term follow up on the other hand, is mandatory in order to assess long term outcomes of TEVAR on the pediatric population.

Related important publications

Hiremath G, Morgan G, Kenny D, Batlivala SP, Bartakian S. Balloon expandable covered stents as primary therapy for hemodynamically stable traumatic aortic injuries in children. *Catheter Cardiovasc Interv.* 2020 Feb 15;95(3):477-483.

ARTICLE NUMBER 5

Determinants and outcomes of nonoperative management for blunt traumatic aortic injuries.*J Vasc Surg.* 2018 Feb;67(2):389-398.

Sandhu HK, Leonard SD, Perlick A, Saqib NU, Miller CC 3rd, Charlton-Ouw KM, Safi HJ, Azizzadeh A.

Abstract

Objective: The natural history and parameters for successful nonoperative management of blunt traumatic aortic injuries (BTAIs) involving the descending aorta are poorly understood. We examined our experience with nonoperative BTAI treatment (anti-impulse, blood pressure) and evaluated for determinants of successful outcomes.

Methods: We performed a review of our institutional prospective trauma registry database for all BTAI patients from 1999 to 2015. Computed tomography angiography was used to classify aortic injuries on the basis of severity: grade I, intimal tear; grade II, intramural hematoma; grade III, aortic pseudoaneurysm; and grade IV, free rupture. Grade IV injuries were excluded from nonoperative management. Baseline characteristics, clinical outcomes, and follow-up lesion resolution were compared within the medically managed cohort and between surgical and nonoperative groups using univariate and multivariable analysis.

Results: Among 338 BTAI patients admitted between 1999 and 2015, 67 BTAI patients were managed nonoperatively; 26 (54%) had grade I BTAI, 22 (46%) had grade II, and 2 (4%) had grade III. Both grade III injuries required a late thoracic endovascular aortic repair after initial medical management and were excluded from analysis. In all, 48 were managed with initial medical therapy, and the remaining 19 died on admission or before definitive treatment. Among the 48 medically managed, the median age was 34 years, and 14 (29%) were female. Six of the 48 (12%) were transferred from other facilities. There was no significant difference in baseline characteristics or early outcomes between BTAI grades. Median injury resolution time was 39 days for grade I and 62 days for grade II ($P = .03$). Compared with a surgical cohort, BTAI grade and Abbreviated Injury Scale score for the chest were the only significant determinants of propensity to operate.

Conclusion: Based on these limited data, it appears that patients with minimal aortic injuries (grades I and II) may be managed medically, with the majority resolving within 8 weeks. Minimal aortic injury is associated with low mortality and excellent intermediate-term outcomes. Further prospective studies are required to validate these findings.

Article review and analysis

Aim of this study: This study presents experience with nonoperative BTAI treatment (anti-impulse, blood pressure).

Methods

Pros: Current Society for Vascular Surgery guidelines recommend TEVAR for aortic injury grades II to IV, although recent retrospective reviews have shown that observation may be safe in selected cases of BTAI involving intramural hematomas (grade II). Nonoperative management consists of antihypertensive therapy with impulse control (negative inotropic therapy) and, when needed, supplementation with a vasodilator, all aimed at minimizing shear stress on the vessel through reduction in blood pressure and cardiac contractility, and prevention of lesion progression or rupture.

This study reports data from a group of patients who presented to one of the largest trauma centers in the US during an 11-year period (1999-2015). It also represents one of the largest retrospective reviews investigating nonoperative management of grades I and II BTAI.

Cons: The shift from open repair to TEVAR and the changes in the TEVAR equipment and techniques should be considered. The early procedures were conducted with off-label use of the TAG device, the first thoracic aortic device approved by the U.S. FDA, which was available in diameters of 26 to 40 mm, intended for patients with aortic diameters of 23 to 37 mm. During this phase, young trauma patients with aortic diameters <23 mm were treated with open repair. The approval of additional smaller diameter devices started in 2008.

A follow-up CT scan was obtained in only 71% of patients in this study at an average time of 40 days. This study has no long-term follow-up.

Results, conclusion, and what it means

Within the grade II injury subcohort, patients who were treated nonoperatively were young (age <35 years), and had increased ISS and presence of arch hematoma.

Use of medical therapy did not significantly affect adverse outcomes (stroke, paraplegia, renal failure, or death) in grade II injuries. After propensity-adjusted multivariable analysis for poor outcomes, only Injury Severity Score (ISS) appeared to be a significant risk factor.

Based on these limited data, it appears that minimal aortic injuries (grades I and II) may be managed medically, with the majority resolving within 8 weeks, as shown on the short term CT scan follow up.

Comments and future research

Further prospective studies are required to validate these findings, with a focus on short and long-term CT scan follow up.

i Related important publications

Rabin J, DuBose J, Sliker CW, O'Connor JV, Scalea TM, Griffith BP. Parameters for successful nonoperative management of traumatic aortic injury. *J Thorac Cardiovasc Surg.* 2014 Jan;147(1):143-9.

Akhmerov A, DuBose J, Azizzadeh A. Blunt Thoracic Aortic Injury: Current Therapies, Outcomes, and Challenges. *Ann Vasc Dis.* 2019 Mar 25;12(1):1-5.

CHAPTER 12.

Endovascular treatment of major visceral arteries in trauma

Authors: *Rishi Kundi and Ravi R. Rajani*

Introduction

Endovascular repair of visceral artery trauma offers many potential advantages. Open surgical exposure of the celiac artery, superior mesenteric artery (SMA), and renal arteries requires laparotomy and can be technically challenging even if the abdomen is already open. Vascular reconstructions in otherwise-contaminated fields remain at high risk of post-operative infection with a resultant high likelihood of patient morbidity.

From a technical perspective, endovascular visceral artery trauma management borrows from many of the lessons we have learned in non-trauma cases. The interventionalist should be prepared to deal with both thrombotic and hemorrhagic presentations; it is also not uncommon for one to rapidly turn into the other. A broad selection of stents, catheters, and embolization options should be readily available. Additionally, imaging quality becomes of particular importance when managing the visceral vasculature. Lastly, management of these injuries involves much more than fixing the blood vessels. The small bowel and kidneys will require their own assessment and management, since they are obviously closely tied to the endovascular intervention.

Unfortunately, there is a paucity of large, high-quality data sets available to evaluate outcomes after endovascular repair. The chosen articles below are primarily single-center retrospective analyses of small volumes. In the future, multicenter collaborative registries represent the next best step at truly evaluating the efficacy of these interventions and their long-term safety.

ARTICLE NUMBER 1

Retrospective Analysis and Systematic Review of Isolated Traumatic Dissections of the Celiac Artery.

Ann Vasc Surg. 2020 Jul;66:250-262.

Birkel J, Kahl T, Thielemann H, Mutze S, Goelz L.

Abstract

Background: Isolated dissections of the celiac artery (CA) after blunt trauma are rarely described. This retrospective analysis and systematic review analyzes epidemiology, radiologic examinations, patterns of injuries, therapeutic measures, clinical courses, and outcomes.

Methods: Retrospective analysis of polytraumatized patients admitted between 1997 and 2012 to a trauma center level I. Systematic literature search was carried out on pubmed.gov, eurorad.org, and google.com.

Results: Isolated traumatic dissections of the CA had an incidence of 0.17% in a retrospective collective (n = 9). Mean age was 31.7 years in 6 male (66.7%) and 3 female (33.3%) patients. Systematic literature search identified 12 primary sources describing 13 males (100%) with a mean age of 41.3 years. Traffic accidents and falls were the most common causes of injury. An intimal flap (77.7%) and a thrombosed false lumen (59.1%) were the most common computed tomographic findings. Twenty-two patients were analyzed, and 16 patients were treated conservatively. The CA was bypassed in 2 symptomatic patients. One patient was treated with a stent. Two patients died because of massive bleeding, and 1 patient died because of liver failure. About 19 discharged patients were asymptomatic on follow-up. Long-term follow-up with magnetic resonance angiography showed stable dissections (n = 1), medium stenosis (n = 1), resolution of the dissection (n = 2), high-grade stenosis of the CA combined with a small pseudoaneurysm (n = 1), or occlusion of the CA with sufficient collateralization (n = 3). Pharmaceutical treatment was individualized with low-molecular-weight heparin, heparin, or warfarin, and acetylsalicylic acid.

Conclusions: Traumatic CA dissections are mostly caused by traffic accidents and falls. Visceral perfusion should be monitored clinically and radiologically. Beginning visceral ischemia requires early invasive treatment. Endovascular and open surgery are possible options. Benefits of specific pharmaceuticals are still up for debate. Follow-up via magnetic resonance imaging or computed tomography angiography is essential to rule out vascular complications.

Article review and analysis

Aim of this study: Blunt vascular injury of the visceral arteries is rare and what literature does exist is primarily concerned with trauma to the renal vasculature. Up to 7% of all blunt trauma patients have thoracolumbar spinal injury, a third of which

is at the nexus of the spine, aorta, celiac ostium and diaphragm, making underdiagnosis of blunt celiac injury likely. The natural history of celiac injury is variable and encompasses self-limited, asymptomatic dissection as well as acute hepatic ischemia and death. The trauma population vulnerable to celiac dissection as well as the optimal means of diagnosis and treatment are unclear.

Methods

Pros: This article is a combination of two separate, but related, studies. First, a retrospective chart review from a single Level I trauma center encompassing all multiply injured patients admitted between 1997 and 2012 and whose electronic medical records documented celiac artery dissection without aortic dissection. An additional systematic literature review was conducted using PubMed, Google, and EuroRAD databases and the terms celiac or coeliac artery, trunk, and axis dissection. The references of the literature returned by these searches were themselves reviewed for additional papers. This represents both the largest single study as well as the largest pooled review of isolated blunt traumatic celiac injuries.

Cons: The rarity of the injury being investigated makes both of the studies poor bases for evidence-based practice, and can be thought of more as a collection of anecdotal data rather than anything against which statistical methods can be applied. The systematic literature review is extremely inconsistent with regard to the data recorded as well as the methods of management used.

Results, conclusion, and what it means

The reported initial imaging findings are notable. All 9 retrospective chart review patients demonstrated obvious intimal flaps and thrombosed false lumina on initial CT imaging. Three exhibited fat stranding around the celiac origin, and three others had evident end-organ ischemia at the time of presentation. One patient had acute focal aneurysmal changes of the celiac.

The systematic review revealed a discrepant incidence of occult injury; of the ten patients who underwent CT imaging at the time of presentation, four had no celiac artery findings. Of the remaining six, five demonstrated intimal flaps, one showed thrombosis of the false lumen, and four had perivascular fat stranding. The significance of perivascular inflammatory changes as a marker for celiac injury should be noted.

Follow-up imaging was most reliably performed in the chart-review portion of the article, and consistently demonstrated that celiac injury did not spontaneously resolve. In nearly half of the patients, the celiac developed either critical stenosis or occlusion. Within the systematic review patients, follow-up imaging was inconsistently performed and at irregular intervals, but seemed concordant: spontaneous resolution was only seen in one patient.

The design and rarity of the studied injury pattern unavoidably results in an enormous disparity of information, and no clear conclusion can be drawn regarding the diagnosis

or treatment of traumatic celiac dissection with two exceptions. First, the natural history of celiac dissection does not favor spontaneous resolution of the lesion. Second, there is obvious potential for endovascular surgical treatment of celiac dissection to improve outcomes.

Comments and future research

It is unlikely, given the rarity of this injury, that any prospective research will be practicable to compare treatment modality. Given the increasing prevalence of both endovascular trauma surgery and non-traumatic visceral endovascular intervention, however, it is likely that in the near future retrospective analyses of patency, morbidity and mortality of endovascular surgery for acute celiac pathology will be possible.

i Related important publications

Katsuura Y, Osborn JM, Cason GW. The epidemiology of thoracolumbar trauma: A meta-analysis. *J Orthop.* 2016 Jul 21;13(4):383-8.

ARTICLE NUMBER 2

Endovascular management of arterial injuries after blunt or iatrogenic renal trauma.

Quant Imaging Med Surg. 2017 Aug;7(4):434-442.

Loffroy R, Chevallier O, Gehin S, Midulla M, Berthod PE, Galland C, Briche P, Duperron C, Majbri N, Mousson C, Falvo N.

Abstract

The kidney is the third most common abdominal organ to be injured in trauma, following the spleen and liver, respectively. The most commonly used classification scheme is the American Association for the Surgery of Trauma (AAST) classification of blunt renal injuries, which grades renal injury according to the size of laceration and its proximity to the renal hilum. Arteriovenous fistula and pseudoaneurysm are the most common iatrogenic biopsy-related or surgery-related vascular injuries in native kidneys. The approach to renal artery injuries has changed over time from more aggressive intervention to more conservative observational or endovascular management, including selective transcatheter arterial embolization (TAE) and the placement of stents/stent grafts. In this article, we describe the role and technical aspects of endovascular interventions in the management of arterial injuries after blunt or iatrogenic renal trauma.

Article review and analysis

Aim of this study: To describe the general principles and technical considerations of renal artery injuries, including those that involve more distal hilar or even parenchymal lesions.

Methods

Pros: This primer is an excellent overview of the role of endovascular surgery for renal artery trauma. It reviews the AAST grading system and, uniquely, describes endovascular intervention for parenchymal and hilar vascular injury as being conceptually contiguous with treatment of traumatic disruption of the main renal artery. This primer is divided into sections on general technical considerations, treatment of blunt renovascular injury, treatment of iatrogenic renovascular injury, and expected complications. The technical considerations section includes a brief discussion of embolization materials focusing on the appropriate use of liquid embolic agents, a modality often overlooked by the endovascular trauma surgeon.

Discussion of iatrogenic renovascular injuries is extremely valuable. The phenomenon of inadvertent renal injury during spinal fixation, percutaneous nephrostomy, or image-guided abscess drainage is well-known to most trauma surgeons, and Loffroy et al. perform admirably in their description of such injuries in their acute and post-acute

phases, when sequelae such as arteriourinary fistulae can present, and which are less intuitively amenable to endovascular therapy.

Explication of complications of endovascular treatment of renal artery injury is brief but comprehensive. The endovascular trauma surgeon is undoubtedly aware of contrast-induced nephropathy and unintentional embolization ischemia; less familiar are the transient but normal hematuria following embolization and the risk of recrudescence of latent urinary tract infection.

Cons: As a narrative introduction, there is little in the way of data demonstrating the efficacy of endovascular intervention for these injuries, and certainly little comparing the various treatment modalities.

Results, conclusion, and what it means

This is an article meant as an introduction to endovascular surgery for renal artery trauma, and is valuable insofar as it does introduce topics that are worth further investigation, but it is not comprehensive. This is more appropriate for the general trauma community as an explanation of what endovascular trauma surgery is capable of with regard to renal artery trauma, but the endovascular practitioner will need a more detailed discussion before venturing into renal territory.

Comments and future research

The framework of this article is excellent, and the structure allows a logical and seamless transition from topic to topic. This would be easily expanded to a comprehensive guide for the practitioner while retaining the same flow and ease of reading.

ARTICLE NUMBER 3

Multidisciplinary Management of Blunt Renal Artery Injury with Endovascular Therapy in the Setting of Polytrauma: A Case Report and Review of the Literature.

Ann Vasc Surg. 2017 Jan;38:318.e11-318.e16.

Beyer C, Zakaluzny S, Humphries M, Shatz D.

Abstract

Background: Injury to the renal artery is a rare but serious concern in patients suffering blunt trauma. Complications of renovascular injury include prolonged hospitalization, kidney loss, and death. There remains considerable controversy regarding the optimal treatment of blunt renal artery injury.

Methods: We describe the management of a 39-year-old woman following blunt polytrauma who underwent a multidisciplinary collaborative procedure with open splenectomy and endovascular repair of an occluded renal artery. A literature review of the past 25 years follows including all publications describing endovascular treatment for blunt renal artery injury.

Results: The literature search identified 27 patients with blunt renal artery injury treated by endovascular means. All patients were treated with angioplasty and stenting; none were treated with angioplasty alone. One patient (4%) required nephrectomy for hypertension and 89% of patients were reported to be in good condition at their last contact with the healthcare system.

Conclusion: The optimal treatment of blunt injury to the renal artery is unknown, but endovascular therapy is a feasible and reasonable choice. Further study is warranted to delineate the appropriate role for endovascular treatment as a component of a multidisciplinary approach to the care of trauma patients with blunt renal artery injury.

Article review and analysis

Aim of this study: Renal artery injury is a rare occurrence in blunt trauma with a natural history that can lead anywhere from spontaneous resolution to death. The optimal treatment of blunt renal artery injury remains unclear, with historical options including nephrectomy, open vascular repair, or observation. The advent of endovascular surgery has added another possibility, theoretically offering the benefits of vascular repair without the morbidity of open surgery and renal ischemia; however, the effectiveness of this approach has not been definitively established. This article attempts to address, simply, if endovascular surgery is an appropriate method of addressing renal artery injury.

Methods

Pros: This paper begins with a case report and uses that incident as an introduction to a more thorough literature review encompassing publications between 1990 and 2015.

The literature search resulted in a pooled review of 27 cases with a relatively narrow interval from time of injury to endovascular reperfusion, with a mean time of 7 hours. More than half of the patients presented with total occlusion of the renal artery, and all underwent stenting. Two patients underwent bailout embolization for hemorrhage, which was either iatrogenic or occult.

Follow-up was excellent and outcomes were reported using a variety of measures. The most frequent modality was radioisotope scintigraphy, which is the gold standard for functional renal imaging. Clinically, one patient underwent nephrectomy for hypertension, an underappreciated longer-term sequela of renal artery stenosis.

Cons: As with any literature review and pooled analysis, there is considerable heterogeneity in data. Moreover, no control is available for comparison. There is no discussion of a current area of debate, namely the type of stent most appropriate for this injury.

Results, conclusion, and what it means

While this literature review includes only 27 patients, its value is substantial considering that the definitive modern description of renovascular injury and its treatment, Knudson et al., included only 89 patients. In that article, patients were treated with open repair or observation, and a third suffered adverse outcomes at rates in line with those reported in this literature review. The two cohorts cannot be directly compared, of course, but it is reasonable to conclude that the outcomes are not severely discrepant. A comparable review was performed by Jahangiri et al. in the interventional radiology literature, but was focused on prolonged ischemia, with a time-to-intervention ranging from two hours to 25 days after injury.

Comments and future research

It is, based on this article and conventional practice, reasonable to pursue endovascular surgical treatment of renal artery injury. Questions regarding subsequent medical therapy, surveillance, and optimal timing of treatment remain unanswered. The rarity of blunt renal artery injury makes conclusive prospective evidence unlikely, but existing registries have the potential for yielding data in the years to come.

Related important publications

Knudson MM, Harrison PB, Hoyt DB, Shatz DV, Zietlow SP, Bergstein JM, Mario LA, McAninch JW. Outcome after major renovascular injuries: a Western trauma association multicenter report. *J Trauma*. 2000 Dec;49(6):1116-22.

Jahangiri Y, Ashwell Z, Farsad K. Percutaneous renal artery revascularization after prolonged ischemia secondary to blunt trauma: pooled cohort analysis. *Diagn Interv Radiol*. 2017 Sep-Oct;23(5):371-378.

ARTICLE NUMBER 4

Traumatic occlusion and dissection of the main renal artery: endovascular treatment.

J Vasc Interv Radiol. 2011 Nov;22(11):1570-4.

Lopera JE, Suri R, Kroma G, Gadani S, Dolmatch B.

Abstract

Purpose: To report experience with endovascular treatment of traumatic injuries of the main renal artery.

Materials and methods: A retrospective review of traumatic injuries to the main renal artery was performed in three major trauma institutions. Eight patients (age range, 17-46 y; mean age, 27 y) presented with main renal artery occlusion (n = 7) or dissection (n = 1) after major blunt abdominal trauma. Associated injuries were present in the majority of patients. The mean time from injury to intervention was 5 hours (range, 2-8 h).

Results: Recanalization of the occluded renal artery with stent placement was successfully achieved in six patients. In two of the eight patients, interventions resulted in extravasation of contrast medium, and embolization of the main renal artery was performed. At follow-up 2-24 months after injury, four patients had kidney atrophy (two treated with embolization and two with stents), two had proven stent patency with functional kidneys, one was normotensive with unknown stent patency, and one was lost to follow-up. One of the patients with an occluded stent developed severe renal hypertension and required nephrectomy.

Conclusions: The majority of occlusions and dissections of the main renal artery after major blunt abdominal trauma can be successfully treated with recanalization and stent placement. However, long-term kidney salvage is not always achieved, and there is a potential of development of renovascular hypertension, which may require late nephrectomy.

Article review and analysis

Aim of this study: Renal artery transection is not uncommon following severe torso trauma and presents with both bleeding and thrombotic concerns. Historically, open surgical treatment was often accompanied by the need for nephrectomy during vascular exposure. Endovascular treatment offers the potential benefit of renal salvage, but there is limited data available regarding real-world outcomes.

Methods

Pros: Despite including only 8 patients, this represents one of the largest published series available describing outcomes after endovascular treatment of renal artery injury. It pulls data from three trauma centers, allowing for a meaningful real-world

description of the intervention.

Cons: The method of intervention was left to the discretion of the treating physician, with two patients requiring embolization of the main renal artery instead of placement of a stent graft for post-recanalization hemorrhage control. There are no specified guidelines or care pathways proposed, which implies a high degree of pre-procedural selection bias. The range of follow-up availability is broad, ranging from 2-24 months.

Results, conclusion, and what it means

Endovascular therapy for main renal artery transection may be technically feasible in selected patients. Providers should be prepared for post-recanalization hemorrhage, with a variety of covered stent options on-hand to exclude the resultant pseudoaneurysm. Alternatively, covered stents should be considered as the intervention of choice in these patients as opposed to the bare metal strategy described here.

Comments and future research

Further studies are needed describing meaningful mid- and long-term outcomes following endovascular repair of renal artery injury. What imaging surveillance is suggested? What are the indications for re-intervention? What is the real rate of renovascular hypertension and what lessons can we learn to mitigate that risk? This remains a low-incidence injury; larger data sets through the use of multicenter trauma registries will be necessary in order to provide meaningful conclusions.

ARTICLE NUMBER 5

Endovascular treatment of superior mesenteric artery pseudoaneurysms using covered stents in six patients.

AJR Am J Roentgenol. 2014 Aug;203(2):432-8.

Kim SK, Lee J, Duncan JR, Picus DD, Darcy MD, Sauk S.

Abstract

Objective: The objective of our study was to evaluate our experience with the use of endovascular treatments for superior mesenteric artery (SMA) pseudoaneurysms using covered stents.

Materials and methods: Between 2002 and 2011, six patients (mean age, 41.7 years; range, 23-65 years) with SMA pseudoaneurysms were treated percutaneously with the placement of covered stents at our institution. The causes of SMA pseudoaneurysms were penetrating trauma ($n = 2$), blunt trauma ($n = 1$), and previous surgical procedures ($n = 3$). The mean diameter of the SMA pseudoaneurysms was 16 mm (range, 4-24 mm). Technical success and clinical success were retrospectively analyzed.

Results: Immediate technical success, defined as exclusion of the pseudoaneurysm and lack of active extravasation, was achieved in all six patients. Secondary balloon angioplasty was needed in one patient with residual narrowing. There was a small dissection of the proximal SMA necessitating placement of a second bare stent across the dissection. A second covered stent (Fluency stent, 8 mm) was placed in the same patient because of recurrent bleeding due to a type II endoleak 5 days after the first covered stent had been placed. This patient had no subsequent episodes of bleeding or bowel ischemia. Follow-up CT in the remaining five patients (mean, 21 months; range, 1-58 months) confirmed stent patency and preserved distal arterial flow to the bowel without episodes of bleeding or bowel ischemia during follow-up (mean, 27 months; range, 11-58 months).

Conclusion: Percutaneous endovascular treatment using a covered stent may be a safe and feasible tool for SMA pseudoaneurysms.

Article review and analysis

Aim of this study: This single-center retrospective analysis was designed to evaluate the efficacy of covered stent grafts in the management of SMA pseudoaneurysms. Six patients were identified, of which half suffered conventional trauma; the other 3 injuries were iatrogenic in nature.

Methods

Pros: Again, this represents one of the largest series available describing outcomes after endovascular treatment of visceral arterial trauma. Despite the unavoidable selection bias, there is reasonable consistency in the technical repairs undertaken. The

outcomes are as expected – endovascular therapy is technically feasible with good short-term outcomes.

Cons: SMA injuries are never treated in isolation. There is limited data provided regarding the status of the small bowel in these cases. Additionally, there is a wide variety in the availability of follow-up data ranging from 1-58 months. In this potentially young cohort of patients, extended duration follow-up would be particularly helpful to evaluate the long-term risk of chronic gastrointestinal problems.

Results, conclusion, and what it means

Endovascular repair of large visceral arterial trauma seems technically feasible. When compared to celiac and renal arteries, management of the SMA may be more technically demanding due to the importance of large jejunal branches in maintaining bowel perfusion. Bare metal stents may play a role in preserving side branch flow, but they are not evaluated in the present study.

Comments and future research

Again, long-term data is not currently available for this patient population. Recommendations for surveillance and anti-platelet therapy are based completely on non-trauma indications for mesenteric stenting and may not be applicable in a younger patient population. Additionally, the difference in outcomes between covered and uncovered stents has not been fully addressed.

CHAPTER 13a.

Endovascular treatment of peripheral arterial injuries in trauma

Authors: *Young Kim, Zachary M. Feldman, Anahita Dua*

Introduction

Peripheral arterial injuries are common after both blunt and penetrating trauma. The open surgical approach is still considered the “gold standard” in many institutions, despite its many drawbacks. These include the morbidity of open exposure, the technical difficulty of vascular control, and the prolonged time to revascularization. Endovascular treatment options, on the other hand, provide a rapid and minimally invasive approach to peripheral vascular trauma. Despite these attractive features, the role of endovascular surgery in these circumstances remains to be established.

Over the past decade, endovascular surgery has grown substantially in the treatment of peripheral vascular trauma. The endovascular approach has even been promoted as a first-line treatment option for certain injury patterns. In this chapter, we present five articles investigating the feasibility and outcomes of endovascular treatment of peripheral vascular trauma.

ARTICLE NUMBER 1

Four-year outcomes following endovascular repair in patients with traumatic isolated popliteal artery injuries.

J Vasc Surg. 2021 Mar 1;50(4):e1-5214(20)32597-0. PMID 33340706.
Chuli Jiang, Zheng Chen, Yu Zhao, Wayne W Zhang, Qiu Zeng, Fenghe Li

Abstract

Objective: The effectiveness of endovascular treatment for popliteal arterial injury has not been well-documented. This study was aimed to investigate the midterm outcomes of endovascular repair of traumatic isolated popliteal arterial injury.

Methods: Medical records of the patients who underwent endovascular repair for traumatic popliteal arterial injuries from January 2012 to February 2020 were reviewed retrospectively. Clinical data including patient demographics, Injury Severity Score, type of injury, classification of acute limb ischemia, concomitant extremity fracture, runoff vessel status, complications, time of endovascular procedure, time interval from injury to blood flow restoration, length of hospital stay, reintervention, and follow-up were collected and analyzed.

Results: Endovascular repair was performed in 46 patients with traumatic popliteal arterial injuries. The mean Injury Severity Score was 15.8 ± 6.2 . The overall limb salvage rate was 89.1%. There were 10 penetrating and 36 blunt injuries (78.3%). The initial angiographic findings revealed occlusion in 34 patients (73.9%), pseudoaneurysm in 2 (4.4%), active extravasation in 9 (19.5%), and arteriovenous fistulas in 1 (2.2%). Technical success was achieved in all 46 patients, via antegrade access in 24 patients (52.2%) and concurrent retrograde access in 22 (47.8%). The mean time interval from popliteal artery injury to blood flow restoration was 10.6 ± 4.9 hours and mean operative time was of 54.9 ± 10.0 minutes. The mean follow-up was 36.1 ± 14.5 months. The primary patency rate was 75.3% at 12 months, 61.9% at 24 months, and 55.7% at 48 months. The secondary patency rate was 92.2% at 12 and 24 months and 85.2% at 48 months. A Cox multivariate analysis revealed that single vessel runoff was an independent risk factor for primary patency loss.

Conclusions: Endovascular repair of an isolated popliteal artery injury may be a safe and effective alternative treatment in select patients, with acceptable midterm outcomes. Single vessel runoff was an independent risk factor for primary patency loss.

Article review and analysis

Aim of this study: The popliteal artery is the second most commonly injured artery in the infrainguinal location, comprising 21% of all extremity arterial injuries. Approximately 50% of popliteal artery injuries result in amputation, due to prolonged ischemia. Endovascular management of popliteal trauma remains an attractive option given its rapid and minimally invasive characteristics; however, the endovascular approach has

mostly been limited to case reports. This study provides midterm outcomes for isolated popliteal artery injuries managed through endovascular covered stenting.

Methods

Pros: This article is a retrospective chart review from a tertiary care center for all patients with isolated traumatic popliteal artery injury from 2012 to 2020. Demographic data and operative and angiographic details are reported in this analysis. Midterm outcomes were collected for all patients, with a mean follow-up period of 36.1 months.

Cons: This study has three limitations. First, this is a retrospective investigation and may be subject to selection bias. Second, sample sizes are small, including ten penetrating and 36 blunt injuries. Third, these results are collected from a single, tertiary referral center, and may not be applicable to a community hospital setting.

Results, conclusions, and what does it mean

This is the largest series on endovascular treatment of isolated popliteal artery injuries to date. While previous case series have described successful stenting of popliteal injuries, this report provides a larger patient cohort, along with operative details and midterm outcomes. Apart from the five patients who underwent amputation owing to class III acute limb ischemia and prolonged time to revascularization, all patients had limb salvage during the four-year follow-up period. Technical success was achieved in all patients at initial endovascular intervention with an acceptable reintervention rate (32.6%) for stent thrombosis or in-folding. This article provides further evidence for endovascular treatment of isolated popliteal artery trauma.

Comments and future research

The need for dual antiplatelet therapy limits endovascular stenting in patients with multisystem trauma. Future investigation should focus on which subset of patients with polytrauma may undergo endovascular stenting as opposed to an open operation. Other studies are needed to compare open versus endovascular management of popliteal artery injury, and the long-term consequences of each approach.

i Related important publications

Anahita Dua, Sapan S Desai, Jaecel O Shah, Robert E Lasky, Kristofer M Charlton-Ouw, Ali Azizzadeh, Anthony L Estrera, Hazim J Safi, Sheila M Coogan. Outcome predictors of limb salvage in traumatic popliteal artery injury. Ann Vasc Surg. 2014 Jan;28(1):108-14. PMID 24332260.

ARTICLE NUMBER 2

Outcome comparison between open and endovascular management of axillosubclavian arterial injuries.

J Vasc Surg. 2016 Mar;63(3):702-9. PMID 26506937.

Bernardino C Branco, Mina L Boutrous, Joseph J DuBose, Samuel S Leake, Kristopher Charlton-Ouw, Peter Rhee, Joseph L Mills Sr, Ali Azizzadeh

Abstract

Background: Endovascular repair (ER) of axillosubclavian arterial injuries is a minimally invasive alternative to open repair (OR). The purpose of this study was to compare the outcomes of ER vs OR.

Methods: A retrospective study was performed of patients who sustained axillosubclavian arterial injuries admitted to two high-volume academic trauma centers between 2003 and 2013. Patients undergoing ER and OR were matched according to 25 different demographic and clinical variables in a 1:3 ratio using propensity scores. The primary outcome was in-hospital mortality. Secondary outcomes were complications and length of stay.

Results: Among 153 patients (79.7% male; mean age, 32.7 ± 15.9 years) who sustained axillosubclavian arterial injuries, 18 (11.8%) underwent ER and 135 (88.2%) had OR. Matched cases (ER, n = 18) and controls (OR, n = 54) had similar demographic and clinical data, such as age, gender, admission systolic blood pressure and Glasgow Coma Scale score, body Abbreviated Injury Scale scores, Injury Severity Score, and transfusion requirements. Patients undergoing ER had significantly lower in-hospital mortality compared with patients undergoing OR (5.6% vs 27.8%; P = .040; odds ratio, 0.7; 95% confidence interval, 0.6-0.9). Similarly, patients undergoing ER had substantially lower rates of surgical site infections and a trend toward lower rates of sepsis. Outpatient follow-up was available in 88.2% (n = 15) of the patients at a median time of 8 months (1-30 months). Two ER patients required open reintervention for stent-related complications (one for a type Ia endoleak and another for stent thrombosis).

Conclusions: In our experience with axillosubclavian arterial injuries, ER was associated with improved mortality and lower complication rates. Patient follow-up demonstrates an acceptable reintervention rate after ER. Further multicenter prospective evaluation is warranted to determine long-term outcomes.

Article review and analysis

Aim of this study: Axillosubclavian arterial injuries are associated with significant morbidity and mortality. Moreover, these injuries are frequently associated with injury to adjacent structures. The open operative approach has been the traditional “gold standard”; however, the surgical exposure of these vessels is technically difficult and

associated with poor outcomes. This novel study compares outcomes between the open and endovascular approaches to traumatic axillosubclavian injury.

Methods

Pros: This retrospective study is the largest study to date comparing open to endovascular repair of axillosubclavian injuries. The most significant pro of this study is the long study period, which spanned 11 years, and included a total of 153 patients with a similar injury pattern who ultimately underwent open or endovascular treatment. Data were collected from trauma registries at three separate Level I trauma centers. Propensity score matching in a 1:3 ratio was utilized to compare outcomes between open and endovascular groups, while controlling for patient-related factors. Finally, prior to this study, only three small series were available comparing outcomes between endovascular and open repair of axillosubclavian injuries, which were all much smaller in their patient cohorts.

Cons: This study is significantly limited by a short follow-up period (median 8 months) and retrospective analysis. While propensity score matching allowed for comparison between groups, this methodology resulted in the exclusion of over 60% of the open repair population. While all patients with axillosubclavian injury were included, this is a heterogenous group of injuries. For instance, left subclavian, left axillary, right subclavian, and right axillary artery injuries were all grouped together when in practice, these injuries are approached differently. Moreover, exclusion criteria also resulted in the removal of several groups, including patients younger than 16 years old (n=32), patients undergoing resuscitative thoracotomy (n=26), and patients who were ultimately managed nonoperatively (n=23). Therefore, results of this study cannot be expanded to include these three groups. Finally, details regarding postoperative antiplatelet and anticoagulant therapy were inconsistent and were not accounted for in this investigation.

Results, conclusions, and what does it mean

Compared with open repair, patients who underwent endovascular repair of axillosubclavian injury had lower rates of in-hospital mortality and wound infection. At a median follow-up period of 8 months, two of 18 patients with endovascular stenting required open reintervention for stent-related complications. These outcomes are promising and argue for an endovascular-first approach to axillosubclavian trauma where clinically appropriate.

Comments and future research

Randomized controlled trials may be logistically impossible given the emergency of axillosubclavian trauma and the rarity of this injury pattern. Future investigation should, therefore, focus on long-term rates of stent-related complications and reintervention among patients treated with endovascular surgery.

i Related important publications

Joseph J DuBose, Ravi Rajani, Ramy Gilani, Zachary A Arthurs, Jonathan J Morrison, William D Clouse, Todd E Rasmussen, Endovascular Skills for Trauma and Resuscitative Surgery Working Group. Endovascular management of axillo-subclavian arterial injury: a review of published experience. *Injury*. 2012 Nov;43(11):1785-92. PMID 22921384.

ARTICLE NUMBER 3

Modern management of traumatic subclavian artery injuries: a single institution’s experience in the evolution of endovascular repair.

Am J Surg. 2010 Jan;199(1):28-34. PMID 19520356.
Matthew M Carrick, C Anne Morrison, Hoang Q Pham, Michael A Norman, Blake Marvin, Jeffery Lee, Matthew J Wall Jr, Kenneth L Mattox

Abstract

Background: Subclavian artery injuries traditionally require morbid surgical procedures. Repair by way of an endovascular approach can potentially decrease the morbidity and mortality associated with these injuries.

Methods: A 2-year retrospective review of trauma patients with subclavian artery injuries was performed at our institution. Relevant data were extracted from patient records and analyzed. These results were then used to develop an algorithm for the management of trauma patients with subclavian artery injuries.

Results: Fifteen patients with subclavian artery injuries were identified. Five patients died in the emergency room. Of the 10 surviving patients, 8 had their diagnosis made at arteriogram. Six patients underwent endovascular repair, and 4 of these repairs were successful. Three patients were managed by way of open repair. Two deaths occurred in the endovascular group, and 1 death occurred in the open group.

Conclusions: Our findings suggest that endovascular management of subclavian artery injuries is an acceptable technique in appropriate candidates and compares favorably with open repair. However, as with open repair, the associated morbidity and mortality remains quite high. We propose an algorithm whereby hemodynamically stable patients with hard signs of vascular injury proceed directly to angiography, whereas open repair is reserved for those patients who are unstable or in whom a catheter-based approach has previously failed.

Article review and analysis

Aim of this study: Subclavian artery injury is often fatal. For those who survive long enough for trauma evaluation, open surgical repair options are associated with significant morbidity. This retrospective analysis reviewed all patients who presented with subclavian artery injury at a single Level I trauma center. Not surprisingly, one-third of the patient cohort died in the emergency room, with their injury diagnosed on post-mortem autopsy. Of the remaining ten patients, six underwent endovascular repair. This case series describes outcomes after endovascular treatment and proposes a treatment algorithm for patients presenting with traumatic subclavian artery injury.

Methods

Pros: This article provides a detailed case series on patients who were treated with endovascular repair for subclavian artery injury. This series provides very granular data on operative approach and short-term outcomes given its single-center nature. The technical considerations are detailed in a separate table, and include details of endovascular access site, type of repair, stent and sheath size, and outcomes after repair. Angiographic images are also provided in the study, in addition to each technical detail of the operative approach. Among patients with an unsuccessful repair, reasons for technical failure are also described. Finally, the authors provide an algorithm for their institutional approach to subclavian artery trauma, based on their experiences.

Cons: This is largely a descriptive case series of 15 patients, of which only 10 survived initial assessment and six underwent endovascular repair. Each patient suffered a unique burden of traumatic injury (see Table 2 in paper), which makes it difficult to group all patients together into a single group given wide variability in injury patterns. Within the subclavian injuries themselves, there is variability in whether the left or right artery was injured, whether the injury was proximal or distal within the artery itself, and whether a blunt or penetrating mechanism was responsible. In practice, there are many differences in the approach to each variation of subclavian artery injury listed above (for instance, exposure of left versus right subclavian artery). In addition to a small sample size, there are no long-term outcomes among surviving patients. Finally, the management algorithm is prudent, but not supported by substantial evidence.

Results, conclusions, and what does it mean

The authors describe their experience of endovascular treatment of subclavian artery injury. As is the nature of subclavian trauma, a third of the patients succumbed to their injury burden prior to surgical intervention. Among those who survived long enough to transport to the endovascular suite, six patients underwent attempted intervention. The injuries included three penetrating right subclavian injuries, two blunt left subclavian injuries, and one penetrating left subclavian injury. Three of six patients had successful repair of their injuries. Two of these six patients succumbed to their injuries, resulting from one pulmonary embolism and one massive head injury, which were unrelated to the subclavian injury itself. These poor outcomes are evidence that patients with subclavian artery injury often present in extremis, and with a large burden of other injuries. Two other patients were managed nonoperatively, including one penetrating right and one penetrating left subclavian injury, with both patients surviving their injury pattern as a result of these findings being asymptomatic and non-flow-limiting injuries. In light of these circumstances, the authors were successful in treating traumatic subclavian artery injury with endovascular surgery in three patients, supporting the feasibility of this approach.

Comments and future research

Future studies should focus on validating this management algorithm in a prospective analysis.

i Related important publications

Sherene Shalhub, Benjamin W Starnes, Thomas S Hatsukami, Riyad Karmy-Jones, Nam T Tran. Repair of blunt thoracic outlet arterial injuries: an evolution from open to endovascular approach. J Trauma. 2011 Nov;71(5):E114-21. PMID 22071946.

ARTICLE NUMBER 4

Trends and outcomes of endovascular therapy in the management of civilian vascular injuries.

J Vasc Surg. 2014 Nov;60(5):1297-1307. PMID 24974784.

Bernardino C Branco, Joseph J DuBose, Luke X Zhan, John D Hughes, Kay R Goshima, Peter Rhee, Joseph L Mills Sr

Abstract

Objective: The rapid evolution of endovascular surgery has greatly expanded management options for a wide variety of vascular diseases. Endovascular therapy provides a less invasive alternative to open surgery for critically ill patients who have sustained arterial injuries. The purpose of this study was to evaluate recent trends in the management of arterial injuries in the United States with specific reference to the use of endovascular strategies and to examine the outcomes of endovascular vs open therapy for the treatment of civilian arterial traumatic injuries.

Methods: A 9-year analysis of the National Trauma Data Bank was performed to identify all patients who sustained arterial injuries. Demographics, clinical data, interventions, and outcomes were extracted. Propensity scores were used to match endovascular patients to those undergoing open operation. Patient outcomes were compared according to treatment approach.

Results: A total of 23,105 patients were available for analysis. Overall, there was a significant increase in the use of endovascular procedures during 9 years (from 0.3% in 2002 to 9.0% in 2010; $P < .001$), particularly among blunt trauma patients (from 0.4% in 2002 to 13.2% in 2010; $P < .001$). This increase was noteworthy and dramatic for injuries of the internal iliac artery (from 8.0% in 2002 to 40.3% in 2010; $P < .001$), thoracic aorta (from 0.5% in 2002 to 21.9% in 2010; $P < .001$), and common/external iliac arteries (from 0.4% in 2002 to 20.4% in 2010; $P < .001$). A significant decrease was noted for open procedures (49.1% in 2002 to 45.6%; $P < .001$), especially for blunt trauma (42.9% in 2002 to 35.8% in 2010; $P < .001$). There was a stepwise increase in the proportion of patients managed by endovascular therapy as the Injury Severity Score increased (highest in the spectrum Injury Severity Score 31-50). When outcomes were compared between matched patients who underwent endovascular and open procedures, patients who underwent endovascular procedures had significantly lower in-hospital mortality (12.9% vs 22.4%; odds ratio, 0.5; 95% confidence interval, 0.4-0.6; $P < .001$). Endovascular patients also had decreased rates of sepsis (7.5% vs 5.4%; odds ratio, 0.7; 95% confidence interval, 0.5-0.9; $P = .025$).

Conclusions: The use of endovascular therapy in the United States has increased dramatically during the last decade, in particular among severely injured blunt trauma patients. Endovascular therapy was associated with improved in-hospital mortality and lower rates of sepsis.

Article review and analysis

Aim of this study: While open surgery has been the traditional “gold standard” for the treatment of vascular trauma, the utilization of endovascular therapy has increased dramatically over the past decade. This study aims to describe national trends in the treatment approach (open vs endovascular) in the management of vascular trauma.

Methods

Pros: This is a nine-year analysis of the National Trauma Data Bank (NTDB), which is a national registry of injured patients across 1205 trauma centers. The NTDB includes detailed information about injury patterns, hospital events (e.g., infection, stroke, DVT), and patient outcomes (e.g., mortality, hospital and ICU length of stay). A total of 23,105 patients underwent open or endovascular repair during the study period, making this the largest study to date comparing endovascular and open approaches to vascular trauma. Propensity score matching with binary logistic regression was utilized to compare outcomes between the two groups. Management trends over the nine-year study period (from 2002 to 2010) are portrayed in easy-to-interpret figures, noting obvious increases in endovascular management of both blunt and penetrating injury patterns, and concomitant decrease in open repair of blunt injuries. Trends in non-operative management have remained similar in both injury types. The ability to monitor these trends over time is only possible with a large database, such as the NTDB.

Cons: Of the nearly 4 million patients included in the NTDB from 2002 to 2010, only 19,693 underwent open surgery and 2570 underwent endovascular surgery for vascular trauma. The NTDB relies on accurate capturing and coding of these injuries, and any patients who succumb to their injuries prior to presenting to the ED are not included. Moreover, in order to perform 1:1 propensity score matching between these two cohorts, over 90% of the original study population were excluded from the analysis. This included 41,328 patients with “unspecified” vascular injury, “undifferentiated” vascular injury, and isolated venous injury. This remains an observational study, with obvious trends in increasing use of endovascular therapy and decrease in mortality. However, it is difficult to link these two trends together given that trauma care has been constantly improving, especially over the study period of 2002 to 2010. Finally, there are significant confounding variables, even with the use of propensity score matching.

Results, conclusions, and what does it mean

In this longitudinal study covering the period 2002 to 2010, the use of endovascular procedures expanded dramatically from 0.3% (2002) to 9.0% (2010) in the treatment of vascular trauma. This increase was most noteworthy in the treatment of common/external iliac artery injuries, increasing from 0.4% to 20.4% during the study period. Other areas of endovascular expansion included treatment of hypogastric and thoracic aortic injuries (likely representing the adoption of TEVAR as the gold standard). Notably, after propensity score matching, patients who underwent endovascular

treatment had lower in-hospital mortality rates. The endovascular group were more likely to be discharged home and less likely to require mechanical ventilation, compared to the open surgery cohort. Endovascular patients also had lower rates of sepsis compared to those undergoing open repair. Outcomes that were not significantly different between the two groups included the following – acute renal failure, compartment syndrome, upper or lower extremity amputation, surgical site infection, pneumonia, or ARDS. These results favor an endovascular approach to civilian vascular trauma where clinically appropriate.

Comments and future research

The present study delineates national trends in the adoption and utilization of endovascular surgery for the treatment of vascular trauma. Given the establishment of the NTDB at trauma centers across the United States, it would be interesting to see an updated analysis on the usage of endovascular techniques from 2011 and onwards.

i Related important publications

Jigarkumar A Patel, Joseph M White, Paul W White, Norman M Rich, Todd E Rasmussen.
A contemporary, 7-year analysis of vascular injury from the war in Afghanistan. J Vasc Surg. 2018 Dec;68(6):1872-1879. PMID 29945835.

ARTICLE NUMBER 5

**Endovascular management for peripheral arterial trauma:
The new norm?**

*Injury. 2017 May;48(5):1025-1030. PMID 28193445.
Anand Ganapathy, Ahmed F Khouqeer, S Robb Todd, Joseph L Mills Sr, Ramyar Gilani*

Abstract

Background: Endovascular therapy is well studied in atraumatic conditions; and there appears to be a growing interest in its application to traumatic injuries. The objective of this study is to compare open and endovascular techniques in the management of peripheral arterial trauma.

Methods: This is a retrospective review of patients admitted to a Level I Trauma Center sustaining injuries to the subclavian, axillary, superficial femoral, and popliteal arteries. Demographics, surgical interventions, complications, and clinical outcomes were evaluated in patients requiring open or endovascular repair between 2009 and 2015.

Results: Sixty-eight patients with 70 total arterial injuries were identified. There were 10 subclavian, 14 axillary, 15 superficial femoral, and 31 popliteal artery injuries. Endovascular (n=20) compared to open repairs (n=50) were more commonly performed: by vascular surgeons (90% vs. 54%, p=0.01); in older patients (median age: 38 years vs. 25, p=0.01); primarily involving upper extremity injuries (60% vs. 24%, p=0.01). Furthermore, endovascular repairs less commonly required fasciotomy (15% vs. 46%, p=0.03) and trended towards lower transfusion requirements (50% vs. 77%, p=0.06). Patients undergoing open repair had lower pre-hospital systolic blood pressures (110 vs. 120, p=0.03) and lower initial hematocrit (31.5 vs. 36.2, p=0.02). However, outcomes between groups were trending higher in the endovascular group with respect to limb salvage rates at discharge (94% vs. 89%), median length of stay (14days vs. 9), and median follow-up (288 days vs. 92) compared to the open group, but the data were not statistically significant. There was increasing utilization of endovascular repair over time (7% of total procedures in 2009; 50% in 2014).

Conclusions: Overall, endovascular and open techniques were not statistically different in early outcomes. Endovascular therapy appears to provide some advantage when it comes to: challenging anatomy, decreasing blood product utilization, and minimizing physiologic derangement. However, patients with injuries resulting in free hemorrhage or significant external blood loss may still be best served with open repair. Despite this, given the increasing use of endovascular techniques, close collaboration is needed between trauma and endovascular specialists to properly select the optimal management for patients with peripheral arterial trauma.

Article review and analysis

Aim of this study: Open surgical repair is the standard of care for treatment of peripheral vascular trauma. While endovascular options have gained popularity in the treatment of non-traumatic vascular diseases over the past two decades, it has been slow to gain traction in the treatment of traumatic injuries. The reasons for this are twofold. First, the utilization of endovascular therapy in trauma has been limited to several case reports and series until recent years. Second, traumatic injury is managed primarily by surgeons who may or may not have endovascular training. This study reports a single-center experience in the management of peripheral vascular trauma utilizing both open and endovascular techniques, and compares short-term outcomes between the two cohorts.

Methods

Pros: This article describes a high-volume Level I trauma center which has extensive experience in patients with polytrauma (approximately 23,000 patients from 2009 to 2015). Of these, 68 patients with 70 peripheral vascular injuries met inclusion criteria. These injuries were evenly spread amongst peripheral arterial beds, and included 10 subclavian, 14 axillary, 15 superficial femoral, and 31 popliteal injuries. This distribution of injury patterns is representative of the types of injuries that are encountered at many Level I trauma centers.

Cons: This is a single-center experience at a Level I trauma center with physicians trained in endovascular surgery. Therefore, these results may not be applicable to community hospitals or centers without physicians trained in trauma and endovascular techniques. The small sample size (68 patients) also limits the statistical analysis of the study, as does the short follow-up period for patients undergoing endovascular treatment. There is an uneven distribution in the two cohorts, with open repair (n=50) outweighing endovascular repair (n=20). Patients undergoing open repair were more likely to be in hemorrhagic shock, as evidenced by lower pre-hospital systolic blood pressures and hematocrit, making direct comparison between the two groups difficult. The authors noted that patients undergoing endovascular repair had lower transfusion requirements and lower fasciotomy rates; however, this may be a result of the severity of the injury burden rather than the open/endovascular approach itself.

Results, conclusions, and what does it mean

Among the 275 patients identified with traumatic vascular injury from 2009 to 2015, 68 patients with a total of 70 injuries met the inclusion criteria. Altogether, the majority of injuries were repaired via an open surgical approach. Patients undergoing an open approach were more likely to have physiologic parameters indicative of greater blood loss, including a lower pre-hospital systolic blood pressure and a lower initial hematocrit value. Transfusion volumes were equal between the two groups (1250 ml vs 1250 ml), as were transfusion rates (77% open vs 50% endovascular). The utilization of

endovascular surgery increased each year during the study period, however, increasing from 7% (2009) to 50% (2014-2015). Patients undergoing an endovascular approach were more likely to be involved in a crush injury or a pedestrian struck injury. The rate of penetrating injuries were not different between the two approaches. Interestingly, the involvement of surgeons trained in vascular surgery significantly increased the utilization of endovascular techniques (90% vs 56%) and decreased the rate of extremity fasciotomy after revascularization (15% vs 46%). Despite these trends, early outcomes were similar between patients undergoing open vs endovascular therapy – including in-hospital mortality, limb salvage rates, and length of hospital stay. Therefore, one may conclude that endovascular therapy is not inferior to the “gold standard” open approach for peripheral vascular trauma. The authors suggest the following selection criteria for endovascular management of traumatic arterial injuries: hemodynamically stable with contained hemorrhage, minimal thrombosis, minimal tissue defects, challenging anatomy, and larger vessel size (>6 mm). If the trauma patient does not meet these criteria, then the authors suggest that open repair would be prudent.

Comments and future research

In this study, the authors describe increased utilization of endovascular techniques for peripheral trauma. While short-term outcomes were similar when comparing open vs endovascular groups, long-term outcomes are lacking and warrant further investigation. Furthermore, in this study, the authors propose several selection criteria for endovascular repair. These criteria include hemodynamic stability, contained hemorrhage, minimal thrombosis and tissue loss, and large vessel caliber (>6 mm). Future studies may investigate the applicability of these criteria to endovascular treatment options and related outcomes.

i Related important publications

Sapan S Desai, Joseph J DuBose, Christopher S Parham, Kristofer M Charlton-Ouw, Jaime Valdes, Anthony L Estrera, Hazim J Safi, Ali Azizzadeh. Outcomes after endovascular repair of arterial trauma. *J Vasc Surg.* 2014 Nov;60(5):1309-1314. PMID 24997806.

CHAPTER 13b.

Endovascular treatment of peripheral arterial injuries in trauma

Authors: *Juan C. Duchesne and Joseph M. Galante*

Introduction

The application of endovascular techniques for peripheral arterial injury has been studied over the past 15 years yet remains an area with limited publications. Endovascular intervention in peripheral arterial injury takes two forms, embolization and cover stent-grafts. Embolization is used to stop hemorrhage in perfusing vessels, i.e., a branch of the profunda femoris. The use of cover stent-grafts in peripheral artery injuries is still in the early stages, and more data is needed to move this into a widely accepted practice. The following is a review of the current literature on endovascular intervention in peripheral artery injuries.

ARTICLE NUMBER 1

Contemporary management of subclavian and axillary artery injuries - A Western Trauma Association multicenter review.

J Trauma Acute Care Surg. 2017 Dec;83(6):1023-1031.
Waller CJ, Cogbill TH, Kallies KJ, Ramirez LD, Cardenas JM, Todd SR, Chapman KJ, Beckman MA, Sperry JL, Anto VP, Eriksson EA, Leon SM, Anand RJ, Pearlstein M, Capano-Wehrle L, Cothren Burlew C, Fox CJ, Cullinane DC, Roberts JC, Harrison PB, Berg GM, Haan JM, Lightwine K.

Abstract

Background: Subclavian and axillary artery injuries are uncommon. In addition to many open vascular repairs, endovascular techniques are used for definitive repair or vascular control of these anatomically challenging injuries. The aim of this study was to determine the relative roles of endovascular and open techniques in the management of subclavian and axillary artery injuries comparing hospital outcomes, and long-term limb viability.

Methods: A multicenter, retrospective review of patients with subclavian or axillary artery injuries from January 1, 2004, to December 31, 2014, was completed at 11 participating Western Trauma Association institutions. Statistical analysis included χ^2 , t-tests, and Cochran-Armitage trend tests. A p value less than 0.05 was significant.

Results: Two hundred twenty-three patients were included; mean age was 36 years, 84% were men. An increase in computed tomography angiography and decrease in conventional angiography was observed over time ($p = 0.018$). There were 120 subclavian and 119 axillary artery injuries. Procedure type was associated with injury grade ($p < 0.001$). Open operations were performed in 135 (61%) patients, including 93% of greater than 50% circumference lacerations and 83% of vessel transections. Endovascular repairs were performed in 38 (17%) patients; most frequently for pseudoaneurysms. Fourteen (6%) patients underwent a hybrid procedure. Use of endovascular versus open procedures did not increase over the duration of the study ($p = 0.248$). In-hospital mortality rate was 10%. Graft or stent thrombosis occurred in 7% and graft or stent infection occurred in 3% of patients. Mean follow-up was 1.6 ± 2.4 years ($n = 150$). Limb salvage was achieved in 216 (97%) patients.

Conclusions: The management of subclavian and axillary artery injuries still requires a wide variety of open exposures and procedures, especially for the control of active hemorrhage from more than 50% vessel lacerations and transections. Endovascular repairs were used most often for pseudoaneurysms. Low early complication rates and limb salvage rates of 97% were observed after open and endovascular repairs.

Article review and analysis

Aim of this study: This was a retrospective analysis sponsored by the Western Trauma Society specifically looking at the potential difference in management over time in patients with blunt and penetrating subclavian and axillary artery injuries. The study involved a retrospective review of patients from January 2004 to December 2014 and encompassed a total of 11 trauma institutions.

Methods

Pros: This study used a very robust cohort of trauma centers with an extended period of time that allowed the study to analyze if there was truly an increase in endovascular use. There is some interesting information about hybrid use, but the numbers are very small and limited for comparison.

Cons: The volume of patients in the endovascular arm was extremely low with only 38 patients compared to 135 patients in the open technique. This is one of the drawbacks of retrospective analysis, especially when there is no intention to treat but instead data gathering of outcomes and procedures. Based on their analysis, an endovascular approach was mostly used as a complication diagnostic and management tool rather than a first modality approach. Lastly, there was no post-discharge follow-up looking at 1 year or 5 year patency rates.

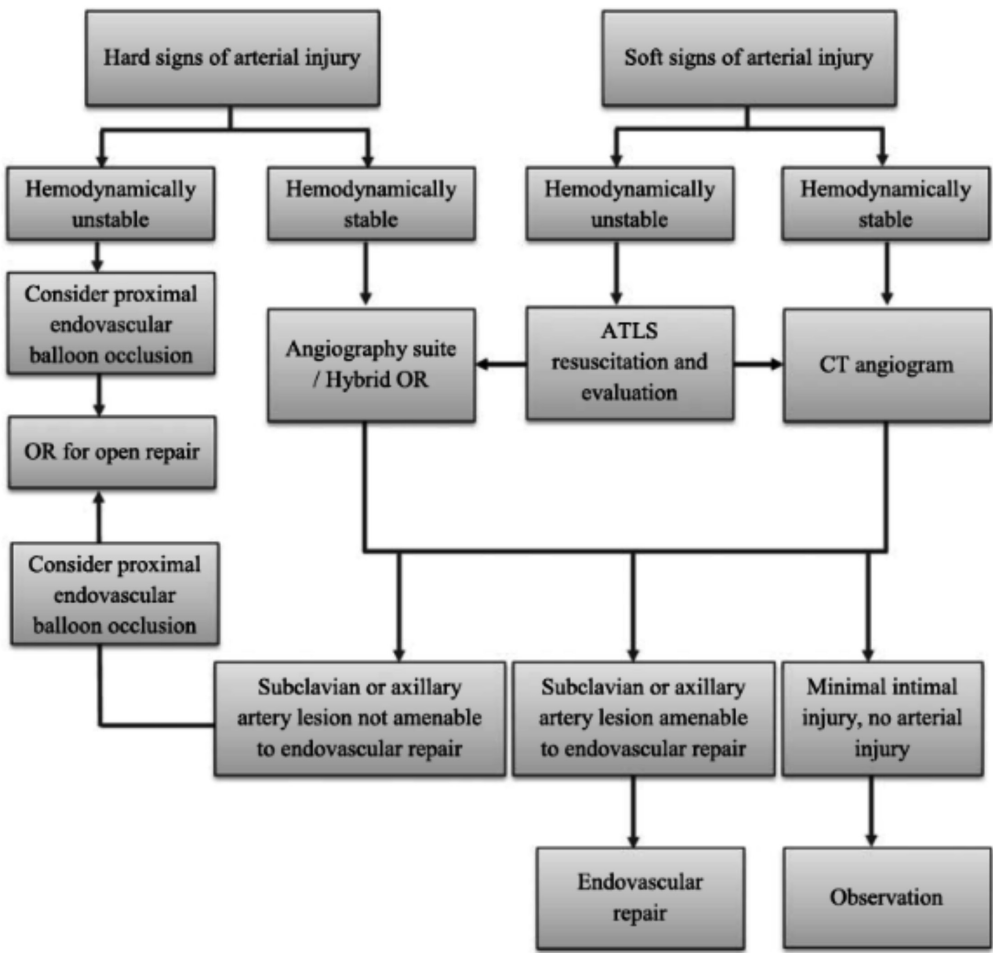
Results, conclusion, and what it means

A total of 233 patients were included with 135 undergoing open repairs and only 38 undergoing endovascular repairs. Over the study period, there was an increase in computed tomography angiography with a concomitant decrease in conventional angiography. There were 120 subclavian and 119 axillary artery injuries. Procedure type was associated with injury grade, with open procedure preference for high grade injuries. Most endovascular repairs were used for pseudoaneurysms. There was no increase in use of endovascular techniques over time.

Limb salvage was achieved in 97% patients. The authors outlined a great algorithm for management of axillary and subclavian artery injuries.

Comments and future research

Based on this analysis, there is a need for a side-to-side comparison in a prospective fashion in specialized trauma centers with hybrid ORs. The fact that this was a retrospective analysis increases the bias likelihood toward the surgeon's preference for open technique. Maybe, as the authors express on their conclusion, there are additional opportunities to use a hybrid approach for the repair of selected complex injuries, using endovascular balloon occlusion for temporary proximal vascular control followed by open vascular or endovascular repair.



OR = operating room; ATLS = Advanced Trauma Life Support; CT = computed tomography.

i Related important publications

Demetriades D, Asensio JA. Subclavian and axillary vascular injuries. *Surg Clin North Am.* 2001 Dec;81(6):1357-73, xiii.

Cox CS Jr, Allen GS, Fischer RP, Conklin LD, Duke JH, Cocanour CS, Moore FA. Blunt versus penetrating subclavian artery injury: presentation, injury pattern, and outcome. *J Trauma.* 1999 Mar;46(3):445-9.

Demetriades D, Chahwan S, Gomez H, Peng R, Velmahos G, Murray J, Asensio J, Bongard F. Penetrating injuries to the subclavian and axillary vessels. *J Am Coll Surg.* 1999 Mar;188(3):290-5.

Franga DL, Hawkins ML, Mondy JS. Management of subclavian and axillary artery injuries: spanning the range of current therapy. *Am Surg.* 2005 Apr;71(4):303-7.

Sobnach S, Nicol AJ, Nathire H, Edu S, Kahn D, Navsaria PH. An analysis of 50 surgically managed penetrating subclavian artery injuries. *Eur J Vasc Endovasc Surg.* 2010 Feb;39(2):155-9.

Carrick MM, Morrison CA, Pham HQ, Norman MA, Marvin B, Lee J, Wall MJ Jr, Mattox KL. Modern management of traumatic subclavian artery injuries: a single institution's experience in the evolution of endovascular repair. *Am J Surg.* 2010 Jan;199(1):28-34.

Piffaretti G, Tozzi M, Lomazzi C, Rivolta N, Caronno R, Laganà D, Carrafiello G, Castelli P. Endovascular treatment for traumatic injuries of the peripheral arteries following blunt trauma. *Injury.* 2007 Sep;38(9):1091-7.

Carrafiello G, Laganà D, Mangini M, Fontana F, Recaldini C, Piacentino F, Pellegrino C, Piffaretti G, Fugazzola C. Percutaneous treatment of traumatic upper-extremity arterial injuries: a single-center experience. *J Vasc Interv Radiol.* 2011 Jan;22(1):34-9.

Danetz JS, Cassano AD, Stoner MC, Ivatury RR, Levy MM. Feasibility of endovascular repair in penetrating axillosubclavian injuries: a retrospective review. *J Vasc Surg.* 2005 Feb;41(2):246-54.

Patel AV, Marin ML, Veith FJ, Kerr A, Sanchez LA. Endovascular graft repair of penetrating subclavian artery injuries. *J Endovasc Surg.* 1996 Nov;3(4):382-8

Figure 1. The management of subclavian and axillary artery injuries still requires a wide variety of open exposures and procedures, especially for the control of active hemorrhage for patients with high grade injuries. The authors need to be commended for putting together a great state of the union picture of the current management in the US of axillary and subclavian injuries. Based on their analysis, it will be crucial to elaborate on a properly designed prospective evaluation of hybrid approaches for these injuries. The flow diagram on the management of these injuries is extremely helpful in locating possible areas of improvement.

ARTICLE NUMBER 2

Radial versus femoral arterial access for trauma endovascular interventions: A noninferiority study.

J Trauma Acute Care Surg. 2020 Sep;89(3):458-463.

Adnan SM, Romagnonli AN, Elansary NN, Martinson JR, Madurska MJ, Dubose JJ, Scalea TM, Morrison JJ.

Abstract

Background: The majority of endovascular interventions for trauma are performed using transfemoral access (TFA). Transradial access (TRA) is a recently integrated alternative at the authors’ institution. This noninferiority study compares the technical success and complication rate of TRA compared with TFA.

Methods: All patients undergoing emergent endovascular interventions between March 2016 and March 2019 were identified from a prospectively maintained database. Data were collected on access type, complications, and procedural success. A noninferiority margin was established from previous randomized trials for technical success (0.475) and complications (0.015).

Results: Over 3 years, 96 patients underwent TRA and 335 patients received TFA. The overall technical success rate was 98.1%, without significance based on access strategy ($p = 0.078$). All femoral arteries and 97.9% ($n = 94$) of radial arteries were accessed as intended. Complications occurred in 1.0% of TRA and 9.9% of TFA groups ($p = 0.002$). In the TFA group, complications included access site bleeding, hematoma, pseudoaneurysm, lower limb ischemia, and femoral artery thrombosis ($n = 6, 14, 3, 3$, and 4 , respectively). In the TRA group, complications included radial artery thrombosis ($n = 1$). Transradial access procedural success and complication rate fell within the lower bound confidence interval of the noninferiority margin, demonstrated the noninferiority of TRA in this data set.

Conclusion: Transradial access in a cohort of trauma patients undergoing endovascular intervention does not appear to be inferior to TFA in relation to technical success and complications. For patients where groin access may be challenging, TRA is a useful, efficacious, and safe alternative. Longer-term study is required to fully characterize the advantages and disadvantages of TRA compared with TFA.

Article review and analysis

Aim of this study: This was a prospective data collection that was reviewed retrospectively to specifically identify if there is a difference in outcomes between a transfemoral approach (TFA) versus a transradial approach (TRA). This is a noninferiority analysis comparing complications between approaches and feasibility of TRA for endovascular approaches.

Methods

Pros: This analysis was performed at a state-of-the-art trauma center and by pioneers in endovascular management in the US. The data was collected prospectively to properly identify if there was any difference in complications between TRA and TFA. The authors mentioned the number of patients might be a weakness in support of their findings but, to date, this is the largest population of trauma patients used to compare different approaches with their respective incidence of complications.

Cons: Although the data was collected prospectively, the analysis was performed retrospectively with consideration of selection bias. This is a single-center analysis review of their outcomes and there is a need for a multicenter analysis. It is uncertain from this analysis what the long term impact of more radiation exposure and contrast in TRA will be since there was no long term follow-up analysis.

Results, conclusion, and what it means

This was a 3-year retrospective analysis at a Level I trauma center. Close to 100 patients underwent TRA and more than 300 patients received TFA. The overall technical success rate was similar for the groups with a higher complication rate in the TFA. Complications in the TFA included: access site bleeding, hematoma, pseudoaneurysm, lower limb ischemia, and femoral artery thrombosis. In the TRA group there was only one complication: radial artery thrombosis. The authors were able to demonstrate that TRA was noninferior to TFA for endovascular interventions.

Comments and future research

Based on this interesting single-center analysis, it would be very productive to have a multicenter analysis comparing both techniques using databases from major trauma centers with hybrid room capabilities. This analysis could be performed retrospectively with the aim of a prospective randomized analysis in the future.

Very well discussed analysis on outcomes and interventions. The authors provide a very comprehensive discussion with important limitations of their analysis, including its retrospective nature, single center and no long-term follow-up of patients with increased radiation and contrast exposure in the TRA. Further validation in a multicenter analysis is definitively warranted with special interest in long term outcomes in those patients managed with TRA with higher radiation exposure and incidence of CVA.

i Related important publications

Romagnoli E, Biondi-Zoccai G, Sciahbasi A, Politi L, Rigattieri S, Pendenza G, Summari F, Patrizi R, Borghi A, Di Russo C, Moretti C, Agostoni P, Loschiavo P, Lioy E, Sheiban I, Sangiorgi G. Radial versus femoral randomized investigation in ST-segment elevation acute coronary syndrome: the RIFLE-STEACS (Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome) study. *J Am Coll Cardiol.* 2012 Dec 18;60(24):2481-9.

Rajani NK, Brown AJ, McCormick LM, Parwaiz H, Kaushal A, Hoole SP, West NE. Institutional Switch from Transfemoral to Transradial Vascular Access for Percutaneous Coronary Intervention was Associated with a Reduction in Bleeding Events: A Singlecenter Experience of >10,000 Consecutive Cases. *J Interv Cardiol.* 2015 Jun;28(3):296-304.

Patel VG, Brayton KM, Kumbhani DJ, Banerjee S, Brilakis ES. Meta-analysis of stroke after transradial versus transfemoral artery catheterization. *Int J Cardiol.* 2013 Oct 15;168(6):5234-8.

Raposo L, Madeira S, Teles RC, Santos M, Gabriel HM, Gonçalves P, Brito J, Leal S, Almeida M, Mendes M. Neurologic complications after transradial or transfemoral approach for diagnostic and interventional cardiac catheterization: A propensity score analysis of 16,710 cases from a single centre prospective registry. *Catheter Cardiovasc Interv.* 2015 Jul;86(1):61-70.

ARTICLE NUMBER 3

Operative Treatment and Clinical Outcomes in Peripheral Vascular Trauma: The Combined Experience of Two Centers in the Endovascular Era.

Ann Vasc Surg. 2020 Jan;62:342-348.
D'Alessio I, Domanin M, Bissacco D, Romagnoli S, Rimoldi P, Sammartano F, Chiara O.

Abstract

Background: Arterial traumas of the extremities are quite rare in civilian records; nevertheless, patients with trauma of limbs are admitted daily in emergency departments worldwide. The up-to-date information about epidemiology and treatment (open vs. endovascular surgery) comes from war records and it is not always easy getting data on mortality and morbidity in these patients. The aim of this study is to analyze the approach (open or endovascular) and the outcome of patients with vascular trauma of upper limbs (from the subclavian artery) and/or lower limbs (distal to the inguinal ligament), in the greater Milan area.

Methods: A retrospective analysis was conducted on data recorded by the emergency departments of two hospitals of the greater Milan between 2009 and 2017. We collected all patients with arterial injuries of the limbs in terms of demography, injury patterns, clinical status at admission, therapy (open or endovascular approach), and outcomes in terms of limb salvage and survival.

Results: We studied 52 patients with vascular trauma of extremities. The main mechanism of trauma was road accident (48.1%), followed by criminal acts (32.7%), self-endangering behavior (13.5%), work (3.8%), and sport accidents (1.9%). Associated lesions (orthopedic, neurological, and/or venous lesions of the limbs) were present in 39 patients (75%). All patients underwent emergency surgery, forty-six patients (88.5%) by open repair (polytetrafluoroethylene or greater saphenous vein bypass grafts, arterial suture or ligation), whereas endovascular approach was used only in 6 patients (11.5%), all treated with embolization. The overall postoperative mortality rate was 5.7% (3 patients). Among survivors, we report 5 major amputations of the lower limbs, 3 of them after bypass graft infection, and 2 after graft failure. The rate of limb salvage was 90.4%.

Conclusion: Isolated arterial trauma of the extremities are rare, usually they occur in the setting of multiple trauma patients. Despite progresses in surgical techniques, there are still controversies in diagnosis and treatment of these patients. We treated most cases with open surgery (n = 46), choosing endovascular approach (embolization performed mainly by interventional radiologists) in difficult anatomic districts. We believe that, during decision-making of the surgical strategy, it is important to consider the anatomical site of lesions and the general condition of the patients. Moreover, in cases of multiple trauma, we suggest a multidisciplinary approach to provide the best medical care to the victims.

Article review and analysis

Aim of this study: The manuscript was published in 2020 by interventional radiologists, vascular surgeons, and trauma surgeons, and examined open vs. endovascular treatment of upper and lower limb trauma since 2009 in the greater Milan area.

Methods

Pros: The authors collected data from two trauma centers over eight years.
Cons: The volume of patients is low, 52 patients in total. The endovascular comparison group only had six patients, and most of the interventions were embolization.

Results, conclusion, and what it means

Most of the injuries were caused by blunt mechanisms and associated with fractures. All the patients had CT angiograms before intervention. The open approach was performed in 88.5% of patients. The authors recognize that the patients had severe and often concomitant injuries that necessitated open intervention. The outcomes for these patients were good, with limb salvage at 90.4%. Limb loss only occurred in the open surgery group.

Comments and future research

The authors recognized three crucial factors that could lead to further research in this area. The first, devastating injuries requiring orthopedic repair may not be amenable to endovascular surgical approaches. The authors based this on their experience. This conclusion is an opportunity for generating data to support their experience. Second, the authors recognized that endovascular surgery might be beneficial in difficult to access areas after penetrating trauma, such as the shoulder. Further research comparing open to endovascular approaches in these areas would be significant. Finally, the authors highlighted the need for multidisciplinary teams to care for the injured patient. Many trauma centers recognize this concept, yet the makeup of the team and the timing of their involvement need to be further elucidated. The authors need to be commended for writing up their experience over eight years. They had few endovascular cases, which is not unreasonable given the time at which the study was conducted. The extent of endovascular intervention was limited to embolization only, which at the time was appropriate. The main takeaways from the manuscript are that severely injured patients with concomitant injuries did not have 100% limb salvage. Second, the authors were conservative in their use of the endovascular approach. More data is needed for the authors to move from the conservative approach to a more liberal approach to endovascular interventions.

ARTICLE NUMBER 4

Systematic review and meta-analysis of open surgical and endovascular management of thoracic outlet vascular injuries.

*J Vasc Surg. 2013 Feb;57(2):547-567.e8.
Sinha S, Patterson BO, Ma J, Holt PJ, Thompson MM, Carrell T, Tai N, Loosemore TM;
London Trauma Network.*

Abstract

Background: Junctional vascular trauma such as that at the thoracic outlet poses particular challenges in surgical management. The use of endovascular techniques for such injuries is attractive as repair may be facilitated without the need for thoracotomy; however, the utility of such techniques is currently based on opinion, small retrospective series, and literature reviews of narrative and not systematic quality. The objective of this study is to provide a complete and systematic analysis of the literature pertaining to open surgery (OS) and endovascular management (EM) of thoracic outlet vascular injuries.

Methods: An electronic search using the MEDLINE, Embase, Cochrane Library, Science Citation Index, and LILACS databases was performed for articles published from 1947 to November 2011. The review conformed to the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement standards. Prospective studies and retrospective cohorts of more than 10 patients were included. The primary outcome was all-cause mortality.

Results: One prospective noncomparative study and 73 retrospective series met the inclusion criteria. There were no randomized studies. All studies were at high risk of bias. Fifteen studies described outcomes for both OS and EM (549 patients). The majority of these studies described EM for traumatic arteriovenous fistulas or false aneurysms in stable patients. Direct comparison between OS and EM was possible in only three studies (comprising 23 OS and 25 EM patients), which showed no difference in all-cause mortality (odds ratio, 0.67; 95% confidence interval [CI], 0.11-4.05), but a shorter operating time with EM (mean difference = 58.34 minutes; 95% CI, 17.82-98.85). These three series included successful EM of unstable patients and those with vessel transection. There were 55 studies describing only OS (2057 patients) with a pooled mortality rate of 12.4% (95% CI, 9.9%-15.2%). Four studies described only EM (101 patients) with a pooled mortality rate of 26% (95% CI, 8%-51%), but these represented a distinct subgroup of cases (mainly iatrogenic injuries in older patients).

Conclusions: The current evidence is weak and fails to show superiority of one modality over the other. EM is currently used primarily in highly selected cases, but there are reports of a broader applicability in trauma. High-quality randomized studies or large-scale registry data are needed to further comment on the relative merits or disadvantages of EM in comparison to OS.

Article review and analysis

Aim of this study: The authors attempted to perform a meta-analysis of open vs. endovascular management of thoracic outlet vascular injuries. This manuscript is included in this section of the text because nine studies involved axillary-subclavian.

Methods

Pros: The authors reviewed a wide array of studies from 1974 to 2011 with a solid meta-analysis methodology.

Cons: There was only one prospective noncomparative study and no randomized studies out of the 74 that the authors included. Direct comparison between operative and endovascular repair was made in only three retrospective studies.

Results, conclusion, and what it means

The data was weak and very limited for endovascular intervention in peripheral arterial injuries. The authors recognized that the literature that existed between 1974 and 2011 was insufficient to deem one approach superior to the other.

Comments and future research

The meta-analysis demonstrates that research in this area is needed, particularly prospective randomized trials. As seen in many of the articles addressing peripheral artery injuries, there is a lack of supporting data to shift from current open practice to a primarily endovascular approach. Without the data, little to no progress will be made. The authors encountered a typical challenge when examining “what has always been done” in relation to new technology. The first stages of change are merely reports of something being possible with little to no scientific rigor applied. The new technology only gains a foothold when a direct comparison is performed either in a retrospective or, ideally, a prospective manner. In 2011, there was minimal direct comparison being performed. Additionally, this is a challenging article to use for peripheral vascular injuries since the authors focused on thoracic outlet injuries.

ARTICLE NUMBER 5

Endovascular treatment of penetrating arterial trauma with stent grafts.

*Vasa. 2018 Feb;47(2):125-130.
Biagioni RB, Burihan MC, Nasser F, Biagioni LC, Ingrund JC.*

Abstract

Background: The endovascular management of arterial injuries has resulted in reduced operating time, blood loss, hospital mortality, lower incidence of sepsis, and decrease in mortality rates. For penetrating trauma, however, the benefits of endovascular therapy are questionable.

Patients and methods: Data were obtained by retrospective analysis of electronic medical records. All patients with vascular trauma seeking care at our institution from January 2010 to December 2015 were reviewed. A total of 223 vascular trauma patients were enrolled. Of these, 18 patients (8 %) were treated with endovascular techniques. The data related to clinical presentation, patient characteristics, technical aspects of the treatment, and follow-up were analysed.

Results: The mean patient age was 35.4 ± 17.8 years, 94 % were male. The mean injury severity score was 10.4 ± 2.5. The most commonly observed trauma mechanism was a gunshot in 10 cases (55 %), followed by lesions provoked by arterial catheter misplacement in five cases (27 %), and stab wounds in three cases (16.6 %). The main injury site was the subclavian artery, accounting for eight cases (44 %), followed by the superficial femoral artery and the tibiofibular trunk in two cases, respectively (18 %). The anterior tibial, fibular artery, axillary, common carotid, superior mesenteric, and profunda femoris were each affected once. Arteriovenous fistula was detected in nine cases (50 %), pseudoaneurysms in nine cases (50 %), and short occlusion in two cases (11 %). The mean follow-up duration was 753 days. The primary patency rate was 92.3 and 61.5 % after one and two years, respectively. The survival rate was 94.4 % after one and two years. Infection of the stents or limb amputations were not identified at follow-up.

Conclusions: The endovascular treatment of penetrating arterial injuries with covered stents is feasible. However, the criteria used to choose the best method must be individualized.

Article review and analysis

Aim of this study: The authors used covered stents to address penetrating arterial injuries in mostly peripheral arteries. The authors then followed the cohort for nearly two years.

Methods

Pros: The study examines the exact questions one must ask when applying endovascular management, is it feasible to place a covered stent and what are the long-term outcomes?

Cons: There is no comparison group. The authors attempt to explain why the patients were selected, yet some were treated with more traditional approaches. Additionally, the results include injuries of the common carotid and superior mesenteric arteries.

Results, conclusion, and what it means

The authors report a high patency rate of covered stents, 92%, at one year, and overall survival of 94%. The stents did not appear to become infected.

Comments and future research

The authors report outstanding results. As mentioned previously, one must have a comparison group. Future studies of this type should compare two cohorts or, more importantly, be performed as part of a randomized study.

This study is very encouraging although one would be cautious about calling for a wholesale change of practice based on this single study. However, despite some of the limitations, it certainly establishes the foundation upon which future studies may be based.

ARTICLE NUMBER 6

Endovascular management of peripheral arterial trauma in patients presenting in hemorrhagic shock.

J Cardiovasc Surg (Torino). 2012 Aug;53(4):495-506.
Trellopoulos G, Georgiadis GS, Aslanidou EA, Nikolopoulos ES, Pitta X, Papachristodoulou A, Lazarides MK.

Abstract

Aim: This study investigated patients who sustained peripheral arterial trauma, presented with clinical signs of shock, and underwent urgent endovascular repair (endo-R).

Methods: Eighteen patients (11 men) aged 62.8 ± 17.5 y (range: 24-78 years) with severe peripheral arterial injuries or spontaneous ruptures who presented with clinical signs of shock were treated on an emergency basis at two institutions from August 2003 to August 2009. The injury mechanism and clinical presentation were assessed in all patients. The time interval from the initial event to the procedure, the time interval from hemodynamic instability to endo-R (HI-to-endo-RTI), the artery involved in the approach to the injured vessel, the method of endo-R, and the endo-R duration were recorded. Stent grafting and/or embolization of the injured vessel were performed. The outcome was assessed mainly by clinical examination and duplex scanning. The duration of follow-up ranged from 6 d to 60 mo (27.4 ± 17.8 mo, mean $\pm$ SD).

Results: Mechanisms of injury included 13 iatrogenic (9 catheter-related) injuries, 2 spontaneous hemorrhages, and 1 case each of gunshot wound, fall injury, and car accident. Traumatic lesions were in the external carotid (N.=1), vertebral (N.=1), subclavian (N.=3), common iliac (N.=1), external iliac (N.=5), internal iliac (N.=3), profunda femoral (N.=1), superficial femoral (N.=2), and popliteal (N.=1) arteries. Stent grafts and embolotherapy were successfully deployed in 12 and 4 patients, respectively, with complete exclusion of the bleeding site. One patient received both treatments and another patient received balloon occlusion therapy. Technical success with no procedural complications occurred in all cases. The mean event-to-procedure time interval, HI-to-endo-RTI, and operative time were 147 min, 42.2 ± 48.2 min (range: 3-180 min), and 40.0 ± 29.6 min (range: 5-110 min), respectively. Thirteen patients had an uneventful postoperative course while three patients died (mortality rate: 17%). One patient had below-knee amputation and another one suffered hemiparesis (morbidity rate: 11%). The durations of the hospital and intensive-care-unit stays were 16.6 ± 19.5 d (range: 2-62 d) and 6.4 ± 14.6 d (range: 0-60 d), respectively. The follow-up duration was 27.4 ± 17.8 mo (range: 0.2-60 mo). Freedom from early or late endo-R major events occurred in 71.4% and 65.6% of cases at 6 mo and 12 mo, respectively, and the rate of primary patency of endografts was 91.7% and 81.8%.

Conclusions: Endo-R of traumatic non-aortic arterial injuries or spontaneous ruptures might be considered as a treatment option-in preference to open repair-even in emergency settings such as in shock patients. However, the safety of endovascular treatment in unstable trauma patients must be proved after comparison with open surgical treatment.

Article review and analysis

Aim of this study: The authors sought to establish if a patient could be emergently treated with endovascular repair when in shock. The bulk of the patients had iatrogenic injuries and therefore lacked the systemic response with severe injury, although the patients were in shock.

Methods

Pros: The study involved patients in shock and had a follow-up period, some up to five years.

Cons: The sample size is small, with only 13 patients. The patients (9) had mainly iatrogenic injuries and were not severely injured trauma patients. The follow-up was limited in some patients to only six days. There was again no comparison group.

Results, conclusion, and what it means

The authors reported that endovascular repair was feasible and the outcomes seem decent. The patency rates were in the 80% range.

Comments and future research

As seen with many of the peripheral vascular studies, further research is needed. One must begin by having a comparison cohort for each study. These methods must progress to direct prospective comparisons in a randomized manner.

The paper is another foundational study upon which further research may be based. One would have difficulty convincing anyone but an “early adopter” of using the endovascular approach for this patient population based solely on this study’s results. The study adds to the literature and allows the construction of a research study to generate more data.

CHAPTER 14.

Endovascular treatment of cardiac arrest

Authors: *Kristofer F. Nilsson and James Daley*

Introduction

Cardiac arrest represents a significant burden to public health which, after decades of research, still carries an unacceptably high mortality rate. Despite the advent of automated external defibrillators, increased bystander cardiopulmonary resuscitation (CPR), automated CPR devices, and post-arrest targeted temperature management, the proportion of patients surviving their cardiac arrest has improved only minimally. In the past two decades, advances in endovascular technology have enabled researchers to investigate novel therapies for this condition, including both extra-corporeal membranous oxygenation (ECMO) and resuscitative balloon occlusion of the aorta (REBOA). The principle of aortic occlusion during cardiac arrest is simple; by occluding the aorta during chest compressions, blood flow may be re-directed towards the heart and the brain. Researchers hypothesize that improved cardiocerebral perfusion in the setting of aortic occlusion may improve patient outcomes, such as return of spontaneous circulation (ROSC) and discharge from hospital with a favorable neurologic status. Furthermore, aortic occlusion may be used to optimize vital organ blood flow during CPR pending ECMO initiation and/or percutaneous coronary revascularization.

This concept has been extensively investigated in the pre-clinical literature where investigators have demonstrated improvements in hemodynamic variables as well as survival in animals undergoing cardiac arrest and aortic occlusion. However, the technology to investigate this hypothesis in a human population in the emergency department has only become available in the past five years, as prior aortic balloon occlusion

catheters were logistically very difficult to use and designed for utilization in the operating room, not the emergency department resuscitation bay. To date, there have been only two small trials published regarding aortic occlusion and cardiac arrest, with a third trial currently enrolling at the time of writing.

ARTICLE NUMBER 1

Feasibility of Pre-Hospital Resuscitative Endovascular Balloon Occlusion of the Aorta in Non-Traumatic Out-of-Hospital Cardiac Arrest.

J Am Heart Assoc. 2019 Nov 19;8(22):e014394.

Brede JR, Lafrenz T, Klepstad P, Skjærseth EA, Nordseth T, Søvik E, Krüger AJ.

Abstract

Background: Few patients survive after out-of-hospital cardiac arrest and any measure that improve circulation during cardiopulmonary resuscitation is beneficial. Animal studies support that resuscitative endovascular balloon occlusion of the aorta (REBOA) during cardiopulmonary resuscitation might benefit patients suffering from out-of-hospital cardiac arrest, but human data are scarce.

Methods and Results: We performed an observational study at the helicopter emergency medical service in Trondheim (Norway) to assess the feasibility and safety of establishing REBOA in patients with out-of-hospital cardiac arrest. All patients received advanced cardiac life support during the procedure. End-tidal CO₂ was measured before and after REBOA placement as a proxy measure of central circulation. A safety-monitoring program assessed if the procedure interfered with the quality of advanced cardiac life support. REBOA was initiated in 10 patients. The mean age was 63 years (range 50–74 years) and 7 patients were men. The REBOA procedure was successful in all cases, with 80% success rate on first cannulation attempt. Mean procedural time was 11.7 minutes (SD 3.2, range 8–16). Mean end-tidal CO₂ increased by 1.75 kPa after 60 seconds compared with baseline ($P < 0.001$). Six patients achieved return of spontaneous circulation (60%), 3 patients were admitted to hospital, and 1 patient survived past 30 days. The safety-monitoring program identified no negative influence on the advanced cardiac life support quality.

Conclusions: To our knowledge, this is the first study to demonstrate that REBOA is feasible during non-traumatic out-of-hospital cardiac arrest. The REBOA procedure did not interfere with the quality of the advanced cardiac life support. The significant increase in end-tidal CO₂ after occlusion suggests improved organ circulation during cardiopulmonary resuscitation.

Article review and analysis

Aim of this study: The investigator's primary outcome was to assess the feasibility and safety of performing REBOA in patients in out-of-hospital cardiac arrest (OHCA). Feasibility was measured by the clinician's ability to inflate the intra-aortic balloon in the proximal thoracic aorta, while safety was measured by comparing the efficacy of chest compressions as measured by end-tidal carbon dioxide (EtCO₂) before and after aortic balloon inflation.

Methods

Pros: This is the first study to assess the feasibility of REBOA performed by non-surgeons in OHCA since the conceptualization of the idea in the 1980s. Even more impressive is that this study took place in rural Norway, where investigators at the helicopter emergency medical service would fly to the location of the patient and perform REBOA in the location where the cardiac arrest initially occurred. The logistical difficulties of such efforts cannot be understated. The procedure was deemed feasible, with an 80% success rate on the first attempt, and 100% success rate with additional attempts at cannulation. Furthermore, investigators were sufficiently powered to detect a significant difference ($P < 0.001$) in end-tidal carbon dioxide (EtCO₂, a measure of resuscitation quality) both before and 90 seconds after aortic occlusion, suggesting that the procedure helped to improve the quality of chest compressions during advanced cardiac life support (ACLS). All investigators were trained in anesthesia and critical care (i.e., non-endovascular specialists) and all procedures were performed percutaneously with ultrasound during chest compressions without the need for an arterial cut-down.

Cons: This was an observational study and, as such, carries a greater risk of bias than if the investigators had included a control group and a randomization scheme. While this study demonstrates the feasibility of REBOA during OHCA, it was unable to assess if REBOA improves patient-centered outcomes. This study has limited generalizability to the greater hospital population given that all procedures were performed by five investigators with advanced training. Furthermore, all procedures occurred in the field in rural Norway, thus increasing the time to aortic occlusion (mean time of 60 minutes into the cardiac arrest). This may have reduced the likelihood of survivors as early interventions in OHCA typically are more effective. Additionally, the investigators were unable to measure real-time invasive blood pressure during the procedure. Diastolic blood pressure may be viewed as a surrogate marker for coronary perfusion pressure and would be an important marker to track in an observational study.

Results, conclusion, and what it means

This study was significant since it was the first of its kind and demonstrated the feasibility of the REBOA procedure during OHCA when performed by physicians proficient in ultrasound and with critical care training. It is significant that none of the investigators are considered endovascular specialists or had residency training in advanced endovascular techniques. Their 80% first-pass success rate is quite notable as arterial cannulation during chest compressions is very difficult due to the increased movement of the patient. This success rate is likely due in-part to the significant preparation and training undertaken by the team of investigators prior to the study's initiation. Each investigator underwent repeated training throughout the study, likely contributing to the 100% success rate of the procedure.

In addition to demonstrating the procedure's feasibility, investigators provided evidence that REBOA is safe and possibly improves the effectiveness of chest compressions

during OHCA. EtCO₂ is an established marker of chest compression quality and its statistically significant improvement after aortic occlusion suggests that aortic occlusion improves chest compression quality and central perfusion. Six patients in this study achieved ROSC, three survived to hospital admission, and one was eventually discharged from the hospital with a favorable neurologic prognosis and returned to a good quality of life. The high rate of ROSC seen after aortic occlusion suggests that aortic occlusion may have led to increased cardiac perfusion as has been hypothesized.

Comments and future research

This observational study lays the groundwork for future research with many questions remaining unaddressed. Subsequent investigations may attempt to replicate this study's results with regard to EtCO₂, as well as include an assessment of real-time blood pressure before and after aortic occlusion. Diastolic blood pressure is a surrogate marker for coronary perfusion pressure and if diastolic blood pressure improves with aortic occlusion, this would provide further evidence that aortic occlusion during OHCA improves cardiac perfusion and may increase the probability of ROSC. While the assessment of feasibility and safety are appropriate outcomes for such a first-in-human trial as this, subsequent research would benefit from the inclusion of a control group with a randomization scheme and larger sample size to assess improvement in patient-centered outcomes, specifically neurologic function at hospital discharge and ninety-day follow up.

ARTICLE NUMBER 2

Resuscitative endovascular balloon occlusion of the aorta (REBOA) during cardiopulmonary resuscitation: A pilot study.*Resuscitation. 2020 Nov;156:27-34.**Levis A, Greif R, Hautz WE, Lehmann LE, Hunziker L, Fehr T, Haenggi M.***Abstract**

Aim: Resuscitative endovascular balloon occlusion of the aorta (REBOA) during cardiopulmonary resuscitation (CPR) increases coronary and cerebral perfusion pressure, which might improve neurologically intact survival after refractory cardiac arrest. We investigated the feasibility of REBOA during CPR in the emergency department.

Methods: Patients in refractory cardiac arrest not qualifying for extracorporeal CPR were included in this pilot study. An introducer sheath was placed by ultrasound-guided puncture of the femoral artery, and a REBOA catheter was advanced to the thoracic aorta in 15 patients undergoing CPR. Primary outcome was correct placement within 10 min of skin disinfection. Secondary outcomes included perfusion markers (mean central arterial blood pressure, end-tidal CO₂, non-invasively measured cerebral oxygenation) and procedural information (number and duration of attempts, complications, verification of correct position and occlusion).

Results: Successful catheter placement was achieved in 9 of the 15 patients (median 9 min 30 s). Median interval from dispatch to start of the procedure was 59 min. A small, albeit significant increase in non-invasively measured cerebral oxygenation was found, but none in blood pressure or end-tidal CO₂. However, two patients with pulseless electrical activity of more than 20 min achieved return of spontaneous circulation immediately after REBOA.

Conclusion: Successful catheter placement was achieved in 9 of the 15 patients (median 9 min 30 s). Median interval from dispatch to start of the procedure was 59 min. A small, albeit significant increase in non-invasively measured cerebral oxygenation was found, but none in blood pressure or end-tidal CO₂. However, two patients with pulseless electrical activity of more than 20 min achieved return of spontaneous circulation immediately after REBOA.

Article review and analysis

Aim of this study: The primary objective of this research trial was to “investigate the feasibility of ultrasound-facilitated REBOA catheter placement during CPR in the everyday setting of the emergency department of a university hospital.” Investigators did not specifically define feasibility in their research report.

The investigators attempted REBOA in 15 patients who were in refractory cardiac arrest, which they defined as no ROSC despite at least ten minutes of high-quality advanced

life support. Significant exclusion criteria included qualifying for the local extracorporeal CPR (e-CPR) program, age less than 18 years old, pregnancy, history of recent torso trauma, and the presence of a known aortic aneurysm. Patients were enrolled as they presented to the emergency department in OHCA. Investigators performing the procedure were specialty trained in critical care medicine and had undergone limited training in REBOA prior to the study's initiation. A 25cm femoral introducer sheath was placed using ultrasound guidance with confirmation of correct placement also by ultrasound. The ER-REBOA (Prytime Medical, Boerne, TX, USA) was advanced into the thoracic aorta and the catheter's balloon filled with 0.9% saline solution until the femoral arterial pressure tracing was lost or they reached a maximum volume of 24 mls. Outcomes measured included real-time blood pressure from the proximal aortic tip of the catheter, EtCO₂, ROSC, and mortality.

Methods

Pros: This was the first trial of its kind to take place in a hospital setting (i.e., emergency department) as well as the largest to date (n=15), as opposed to the previously discussed study from Norway that took place in the field and enrolled 10 patients. The authors broke new ground by investigating the ability of point-of-care-ultrasound to confirm sheath placement during chest compressions, something that has not yet been reported on in a clinical setting.

Cons: A significant flaw with this trial is one that the authors were unable to avoid due to the advanced nature of their institution's resuscitation program; because e-CPR was available at their hospital, the authors had to exclude all patients from REBOA who were eligible for e-CPR. This makes ethical sense since the evidence base behind the effectiveness of e-CPR in OHCA is more robust than for REBOA; however, from a research perspective, this introduces a significant amount of bias in the study. Since the investigators had to exclude those who were eligible for e-CPR, the study population who underwent REBOA consisted of an older, more procedurally difficult, and more comorbid population than what would be typical. Furthermore, those eligible for e-CPR are much more likely to survive than the patients included in this trial. This means that it is much more difficult for the investigators to demonstrate the feasibility of REBOA, as well as any positive effect on patient outcomes that REBOA may induce, since these could be masked by a population that is unlikely to survive despite any intervention.

This article differs from the previously discussed Norwegian study in terms of the number of study investigators and the REBOA training that they received prior to the study's initiation. While this study's authors do not describe the number of clinicians performing REBOA or their training program, direct correspondence with the authors revealed that the procedure was performed by the on-call intensive care physician, leading to many physicians performing the REBOA procedure, typically for the first time. Furthermore, the trial included only a limited pre-training program which did not include reassessments or re-training. This is in contrast to the previously described study from Norway, where the clinical team only included five physicians who went

through an extensive initial training with repeated reassessments. A less extensive training program, as in this study, will make it more difficult for investigators to demonstrate the feasibility of the procedure.

Results, conclusion, and what it means

Investigators were able to successfully place the catheter in 9 of 15 (60%) patients. Median time to balloon inflation was 9 minutes and 30 seconds, with 6 patients undergoing inflation in less than 10 minutes. In three patients, the procedure was abandoned early because total resuscitation time had exceeded 60 minutes and the physician in charge of clinical care felt further efforts were futile and stopped all resuscitative efforts.

Point-of-care ultrasound seemed to be both helpful and a hindrance, depending on the patient. In one patient, ultrasound visualized the guidewire in the inferior vena cava (IVC), allowing the team to repeat the procedure and obtain proper arterial cannulation. In another patient who was obese, the team was unable to locate the guidewire on ultrasound, which led to a significant delay in the procedure, despite the catheter being placed in the common femoral artery on the initial attempt. In a third patient, clinicians could not visualize any guidewire in the IVC or aorta, despite it actually being in the IVC, and the REBOA balloon was subsequently inflated in the IVC. Their experience highlights that it is important to utilize ultrasound, but not solely rely on it. Ultrasound is often quite specific, but poorly sensitive. In this context, if one can see the guidewire on ultrasound, then one can be quite certain of its location; however, if one cannot see the guidewire in the aorta, this does not necessarily mean that the wire is not correctly placed. Investigators in future studies may consider using a bedside blood gas analysis tool to help determine arterial or venous placement when ultrasound is unable to visualize the guidewire. However, the intent to confirm adequate positioning of the guide wire is important, since balloon inflation in IVC severely obstructs preload and CPR effectiveness.

After aortic balloon inflation, the investigators noted a statistically significant but minor increase in cerebral oxygenation and a near-significant ($p=0.08$) increase in mean arterial blood pressure, with no significant change in EtCO₂. Unfortunately, all 15 patients died either in the emergency department or the ICU. Of the 9 patients who successfully underwent REBOA, two patients with a “relatively short duration of CPR” achieved ROSC “immediately” after aortic balloon inflation, with marked increases in their cerebral oxygenation as measured by near-infrared spectroscopy (NIRS). In both cases, care was later withdrawn due to hypoxic ischemic cerebral injury, highlighting ethical aspects of introducing novel interventions in the cardiac arrest patient population. The authors concluded that, while “REBOA during CPR is not easy to accomplish,” it is “feasible.” Additionally, they suggested that performing REBOA earlier in the course of a patient’s arrest may increase success rates and added that a structured training program with repeated training over time “is crucial.”

Despite their less-than-perfect outcomes, this work was of major importance since it

helped to define the limitations of REBOA and those of the clinician’s performing the procedure. The mean time to the *start* of the REBOA procedure was approximately 60 minutes into the patient’s cardiac arrest. This was because other patients with shorter arrest times were diverted to the institution’s e-CPR program. While REBOA *may* be an effective treatment in OHCA, it is unlikely that any therapy could improve outcomes in such prolonged CPR situations. The minimal and non-significant change in blood pressure after aortic balloon inflation could have been secondary to extreme vasoplegia due to prolonged OHCA. Given their highly comorbid population who had undergone a prolonged OHCA (>45 minutes for all patients), it is not surprising that none of the patients survived.

This study helped to define the importance of training and re-training clinicians. The authors note that the clinicians were only trained once and received no follow-up training. This stands in contrast to the more aggressive training program undertaken in the Norwegian study and so do their outcomes. It is apparent that if one hopes to have a highly successful REBOA program for OHCA, beginning with a small group of highly trained clinicians is likely the best approach.

Comments and future research

The two studies that we have now discussed involving REBOA in OHCA are both plagued by difficulty in their patient selection. The Norwegian study is difficult to generalize to other populations as all the patients had prolonged CPR prior to undergoing REBOA in the field. The patients in this study from Switzerland were most likely not going to survive despite any efforts due to their high comorbidities, age, and prolonged CPR. Further trials should attempt to focus on a patient population that is early into their cardiac arrest and more generalizable to urban emergency departments.

Additionally, this study demonstrates that there is much research needed regarding how to properly train clinicians in performing REBOA. Most physicians in this study had not performed REBOA prior to patient enrollment and had only undergone one training session. Given this limited training and experience in combination with an incredibly difficult patient scenario, a 60% success rate seems much more positive than one might initially think. However, it is clear that in order to achieve higher success rates, one must invest in the clinicians performing the procedure and repeatedly train them throughout the study period. At this point, it is unclear what type of training is optimal and how often it should be repeated. Future research should focus on skill depreciation across various specialties (surgical and non-surgical) and optimal timing for re-training sessions.

ARTICLE NUMBER 3

Intraaortic balloon occlusion during refractory cardiac arrest. A case report.*Resuscitation. 2009 Feb;80(2):281-3.*

Aslanger E, Golcuk E, Oflaz H, Yilmaz A, Mercanoglu F, Bugra Z, Umman B, Nisançi Y.

Abstract

Despite recent advances in its management, the outcome from cardiac arrest is often poor despite appropriate cardiopulmonary resuscitation (CPR). The coronary perfusion pressure (CPP) achieved during CPR is associated with successful return of spontaneous circulation (ROSC). Continuous balloon occlusion of the descending aorta is an experimental method that can occlude the ‘unnecessary’ part of the circulation, thus diverting generated pressure and blood flow to the heart and brain. We present a case report with a patient unresponsive to standard CPR in which constant intra-aortic balloon occlusion achieved ROSC and successful survival.

Article review and analysis

Aim of this study: While this case report is not a research study, it is important to discuss here since this is the first occurrence of the use of aortic occlusion to promote coronary perfusion pressure augmentation in the setting of a medical cardiac arrest.

In this report, a 74-year-old female suffered a myocardial infarction due to total occlusion of her right coronary artery and partial occlusion of the left circumflex artery that were not amenable to angiographic intervention. She then clinically decompensated in the cardiac intensive care unit, requiring a dopamine infusion and intubation for severe pulmonary edema. Subsequently, she went into cardiac arrest and CPR with advanced life support was initiated and performed for 20 minutes, when her rhythm changed from pulseless electrical activity to asystole. After 5 minutes of asystole, physicians inserted an intra-aortic balloon catheter via a previously-placed 7Fr sheath and began continuous occlusion of the aorta. After approximately 60 seconds of aortic occlusion, she regained normal sinus rhythm and a palpable pulse, and was subsequently placed on an intra-aortic balloon pump for hemodynamic support. Eventually she made a “good recovery” and was discharged home two weeks after her cardiac arrest.

Methods

Pros: This case report highlights how novel technology and interventions are most typically introduced into clinical care: through a clinician on the cutting edge of their profession who is willing to take a risk to do what they think is best for the patient, even if it may not be the standard of care. At the time of this publication, aortic occlusion had been studied with some success in the pre-clinical arena, but had not been attempted in the medical cardiac arrest patient. When the patient decompensated with

a 7Fr sheath already in place, the authors identified an opportunity to provide a novel intervention and, in this particular patient, it had excellent results. It seems likely that aortic occlusion was what induced ROSC in this patient, given the prior 25 minutes of ALS without ROSC and her subsequent deterioration into asystole.

Cons: While this is a trail-blazing success story for aortic occlusion in cardiac arrest, it remains a case report with an “n” of one. This report is encouraging, however by no means does it provide conclusive evidence that REBOA is effective in the setting of medical cardiac arrest. Additionally, while the authors were able to measure increases in diastolic blood pressure after aortic occlusion, they were unable to directly measure coronary perfusion pressure.

Results, conclusion, and what it means

At the three-month follow up visit, the patient was noted to have made a “good recovery” and declined the recommended coronary artery bypass graft surgery. The authors concluded that intra-aortic balloon occlusion may increase cardiocerebral perfusion and promote survival during cardiac arrest. Their experience helped to lay the groundwork for the two previously discussed trials in aortic occlusion and cardiac arrest.

Comments and future research

Further studies are needed to delineate the timing of aortic occlusion and whether its effectiveness decreases with prolonged arrest time, as is suspected. Both the Swiss and the Norwegian studies, which have been previously discussed here, included patients with refractory OHCA who did not undergo aortic occlusion until far into their resuscitation (approximately 60 minutes for each study). This case report differs from other studies in that the patient underwent aortic occlusion at 25 minutes into her cardiac arrest, which suggests that REBOA may be more effective as an early intervention in OHCA. Further studies on a much larger scale are needed to delineate who may benefit from REBOA during their cardiac arrest and how that potential benefit may decrease over the course of a patient’s resuscitation.

ARTICLE NUMBER 4

Resuscitative endovascular balloon occlusion of the aorta in zone I versus zone III in a porcine model of non-traumatic cardiac arrest and cardiopulmonary resuscitation: A randomized study.

Resuscitation. 2020 Jun;151:150-156.

Dogan EM, Hörer TM, Edström M, Martell EA, Sandblom I, Marttala J, Krantz J, Axelsson B, Nilsson KF.

Abstract

Introduction: Resuscitative endovascular balloon occlusion of the aorta (REBOA) in zone I increases systemic blood pressure during cardiopulmonary resuscitation (CPR), while also obstructing the blood flow to distal organs. The aim of the study was to compare the effects on systemic blood pressure and visceral blood flow of REBOA-III (zone III, infrarenal) and REBOA-I (zone I, supraceliac) during non-traumatic cardiac arrest and CPR.

Methods: Cardiac arrest was induced in 61 anesthetized pigs. Thirty-two pigs were allocated to a hemodynamic study group where the primary outcomes were systemic arterial pressures and 29 pigs were allocated to a blood flow study group where the primary outcomes were superior mesenteric arterial (SMA) and internal carotid arterial (ICA) blood flow. After 7-8 min of CPR with a mechanical compression device, REBOA-I, REBOA-III or no aortic occlusion (control group) were initiated after randomization.

Results: Systemic mean and diastolic arterial pressures were statistically higher during CPR with REBOA-I compared to REBOA-III (50 mmHg and 16 mmHg in REBOA-I vs 38 mmHg and 1 mmHg in REBOA-III). Systemic systolic, mean and diastolic arterial pressures were statistically elevated during CPR in the REBOA-I group compared to the controls. The SMA blood flow increased by 49% in REBOA-III but dropped to the levels of the controls within minutes. The ICA blood flow increased the most in REBOA-I compared to REBOA-III and the control group (54%, 19% and 0%, respectively).

Conclusion: In experimental non-traumatic cardiac arrest and CPR, REBOA-I increased systemic blood pressures more than REBOA-III, and the potential enhancement of visceral organ blood flow by REBOA-III was short-lived.

Article review and analysis

Aim of this study: The primary aim of this study was to investigate whether infrarenal REBOA placement (Zone III) was as effective as supraceliac placement (Zone I) on systemic blood pressure augmentation in CPR. Other aims included the investigation of differences in cerebral and visceral blood flow due to occlusion zone allocation.

Theoretically, Zone III occlusion would be more favorable for surviving patients, due to preserved visceral blood flow during CPR.

Methods

Pros: This study included a substantial number of animals increasing the statistical power. The animals were allocated to the study groups by randomization, limiting confounders. The investigators included a control group with no occlusion, showing that Zone I occlusion induced blood pressure and blood flow increments, thus validating the model. The use of a mechanical compression device probably made the CPR more standardized than manual compressions.

Cons: This is an experimental study in anesthetized pigs. Although pigs are extensively used in research studies on CPR due to their similarities to humans in size, anatomy and physiology and the possibility to use mechanical compression devices intended for humans, the translational value must be considered. First, the use of anesthetics could interfere with both the physiological response and the ability to achieve ROSC. Certainly, only a minority of the pigs received ROSC with no statistically significant differences between the groups. Second, the size of the lower limbs of pigs is much smaller than humans, meaning that the recruitable blood volume by Zone III occlusion is lower, perhaps underestimating the effects of Zone III occlusion. Third, as in many experimental studies, young and healthy animals were used, which does not correspond to the human CPR population. The method for inducing cardiac arrest was by right ventricular electric shock, not by myocardial ischemia which is the main etiology to non-traumatic cardiac arrest in humans. Fourth, coronary blood flow was not measured, which is an important determinant of effective CPR and likelihood of ROSC.

Results, conclusion, and what it means

The investigators confirmed previous experimental studies that have shown that Zone I occlusion induced increased systemic blood pressure and carotid blood flow compared to controls. However, the main finding was that Zone III occlusion was inferior to Zone I occlusion in improving central hemodynamics during mechanical compression. Furthermore, Zone III occlusion only provoked a transient increase in visceral blood flow. The investigators, therefore, concluded that the most favorable position of REBOA for enhancement of CPR may be Zone I. The value of this study was that it was the first that explored the use of REBOA outside of Zone I, and these findings were also shortly thereafter confirmed by another research group (Nowadly et al, *Am J Emerg Med*, 2020;38:1915-20). Despite considering the limitation of translating experimental work to humans, taken together these two studies indicate that investigating Zone I occlusion in human cardiac arrest and CPR is more prioritized than Zone III occlusion, if blood pressure augmentation is the main target.

Comments and future research

The use of REBOA in trauma patients has incorporated techniques, such as partial and intermittent REBOA, aimed at limiting the lower body ischemia-reperfusion injury. The risk of post-deflation organ injuries is the most demanding factor limiting extensive and prolonged use of REBOA. The investigation of Zone III occlusion in the present study can be regarded as such an attempt and should perhaps be followed by investigations of partial and intermittent REBOA in cardiac arrest and CPR. These techniques may be of particular interest in reducing visceral organ ischemia if REBOA is to be used as a bridge to ECMO initiation, and not primarily for ROSC where the duration of occlusion may be longer. In such a setting, Zone III occlusion may also be revisited.

ARTICLE NUMBER 5

Improved haemodynamics and restoration of spontaneous circulation with constant aortic occlusion during experimental cardiopulmonary resuscitation.

Resuscitation. 1999 Apr-May;40(3):171-80.

Gedeborg R, Rubertsson S, Wiklund L.

Abstract

Continuous balloon occlusion of the descending aorta is an experimental method that may improve blood flow to the myocardium and the brain during cardiopulmonary resuscitation (CPR). The aim of the present investigation was to evaluate the effects of this intervention on haemodynamics and the frequency of restoration of spontaneous circulation. Ventricular fibrillation was induced in 39 anaesthetised piglets, followed by an 8-min non-intervention interval. In a haemodynamic study (n10), closed chest CPR was performed for 7 min before the intra-aortic balloon was inflated. This intervention increased mean arterial blood pressure by 20%, reduced cardiac output by 33%, increased coronary artery blood flow by 86%, and increased common carotid artery blood flow by 62%. All these changes were statistically significant. Administration of epinephrine further increased mean arterial blood pressure and coronary artery blood flow, while cardiac output and common carotid artery blood flow decreased. In a study of short-term survival, nine out of 13 animals (69%) in the balloon group and in three out of 13 animals (23%) in the control group had spontaneous circulation restored. The difference between these two proportions was 0.46, which was statistically significant with a 95% confidence interval from 0.12 to 0.80. In conclusion, balloon occlusion of the descending aorta increased coronary and common carotid artery blood flow and the frequency of restoration of spontaneous circulation. It was also noted that epinephrine appears to augment the redistribution of blood flow caused by the aortic occlusion.

Article review and analysis

Aim of this study: This study investigated the effects of aortic Zone I occlusion on central hemodynamics, coronary and carotid arterial blood flow, and frequency of ROSC compared with no occlusion in a porcine model of CPR.

Methods

Pros: The animals in the survival study were allocated to the study groups by randomization. The investigators applied a relatively long “no-flow” time (8 min), which could be regarded clinically relevant by simulating no or badly performed by-stander CPR. Thereafter, they performed CPR for four minutes before inflation of the occlusion balloon in the survival study. Determination of these intervals in the design of a cardiac arrest study, where ROSC is the primary outcome, is delicate. The “no-flow” time

should be long enough so that ROSC is not achieved before the time for the intervention is reached and not too long so that too few animals achieve ROSC. Furthermore, the time intervals should be of clinical relevance. Obviously, the investigators succeeded in their study design.

Cons: The limitations in translating the experimental model described for the fourth article also apply to this study. Further limitations are that the investigators did not measure blood flow in the survival study and that the time intervals and other protocol items differed between the hemodynamic and survival studies, thus excluding the possibility to determine which variable was most important for ROSC achievement. However, since the investigators aimed at performing the survival study by intact, closed chest CPR, which is more relevant for the clinical condition, the animals could not be instrumented with coronary blood flow probes.

Results, conclusion, and what it means

The investigators found that intra-aortic balloon occlusion increased systemic blood pressure, coronary and carotid blood flow and, most importantly, frequency of ROSC compared to a control group. This study represents the early work with aortic occlusion in cardiac arrest and CPR. Despite not being the first experimental study to show augmented blood pressure and blood flow in this setting, it is one of the first, and most clinically relevant studies showing increased frequency of ROSC. Return of spontaneous circulation is the most relevant outcome variable in a short experimental study of this kind and certainly superior to physiological measures for showing the effectiveness of aortic occlusion. Even better would have been long-term survival and neurological function. Although such studies are possible to perform in pigs, they are associated with several difficulties.

Comments and future research

This study, and other similar studies performed 20 to 30 years ago, were made before clinical endovascular techniques had been developed to today's standards, which at that time limited the possibilities to proceed to clinical investigations. However, they laid the ground for the current rapid development, with human studies on aortic occlusion in CPR published and several in progress. In addition to clinical trials, it would be valuable to investigate the effects of aortic occlusion in cardiac arrest of alternate etiologies (i.e., non-traumatic, non-cardiac), both for safety reasons and as new indications. For example, acute massive pulmonary embolism is a rather common cause of non-traumatic cardiac arrest but, to our knowledge, the effects of aortic occlusion in this condition are unknown.

CHAPTER 15.

Endovascular treatment of ruptured Thoracoabdominal Aortic Aneurysm (rTAAA)

Authors: *Nuno Diaz and Zoran Rancic*

Introduction

Rupture is a fatal complication of thoracoabdominal aortic aneurysm (TAAA). For years, rupture was either not treated or treated by open repair. The first transfemoral stent-graft deployment by Volodos et al. in March 1987 in a 53-year-old patient with traumatic aneurysm of the thoracic aorta (TAA)¹ led to an increase in the use of endovascular tools in the thoracic and, subsequently, thoracoabdominal aorta. TAAA treatment currently includes open, hybrid and total endovascular procedures. The hybrid approach enables treatment of complex aortic aneurysms involving the aortic arch and the renovisceral arteries. Extra-thoracic or intrathoracic debranching enables the maintenance of perfusion to supra-aortic trunks followed by stent-graft exclusion of diseased aorta. Debranching of the renal and visceral arteries precedes exclusion of the aneurysmatic aorta by stent-graft of the aneurysmatic aorta. Complete endovascular treatment of TAAA includes the use of branched stent-grafts (single-, multi-branched, with inner- or outer branches), fenestrated stent-graft (custom-made or physician modified) and parallel grafts (in chimney, periscope, or sandwich fashion).

The use of complete endovascular treatment of TAAA is increasing. The reports show excellent short-term outcome even in the elderly. However, information concerning long-term outcome is missing, and the reports emphasize

the necessity of continuous follow-up to look for progression of aortic pathologies and stent-graft complications.

Reports on the use of complete endovascular treatment of TAAA in rupture are few. Most of the case studies include both symptomatic and ruptured TAAA, so that the clear value in patients with frank rupture is mostly lacking.^{3,5}

Here we present four articles that, in our opinion, may facilitate the treatment of rTAAA keeping in mind the use of aortic balloon occlusion as one adjunct in the open or endovascular treatment of rTAAA.

1. Volodos NL. The First Steps in Endovascular Aortic Repair: How It All Began. *J Endovasc Ther.* 2013;20 (Suppl):I-3-I-23
2. Motta F, Oderich GS, Tenorio ER, Schanzer A, Timaran CH, Schneider D, Sweet MP, Beck AW, Eagleton MJ, Farber MA, United States Aortic Research Consortium. Fenestrated-branched endovascular aortic repair is a safe and effective option for octogenarians in treating complex aortic aneurysm compared to non-octogenarians. *J Vasc Surg.* 2021 Feb 3; *So741-5214*(21)00148-8
3. Hongku K, Sonesson B, Björnsen K, Holst J, Resch T, Dias NV. Mid-term Outcomes of Endovascular Repair of Ruptured Thoraco-abdominal Aortic Aneurysms with Off the Shelf Branched Stent Grafts. *Eur J Vasc Endovasc Surg.* 2018 Mar;55(3):377-384.
4. Gallitto E, Faggioli G, Pini R, Mascoli C, Freyrie A, Vento V, Ancetti S, Stella A, Gargiulo M. Total Endovascular Repair of Contained Ruptured Thoracoabdominal Aortic Aneurysms. *Ann Vasc Surg.* 2019 Jul;58:211-221.
5. Spanos K, Kölb T, Theodorakopoulou M. et al. Early Outcomes of the t-Branch Off-the-Shelf Multibranched Stent-Graft in Urgent Thoracoabdominal Aortic Aneurysm Repair. *J Endovasc Ther.* 2018;25(1):31-9.

ARTICLE NUMBER 1

Ruptured aneurysm of the descending thoracic and thoracoabdominal aorta. Analysis according to size and treatment.

Ann Surg. 1991 May;213(5):417-25; discussion 425-6.
Crawford ES, Hess KR, Cohen ES, Coselli JS, Safi HJ.

Abstract

Acute rupture was confirmed at operation in 117 patients treated for descending thoracic or thoracoabdominal aortic aneurysm. Descending thoracic (n = 80) aortic rupture occurred into lung or esophagus in 8, the pleural cavity in 49, and the mediastinum in 23. Upper abdominal aortic (n = 37) rupture occurred into peritoneal cavity in 3 and into retroperitoneal tissues in 34. Aneurysmal size (range, 5 to 17 cm; median, 8 cm) could be determined retrospectively in 86 patients; 59 (74%) descending thoracic and 27 (73%) abdominal aorta. Size (external diameter) in the former was 8 (14%), 5 to 6 cm; 21 (36%), 6 to 8 cm; 23 (39%), 8 to 10 cm; and 7 (12%) greater than 10 cm. Size at the abdominal site was similar. Thus size was not greater than 10 cm in 52 (88%) (range, 5 to 10 cm), which contradicts opinions that thoracic aneurysms rupture only when size exceeds 10 cm. Twenty-nine patients (25%) were hypotensive (systolic blood pressure less than 100 mmHg), of whom 16 (55%) had cardiac arrest before operation. Associated conditions included advanced age (greater than or equal to 75 years) in 26 (22%), coronary artery disease in 41 (35%), chronic obstructive pulmonary disease in 46 (39%), renal insufficiency in 25 (21%), and cardiovascular disease in 22 (18%). The overall early survival rate (30-day) was 89 of 117 patients (76%); 69% in patients with hypotension, 56% of patients with cardiac arrest, 88% in good-risk patients. Five-year (Kaplan-Meier) survival was 28%. Because elective operation is associated with 92% survival, this should be considered before rupture when aneurysm is 5 cm or larger in good-risk patients, in patients with symptomatic aneurysms, and in most patients with larger aneurysms.

Article review and analysis

Aim of this study: This article reviews and analyses 117 patients treated for acute rupture of descending thoracic (TAA) and thoracoabdominal aorta (TAAA) grouped according to size, treatment and period of surgery (1958-1988 and 1989-1990), and compared with patients who underwent open surgery for non-ruptured aneurysms.

Methods

Retrospective analysis of almost 30 years' experience from pioneering and leading cardiovascular center.

Pros: There is a clear definition of aortic rupture ("fresh blood" outside the wall of the aneurysm). The study excluded symptomatic patients. Only patients with primary true aneurysm (after acute or chronic dissection, or degenerative), including patients with Marfan's syndrome, were analyzed. In total, 33 different factors (pre, intra- and post-operative) were studied. Univariate and multivariate logistic regression analysis were used to identify clinical predictors for early mortality.

Cons: Post hoc analysis, as well as many statistical analyses in a small number of patients in each subgroup, raise caution when interpreting the statistical results.

Results, conclusion, and what it means

The size of ruptured TAAA and TAA was 5-6 cm in 14% of patients, 6-8 cm in 36%, 8-10 cm in 39%, and more than 10 cm in 12%. The size at the abdominal site was similar. In all cohorts, the size of the aneurysm was less than 10 cm in 52 patients (88%).

30-day survival of all patients in the ruptured cohort was 76% (89/117), and varied depending on extent of aortic surgery replacement: it was 100% in patients with "sub-total" replacement of descending aorta (DES), 64% in patients with total DES replacement, and 74% in patients requiring thoracoabdominal replacement. The most frequent cause of death within 30-days was cardiac (75%), followed by pulmonary (36%), renal (32%), sepsis (18%) and stroke (14%). Interestingly, out of 13 patients with hypotension without cardiac arrest, only one died. 30-day mortality after rTAA was 20% compared to 24% in patients with rTAAA. During the same period, 30-day mortality for elective surgery in TAA and TAAA was 8% and 7%, respectively. Both univariate and multivariate analysis showed that the risk factors for early mortality were cardiac arrest, postoperative cardiac complications, postoperative renal failure, and earlier period of the operations at the institution. 30-day spinal cord ischemia (SCI) in patients who survived surgery was 22% after rTAA compared to 30% in patients with rTAAA. During the same period, 30-day SCI for elective surgery for TAA and TAAA was 5% and 14%, respectively. 30-days postoperative hemodialysis in patients who survived surgery was 16% after rTAA compared to 21% in patients with rTAAA, and after elective surgery for TAA and TAAA was 3% and 7%, respectively.

This paper broke some established concepts. First, that TAA only ruptured if larger than 10 cm in diameter and that it required surgical treatment on an elective basis. This study of aneurysm size at rupture recommended surgery in patients with TAA/TAAA larger than 5 cm in diameter measured by CT scan, in symptomatic patients and in patients with rupture. The same indications for treatment are still in use for TAA and TAAA according to the actual ESVS guidelines, even if the size threshold is slightly larger (≥ 56 -60 mm). What has changed is the recommendation that, in patients with ruptured descending thoracic aortic aneurysm, endovascular treatment should be the

first treatment option when the anatomy is appropriate. Second, in many centers nowadays ruptured aneurysms, even in stable patients, constitute an emergency, with the need for operation within one hour. The study showed that the interval between onset of acute symptoms (change in the nature of the aneurysm or rupture) and surgery was more than one day (median, 3 days) in 84% of patients. This means that rTAA and rTAAA in exceptional situations (after midnight, no team available) might be treated as emergent (immediate), but also urgent (with some delay). Third, uni- and multivariate analysis identified factors leading to early death: cardiac arrest, postoperative cardiac complications and postoperative renal failure. These risk factors are still risk factors in open surgical treatment of rTAA and rTAAA, despite improvements in anesthesiology support and surgical-technical improvements. This is the reason why complete endovascular treatment has replaced open surgery in most patients. Fourth, the authors advocate in some situations "damage control surgery" and not extensive repair. In one patient with TAAA and rupture of "isolated" descending aorta, the first surgery was partial descending aorta replacement. The second surgery was complete thoracoabdominal replacement after recovery of the patient during the same hospitalization. The same principles are in use in ruptured AAA.

Comments and future research

This study published in 1991 analyzed the results of surgery for TAAA during the period from 1962-1990. The series of open surgery for TAAA are mostly coming from big vascular centers and real world experience is missing. It appears that the results do not achieve the same levels if extrapolated from emergent acute complex abdominal aortic repairs. Despite the lack of recommendations for the treatment of ruptured TAAA in the ESVS guidelines, open surgery was successful in high volume centers, but it is unknown if the current use of endovascular repair may have influenced these results.

i Related important publications

Riambau V, Böckler D, Brunkwall J, Cao P, Chiesa R, Coppi G, Czerny M, Fraedrich G, Haulon S, Jacobs MJ, Lachat ML, Moll FL, Setacci C, Taylor PR, Thompson M, Trimarchi S, Verhagen HJ, Verhoeven EL, Esvs Guidelines Committee, Kolh P, de Borst GJ, Chakfé N, Debus ES, Hinchliffe RJ, Kakkos S, Koncar I, Lindholt JS, Vega de Ceniga M, Vermassen F, Verzini F, Document Reviewers, Kolh P, Black JH 3rd, Busund R, Björck M, Dake M, Dick F, Eggebrecht H, Evangelista A, Grabenwöger M, Milner R, Naylor AR, Ricco JB, Rousseau H, Schmidli J. Editor's Choice - Management of Descending Thoracic Aorta Diseases: Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg.* 2017 Jan;53(1):4-52.

Latz CA, Boitano L, Schwartz S, Swerdlow N, Dansey K, Varkevisser RRB, Patel V, Schermerhorn M. Contemporary mortality after emergent open repair of complex abdominal aortic aneurysms. *J Vasc Surg.* 2021 Jan;73(1):39-47.e1.

ARTICLE NUMBER 2

Mid-term Outcomes of Endovascular Repair of Ruptured Thoraco-abdominal Aortic Aneurysms with Off the Shelf Branched Stent Grafts.

Eur J Vasc Endovasc Surg. 2018 Mar;55(3):377-384.

Hongku K, Sonesson B, Björnsen K, Holst J, Resch T, Dias NV.

Abstract

Objective: To assess the mid-term outcomes and feasibility of branched endovascular repair (b-EVAR) of ruptured thoracoabdominal aortic aneurysms (rTAAAs).

Methods: All patients undergoing b-EVAR of rTAAAs between 2011 and 2016 were included. Pre-, intra and postoperative imaging was reviewed to assess technical success, outcomes, and feasibility of b-EVAR in the emergent setting.

Results: Eleven emergency b-EVAR of rTAAAs (10 aneurysms and 1 chronic dissection) were performed using off-the-shelf (OTS) branched stentgrafts. Only 18% of patients complied to the anatomical instruction-for-use of the OTS device; a small aortic lumen and occluded target vessels were the main violations. Median operative time was 430 (IQR 395-629) minutes. Technical failure was 36% including one intraoperative death, one target vessel catheterization failure, one type Ia and one type III endoleak. Thirty-day mortality was 27%. Only early re-intervention was for the type Ia endoleak. Spinal cord ischemia occurred in 4 patients (30%), of which 2 recovered completely. Median clinical follow-up was 15 (IQR 7-39) months respectively. The median clinical follow-up index (FUI) was 0.65 (0.32-0.95). Overall survival was $75 \pm 21.7\%$ at 18 months. Four branch occlusions occurred; one renal stent occlusion led to permanent hemodialysis. Branch patency was $87.5 \pm 8.3\%$ and $72.2 \pm 12\%$ at 1 and 2 years, respectively. One stentgraft migrated but no late major endoleak occurred.

Conclusion: Emergency b-EVAR of rTAAA with OTS device is feasible despite a low anatomical suitability. With proper adjunctive procedures, it can be offered to most hemodynamically stable patients. These time-consuming complex procedures are not suitable for unstable patients. Often the procedure is done as life-saving in the emergency setting and reinterventions may be needed later. Consequently, the success rates are lower than in the elective setting. These results need to be confirmed by larger studies and longer follow-up.

Article review and analysis

Aim of this study: The study aimed to assess the feasibility and mid-term outcomes of the use of branched EVAR (b-EVAR) for the treatment of ruptured thoracoabdominal aneurysms (rTAAAs) using an off-the-shelf (OTS) device. This presents the six-year experience of one of the leading endovascular centers in Europe, with well-established

elective b-EVAR and wide experience in the use of branched stent-grafts, both custom made (CMD) and OTS.

Methods

Pros: In this study, the authors included only patients with rupture (9 with contained, 2 with free rupture), and only patients with thoracoabdominal aneurysm (TAAA) according to the Crawford classification (type I, one patient; type II, six patients; type III, two patients, and type IV, two patients); all but one (chronic aortic dissection) were degenerative in origin. Clear inclusion criteria facilitate straightforward conclusions. All patients underwent surgery with commercially available Zenith t-branch or custom-made Pre-t-branch Cook (available at the author's unit as an OTS alternative for acute situations). All the definitions conform to reporting standards for endovascular treatment of abdominal and thoracic aortic aneurysm, which makes comparison with other studies possible. There is a clear logistic and standard operating procedure for the treatment of patients with rTAAA, and the implementation of defined perioperative strategies in the management of one aortic rupture: the use of local anesthesia principles of hypotensive hemostasis and permissive hypovolemia, if possible, and the use of aortic occlusion balloon (before or during the operation).

Cons: The design of the study is retrospective with the consequent potential bias. The number of patients is limited, but rTAAA are rare and this is a case series focused only on rTAAA. There was a delay before the treatment of the rupture (median one day). On the other hand, hemodynamic stabilization might contribute to a higher chance of surviving such a complex procedure (median operative time 430 minutes). In the study we do not see other complete endovascular strategies implemented in the treatment of rTAAA (physician modified, and use of parallel grafts such as periscope, chimney and sandwich techniques). Moreover, there were no open repair rTAAA during the observation period, eliminating the possibilities to compare the results of OTS grafts with other strategies. Follow-up data were limited (median for clinical FU was 15 months, and for imaging 14 months), which affects the validity of the results.

Results, conclusion, and what it means

Anatomical suitability of OTS Zenith t-branch in rTAAA according to IFU was 18% (2 out of 11 patients). The surgeons' reasons for anatomical violation were small aortic lumen at visceral segment (5/11), at least one target vessel occlusion (4/11), small target vessel diameter (2/11) and severe aortic angulation (2/11). In order to overcome the IFU limitations, different adjuncts were used in 8/11 patients for access challenges (endarterectomy with patch plastic, paving and cracking with endoconduit, iliac stenting), preventing retrograde perfusion from target vessels (use of vascular plugs for closure of branch cuff), and optimizing proximal sealing zone (with left carotid-subclavian bypass). The use of adjuncts in rupture requires experience and skill. Of importance is that the patient cohort had received previous aortic surgery (45%), and synchronous

aortic aneurysm was present in 45%. Median operation time was 430 (395-629) minutes. This time-consuming procedure might be unsuitable in patients with hemodynamic instability. In an attempt to stabilize unstable patients, the authors used preoperative and intraoperative aortic balloon (REBOA) in two patients. There was only one intraoperative death in a young patient with post-dissection TAAA and irreversible hemorrhagic shock. Immediate covering of the branch-EVAT with a thoracic stent graft, as a lifesaving technique, was unsuccessful. Overall technical success was 64% (7/11 patients). There were three technical failures: one endoleak type I, one endoleak type III, and a failed catheterization of the right renal artery. 30-day mortality was 27% (3/11 patients): besides one operative death caused by hemorrhagic shock, two other causes of death were multi-organ systemic failure (MOSF) due to colonic ischemia in one patient, and post-operative pneumonia in another patient with chronic obstructive pulmonary disease. Spinal cord ischemia (SCI) was present in 27% (3/11 patients), and all presented immediately. In two patients, SCI resolved immediately, and in a third patient the course is not clear because the patient had weakness in both legs and died of MOSF and pneumonia. All the patients had risk factors for SCI, including previous infrarenal AAA open repair, occlusion of left subclavian artery, internal iliac and femoral arteries. All the patients with SCI had spinal drainage (SD) (in two placed perioperatively and in one on demand after symptoms occurred). In total, SD was used in eight patients: in seven prophylactically (five preoperative and two immediate post-operative), and in one on demand. There is an ongoing debate concerning the use of SD to prevent spinal cord ischemia in patients with rTAAA. There were two complications from SD: one subdural hematoma and one meningeal infection. There must be a balance between complications of SD and the frequency of SCI. It seems that, despite the limited number of patients in this study, the use of SD had a significant value. Postoperative renal insufficiency occurred in four patients with only one requiring temporary hemodialysis. The factor contributing to lower renal insufficiency is surely the imaging modalities during the operative procedure: CO₂ angiography used in 82% of patients, overlay image fusion in 27%, and core bean CT in 64% of the patients. The median duration of clinical follow-ups (FUs) was 15 months, and imaging FUs 14 months. There was no Endoleak Type Ia or III. There were no stent graft related reinterventions after 30 days post-operatively. There were four occlusions of branches during FU (2 left renal, two celiac trunk). The reasons for occlusion were compression of the bridging stent (BS) in small and angulated aorta, BS malposition, and compression by previous aortic stent. There were no BS occlusions in small diameter arteries on preoperative CTA. In summary, there is a lower success rate in the use of OTS b-EVAR in rTAAA than in elective settings. On the other hand, the procedure is lifesaving in the acute situation and, in centers with enough experience in elective cases, might be of use as one of the options for treatment.

Comments and future research

Because of the rarity of rTAAA, there is a need for a multicenter collaborative study on the use of off-the-shelf stent-grafts. It would be useful to compare all complete endovascular strategies in rTAAA: physician modified fenestrated stent graft, off-the-shelf branched EVAR, parallel grafts as well as a combination of these, in stable and unstable patients. Furthermore, it would be interesting to see the influence of lower blood pressure during preoperative CTA on sizing for complex endovascular procedures, and later the influence of sizing on long term results: on imaging and, more important, clinically. It would be interesting to see the influence of reinterventions on aneurysm-related death.

ARTICLE NUMBER 3

Multiple Periscope and Chimney Grafts to Treat Ruptured Thoracoabdominal and Pararenal Aortic Aneurysms.*J Endovasc Ther.* 2011 Oct;18(5):642-9.

Pecoraro F, Pfammatter T, Mayer D, Frauenfelder T, Papadimitriou D, Hechelhammer L, Veith FJ, Lachat M, Rancic Z.

Abstract

Purpose: To report midterm outcomes after urgent endovascular repair of ruptured pararenal or thoracoabdominal aortic aneurysms using multiple periscope and chimney grafts to preserve renovisceral branch perfusion and facilitate aneurysm exclusion.

Methods: Nine consecutive men (mean age 72 ± 14 years, range 40-88) presenting with ruptured thoracoabdominal ($n = 6$), pararenal ($n = 2$), or infrarenal ($n = 1$) aortic aneurysm underwent urgent endovascular repair with at least 1 periscope graft delivered via a transfemoral access; chimney grafts were installed from an axillary access. In all, 17 periscope and 7 chimney grafts were used to reperfuse 11 renal and 13 visceral arteries in the 9 patients. The aortic aneurysms were excluded using thoracic devices ($n = 7$), an aortic extension cuff ($n = 1$), and bifurcated stent-grafts ($n = 2$).

Results: All procedures were completed without technical complications except for a dislocated stent-graft from the right renal artery; the artery could not be re-accessed, and the right kidney was sacrificed. One patient died of multiple organ failure (11% 30-day mortality). At a mean follow-up of 10 months (range 3-24), 5 of the 9 patients had recovered completely; 3 patients died of unrelated causes. Imaging showed no aneurysm growth in any patient, with a mean 20% shrinkage in aneurysm size. All periscope and chimney grafts remained patent, and no aortic stent-graft migration was observed. Renal function and the glomerular filtration rate remained stable in all patients.

Conclusion: The periscope and chimney graft technique provides a simpler, less invasive way to maintain blood flow to the renovisceral arteries during urgent endovascular aortic repairs. The very low 30-day mortality rate and the stability of the repairs in the midterm are encouraging. This technique has the potential to profoundly influence the treatment of acute aortic pathologies.

Article review and analysis

Aim of this study: The rationale for this almost decade old study was to present the method that will facilitate the exclusion of rTAAA and pararenal (PRAA) aneurysm. At time of publication, open repair of rTAAA was the gold standard and the use of branched and physician-modified stent-grafts (PMSG) were only possible in a few centers with the necessary skills and off-the-shelf (OTS) devices. In the authors' center, parallel grafts were in use: in chimney fashion to extend the proximal landing zone

(with antegrade perfusion of target renovisceral vessel) for a couple of years, and in periscope fashion to extend the distal landing zone (with retrograde perfusion) already in use for ruptured thoracoabdominal aneurysms. The aim of the study was to report early and mid-term results of the treatment of rTAAA using multiple parallel grafts.

Methods

Pros: Nine consecutive men with rupture (all confirmed with CTA, thoracoabdominal including aortic arch, supra-aortic trunks, and femoral arteries) were operated on from August 2008 to April 2011. All patients were treated according to the center's standard protocol for ruptured aorta patients, including blood pressure lowered to a goal of 90 mmHg. The definition of shock was systolic blood pressure /heart rate < 1 . Three patients were still unstable and in shock, and they received an immediate operation as damage control. Five patients underwent urgent or delayed surgery after correction of acid-base and coagulation disorders. The technique for chimney or periscope graft is standardized and presented in the paper. All the patients underwent immediate post-operative CTA.

Cons: This is a retrospective analysis of prospectively collected data. The group of patients is not homogenous: there were six patients with rTAAA, two with ruptured pararenal aortic aneurysm and one with ruptured AAA.

Results, conclusion, and what it means

In total, 24 target arteries were revascularized (11 renal, 6 superior mesenteric arteries and 7 celiac trunks) either in chimney (7) or in periscope (17) fashion. Most of the chimney/periscopes were stent-grafts (21/24) but also bare stents (3/24). If the final angiography at the end of the procedure or the arterial phase of pre-discharge CTA showed any significant high-flow endoleak (filling the aneurysm sac partially or totally) correction of that endoleak was performed during the initial hospitalization. If there was low-flow type I and/or type II endoleak at the same examinations, surveillance and conservative treatment were chosen. The low flow endoleak, deriving most likely from the gutters between the chimney or periscope graft and aortic stent graft, can be expected and may be considered a drawback of the procedure. However, in the face of a rupture, with coagulation impairment, insisting on perfect angiography could result in an operation that is more complex with potential harm to the patient. There was one technical failure because of dislocation of a parallel graft to the renal artery where the re-access also failed. Evacuation of a large hematoma in the thorax of three patients occurred several days after stabilization, during the same hospitalization. 30-day mortality was 11%: one patient died due to multiple organ failure on the ninth day postoperative. Postoperative CTA revealed six endoleaks, and only two required in-hospital treatment. Endoleak type Ib/II originating from the celiac trunk needed correction and relining of a bare metal stent with a stent graft. The other high flow endoleak required extension of the aortic stent graft proximally with consecutive extension of parallel grafts and glue embolization. Within 30 days, one patient

developed SCI and permanent paraplegia (11%). Mean follow up was 10 months (3-24). Three patients died during follow up. One patient presented with an aorto-esophageal fistula and underwent partial resection of the esophagus and open repair for a thoracoabdominal aneurysm; the patient declined any further therapy after postoperative paraplegia. A second patient died after spinal surgery not related to the rupture of a mycotic pararenal aneurysm. A third patient developed paraplegia after initial surgery for rTAAA and developed an infected sacral wound and sepsis. CT follow-ups showed no aneurysm growth in any patients. All chimney/periscope grafts remained patent. In two patients with persistent endoleak, the aneurysm sac shrank and the endoleak continued to be managed conservatively. In summary, the use of multiple chimney and periscope grafts in patients with rTAAA is less invasive, feasible, and with a potential to influence the treatment of acute aortic pathologies. At times it may also allow less extensive repairs than the use of other endovascular solutions presented in this chapter.

Comments and future research

This study, published almost 10 years ago, influenced the treatment of acute aortic pathologies. Over time, other complete endovascular strategies (fenestrated and branched stent grafts) are now offering less invasive treatment with similar perioperative results. The parallel grafts technique needs standardization in every center. The sizing of stent grafts (aortic and those to target the vessel) in hypovolemia and low blood pressure in patients with rTAAA needs investigation, especially its influence on the new onset of endoleaks and clinical implication. One randomized study comparing the different complete endovascular options for rTAAA would be useful, but extremely difficult to organize, taking into consideration the difficulties in the studies regarding ruptured infrarenal aortic aneurysms.

i Related important publications

Rancic Z, Pfammatter T, Lachat M, Hechelhammer L, Frauenfelder T, Veith FJ, Criado FJ, Mayer D. Periscope graft to extend distal landing zone in ruptured thoracoabdominal aneurysms with short distal necks. *J Vasc Surg.* 2010 May;51(5):1293-6.

Lachat M, Veith FJ, Pfammatter T, Glenck M, Bettex D, Mayer D, Rancic Z, Gloekler S, Pecoraro F. Chimney and periscope grafts observed over 2 years after their use to revascularize 169 renovisceral branches in 77 patients with complex aortic aneurysms. *J Endovasc Ther.* 2013 Oct;20(5):597-605.

Mayer D, Pfammatter T, Rancic Z, Hechelhammer L, Wilhelm M, Veith FJ, Lachat M. 10 years of emergency endovascular aneurysm repair for ruptured abdominal aortoiliac aneurysms: lessons learned. *Ann Surg.* 2009 Mar;249(3):510-5.

ARTICLE NUMBER 4

Outcome of Surgeon-Modified Fenestrated/Branched Stent-Grafts for Symptomatic Complex Aortic Pathologies or Contained Rupture.

J Endovasc Ther. 2017 Dec;24(6):825-832.

Tsilimparis N, Heidemann F, Rohlfes F, Diener H, Wipper S, Debus ES, Kölbel T.

Abstract

Purpose: To analyze the outcome of surgeon-modified fenestrated and branched stent-grafts (sm-FBSG) in high-risk patients with symptomatic complex aortic pathology or contained rupture.

Methods: A single-center retrospective analysis was conducted of 21 consecutive patients (mean age 70 years, range 58-87; 16 men) treated with a sm-FBSG from April 2014 to September 2016. The indications included 11 thoracoabdominal and 10 pararenal aortic pathologies, which presented as symptomatic in 8 and as contained rupture in 13 patients. The mean aneurysm diameter was 7.4 ± 2.3 cm.

Results: Technical success was 100%. From 1 to 4 (mean 3) renovisceral branch vessels were targeted with fenestrations. The mean length of in-hospital stay was 19 days (range 1-78). There was 1 death within 30 days and 2 further in-hospital deaths. Two patients suffered permanent spinal cord injury, 2 developed respiratory failure, and 2 had renal failure requiring temporary or permanent dialysis. No myocardial infarction, stroke, or bowel ischemia occurred. Six early endoleaks (3 type II and 3 minor type III) were detected. Mean follow-up was 11.2 months (range 2-33) in 17 patients. One late aneurysm-related death occurred. All 13 follow-up imaging studies showed patent target renovisceral vessels, with 1 type I and 2 type II endoleaks.

Conclusions: Sm-FBSG can be utilized for urgent treatment of complex abdominal and thoracoabdominal aortic pathologies in high-risk patients with anatomy unsuitable for commercially available stent-grafts.

Article review and analysis

Aim of this study: The authors analyzed the outcome of using “surgeon-modified fenestrated and branched stent grafts (sm-FBSG) in patients with symptomatic or rTAAA and PRAA. The creation of sm-FBSG occurs directly prior to surgery by modifying a commercially available aortic stent so that perfusion to the renal and visceral arteries is maintained through the fenestrations and/or branches.

Methods

Pros: This is a single-center experience which, in this case, limits the biases coming from the graft modification itself and, thereby, standardizes the technique. All patients were aware that the modification of available stent grafts is outside the instructions

for use and that modification potentially could affect durability of the stent-graft. CTA before treatment and at discharge was obligatory. There are clear definitions of technical success (successful stent graft deployment, revascularization of all intended vessels, and aneurysm exclusion), primary outcomes (30-day mortality, 30-days reintervention, and complications) and secondary outcomes (long-term survival, graft patency, late reintervention, and incidence of EL).

Cons: Retrospective analysis. The patient cohort is heterogeneous concerning the clinical presentation (symptomatic in eight and contained rupture in 11 patients). All patients with rupture were hemodynamically stable. The outcome of patients who were unstable and underwent open surgery for similar aortic pathology is not clear. It was a highly selected patient population. Aortic pathology and extension were also heterogeneous. The pararenal aortic segment was involved in ten patients and thoracoabdominal in 11 patients. Dominant aortic pathology was degenerative aneurysm (in 15 patients), followed by penetrating aortic ulcer (five patients), and false lumen aneurysm (one patient). There were five different stent grafts modified into sm-FBSG.

Results, conclusion, and what it means

Sixteen patients had a modification with three or four fenestrations, and four patients had only one fenestration. One patient received a modified t-branch with two directional branches for the superior mesenteric artery and celiac trunk. In total, 69 vessels were accessed with 58 fenestrations, 9 scallops and 2 directional branches. Technical success was 100%. There was a learning curve for the treatment of the 14 patients with four fenestrations: for the first seven procedures, the mean procedure time was 435 minutes (range 200-635), while for the second half this was 342 minutes (range 265-435). This points to the necessity that the centers who plan to use sm-FBSG for rupture TAAA need to gain experience with elective and symptomatic TAAA. 30-day mortality was 5%. One patient with a symptomatic pararenal aortic aneurysm had lower limb ischemia-reperfusion syndrome after a procedure longer than 6 hours. This case highlights the importance of maintaining the perfusion of the lower limbs through shorter procedure time, replacing a larger sheath with a smaller after main stent graft deployment, or use of some adjunctive as a sheath-shunt technique [1]. Two other patients died in-hospital: one died from sepsis and MOSF after sm-FBSG and gastrectomy for an aortogastric fistula. Another died from sepsis of unknown origin. These patients highlight the importance of the underlying diagnosis, the patient's general condition and perioperative and postoperative management. Spinal cord ischemia occurred in 9.5% (four patients); in two, the paralysis remained permanent. It is interesting that the authors have a clear procedure for when to use cerebrospinal fluid (CSF) drainage to prevent SCI. CSF drainage is strongly considered if there are two or more risk factors: more than 20cm planned coverage of thoracic aorta, previous infrarenal aortic repair, occlusion of the hypogastric or vertebral arteries or planned coverage of the left subclavian artery. The postoperative protocol includes permissive hypertension with MAP

80-90 mmHg, Hb >9g/dL and continuous neurological surveillance. Interestingly, some of these risk factors occurred during the procedure in patients developing SCI: in one patient, rupture of the iliac artery with prolonged hypotension and prolonged procedure. In another patient with moderate perioperative hypotension with an EF of 25%, an additional blood loss of 800 ml accentuated the SCI. Interestingly, the authors emphasized that, after this experience, they became more liberal with the use of CSF drainage in emergencies. On the other hand, intraspinal bleeding and hematoma, as well as infection, are the other side of coin. There was no major perioperative stroke or cardiac event. There were two early reinterventions: revascularization of the hypogastric artery in one patient with SCI resulted in complete recovery, and the use of a covered vascular stent to prevent late endoleak due to proximal infolding of the stent graft. This latter reintervention emphasizes the importance of intraoperative cone beam CT, while the former of immediate postoperative clinical examination and cessation of sedation in patients operated on under general anesthesia, to evaluate leg movements. Mean follow up was 11.2 months (range 2- 33) in 17 patients. In total, only 13 patients received CTA as follow up imaging, which leads to some caution in the assessment of the patency of the target vessels (all patent) and presence of endoleaks (only one type I). There was one late aneurysm-related death due to endoleak type Ia in a patient with mycotic contained rTAAA and new aortoenteric fistula. Besides a bowel resection, the treatment of endoleak was endovascular: chimney graft to extend proximal landing zone for subsequent TEVAR. This treatment highlights the importance of combining different endovascular techniques for the treatment of complex aortic pathologies, especially in situations of rTAAA. The conclusion of this paper, which we find adequate, is that despite the limitations, the use of surgeon-modified FBSG is a valuable alternative in selected high-risk patients requiring emergent treatment for rTAAA.

Comments and future research

We need larger cohorts and longer follow-up that will allow direct comparison between in-hospital outcomes in the custom-made SG and sm-FBSG groups. There should be more variety in off-the shelf fenestrated/branched stent grafts that will adjust to anatomical requirements in patients who are elective, but more importantly in patients with rTAAA. Finally, the durability of modifications of commercially available products needs to be assessed and should also include other alternatives, such as in-situ fenestration for the repair of these complex pathologies.

i Related important publications

Hanley SC, Neequaye SK, Steinmetz O, Obrand D, Mackenzie K, Abraham CZ. Sheath-shunt technique for avoiding lower limb ischemia during complex endovascular aneurysm repair. *J Vasc Surg.* 2015 Sep;62(3):762-6.

CHAPTER 16.

Endovascular treatment of ruptured Abdominal Aortic Aneurysm (rAAA)

Authors: *Offer Galili and Hashem Hayeq*

Introduction

Ruptured abdominal aortic aneurysm is a catastrophic event with a high mortality rate (approximately 50%) after conventional open surgical repair, despite improvements in surgical techniques and advances in intensive care support. Endovascular aneurysm repair (EVAR) has been established as the treatment of choice for planned AAA repair with reduced early morbidity and mortality compared to conventional open surgery. In light of the reduced physiological insult to the body compared to conventional open surgical repair, several trials have investigated whether emergency EVAR shows a significant improvement in outcomes over open surgical repair for patients with ruptured AAA. The accumulating data indicates that emergency EVAR is feasible with promising short and mid-term results and indeed can replace conventional open repair as the preferred treatment for this fatal condition.

In this chapter, we present five recent significant pivotal trials comparing EVAR with open surgical repair for ruptured AAA. We have assessed and analyzed the available evidence and evaluated the conclusions and clinical impact of the trials.

ARTICLE NUMBER 1

Five-year survival following endovascular repair of ruptured abdominal aortic aneurysms is improving.*J Vasc Surg.* 2020 Jul;72(1):105-113.e4.

Varkevisser RRB, Swerdlow NJ, de Guerre LEVM, Dansey K, Stangenberg L, Giles KA, Verhagen HJM, Schermerhorn ML; Society for Vascular Surgery Vascular Quality Initiative.

Abstract

Objective: Increasing experience and improving technology have led to the expansion of endovascular aneurysm repair (EVAR) for ruptured abdominal aortic aneurysms (AAA). We investigated whether the 5-year survival after both EVAR and open repair for ruptured AAA changed over the last 14 years.

Methods: We identified repairs for ruptured infrarenal AAA within the Vascular Quality Initiative registry between 2004 and 2018. We compared the 5-year survival of both EVAR and open repair between the early (2004-2012) and late (2013-2018) cohorts. In addition, we compared EVAR with open repair in the early and late cohorts. We used propensity score modeling to create matching cohorts for each analysis. Kaplan-Meier analysis was used to estimate survival proportions and univariate Cox proportional hazards analysis was used to compare differences in hazard of mortality in the matched cohorts.

Results: We identified 4638 ruptured AAA repairs. This included 409 EVARs in the early cohort and 2250 in the late cohort, as well as 558 open repairs in the early cohort and 1421 in the late cohort. Propensity matching resulted in 366 matched pairs of late vs early EVAR and 391 matched-pairs of late vs early open repair. When comparing EVAR with open repair, propensity matching resulted in 277 matched pairs of early EVAR versus open, and 1177 matched pairs of late EVAR versus open. In matched EVAR patients, 5-year survival was higher in the late cohort (63% vs 49%; hazard ratio [HR], 0.77; 95% confidence interval [CI], 0.61-0.97; $P = .027$), whereas there was no difference between matched late vs early for open repair patients (52% vs 59%; HR, 1.04; 95% CI, 0.85-1.28; $P = .69$). In the early cohort, there was no survival difference between EVAR and open repair (51% vs 46%; HR, 0.88; 95% CI, 0.69-1.11; $P = .28$). However, in the late cohort EVAR was associated with higher survival compared with open repair (63% vs 54%; HR, 0.69; 95% CI, 0.60-0.79; $P < .001$).

Conclusions: The 5-year survival after EVAR for ruptured AAA has improved over time, whereas survival after open repair remained constant. Consequently, the relative survival benefit of EVAR over open repair has increased over time, which should encourage further adoption of EVAR for ruptured AAA.

Article review and analysis

Aim of this study: With the increased use of EVAR for intact AAA, its application for ruptured AAA remains somewhat controversial, especially with regard to the long-term

survival after EVAR for ruptured AAA. This study investigates whether the 5-year survival after EVAR and open repair has improved over time as well as the difference in 5-year survival between the two approaches over time.

Methods

Pros: The data were originated from the SVS's Vascular Quality Initiative (VQI), comprising data from more than 550 centers, thus representing a real-world experience. Matching cohorts were used for each comparison using propensity score modeling in order to account for differences in baseline, anatomical and procedural characteristics.

Cons: It is a retrospective analysis that cannot adjust for the operators' decisions in real time. Furthermore, only survival is analyzed and there is no comparison of the rate of adverse events and its consequences after 5 years. Surveillance regimens and reinterventions, which may have a significant impact on survival of patients after treatment of ruptured AAA, were not investigated.

Results, conclusion, and what it means

Five-year survival following EVAR for ruptured AAA has improved for patients treated in the late cohort. Open repair demonstrated improved survival in the late cohort only when patients who did not survive the perioperative period were excluded. A survival advantage for EVAR versus open repair was significant only in the late cohort. In recent years, EVAR for ruptured AAA has had an improved mid-term and possibly long-term survival and an increasing survival benefit compared with open repair.

The results of this study, which are based on a wide and real-world database, join the results of the Immediate Management of Patient with Rupture: Open Versus Endovascular repair (IMPROVE) study, which found no difference in perioperative mortality for either approach, but a survival benefit at three year follow up. This novel finding of increased differences in survival between EVAR and open repair in recent years should encourage vascular surgeons to adopt and develop EVAR as a first line strategy for ruptured AAA.

Comments and future research

Further investigation should focus on the rate of reinterventions and adverse events, rather than mortality, and long-term consequences. An interesting and important aspect for clinical practice is the recommended surveillance regimen after treatment of ruptured AAA. The impact of surveillance on survival is not well investigated.

i Related important publications

IMPROVE Trial Investigators. Comparative clinical effectiveness and cost effectiveness of endovascular strategy v open repair for ruptured abdominal aortic aneurysm: three year results of the IMPROVE randomised trial. *BMJ*. 2017 Nov 14;359:j4859.

ARTICLE NUMBER 2

Meta-Analysis and Meta-Regression Analysis of Outcomes of Endovascular and Open Repair for Ruptured Abdominal Aortic Aneurysm.

Eur J Vasc Endovasc Surg. 2020 Mar;59(3):399-410.

Kontopodis N, Galanakis N, Antoniou SA, Tsetis D, Ioannou CV, Veith FJ, Powell JT, Antoniou GA.

Abstract

Objective: The aim was to assess peri-operative mortality of endovascular aneurysm repair (EVAR) vs. open repair for ruptured abdominal aortic aneurysm (AAA) and to investigate whether outcomes have improved over the years and whether there is an association between institutional caseload and peri-operative mortality.

Methods: Electronic information sources (MEDLINE, EMBASE, CINAHL and CENTRAL) were searched up to August 2019. A systematic review was carried out according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines using a registered protocol (CRD42018106084). Studies were selected that reported peri-operative mortality of EVAR for ruptured AAA. A proportion meta-analysis was conducted, and summary estimates of odds ratios (ORs) and 95% confidence intervals (CIs) for EVAR vs. open surgical repair were obtained using random effects models. Mixed effects regression models were developed to investigate outcome changes over time and with institutional caseload.

Results: One hundred and thirty-six studies were included in quantitative synthesis reporting a total of 267 259 patients (EVAR 58 273; open surgery 208 986). The pooled peri-operative mortality of EVAR and open surgical repair was 0.245 (95% CI 0.234-0.257) and 0.378 (95% CI 0.364-0.392), respectively. EVAR was associated with reduced peri-operative mortality (OR 0.54, 95% CI 0.51-0.57, $p < .001$). Meta-regression analysis found decreasing peri-operative mortality over the years following EVAR ($p < .001$) and open repair ($p < .001$), and a decreasing OR of peri-operative mortality in favor of EVAR ($p = .053$). Meta-regression found a significant positive association between peri-operative mortality and institutional case load for open repair ($p = .004$).

Conclusion: If EVAR can be done, it is a better treatment for ruptured AAA in view of the reduced peri-operative mortality compared with open surgery. The outcomes of both EVAR and open surgical repair have improved over the years, and the difference in peri-operative mortality in favor of EVAR has become more pronounced. There is a significant association between peri-operative mortality and institutional case load for open repair of ruptured AAA.

Article review and analysis

Aim of this study: The objective of this study was to assess and compare the peri-operative mortality of endovascular aneurysm repair (EVAR) vs. open repair for ruptured abdominal aortic aneurysm (AAA). Differences in mortality between the two treatment methods were also assessed over time and with regard to institutional caseload, as secondary objectives. These parameters may indicate the significance of operator and institutional experience on peri-operative mortality for ruptured AAA.

Methods

Pros: This study is a systematic review of the literature with meta-analysis of all observational and comparative studies of EVAR vs. open repair for ruptured AAA. The independence of the selection of studies and its assessment of consistency and the statistical analysis methods used addresses possible biases, such as heterogeneity between the included studies, publication biases etc. As an extensive systematic review with strong statistical analysis, the study provides information that reflects the real world and therefore can be applied in other hospitals.

Cons: The review of the literature and the inclusion of studies to this meta-analysis is based on the definition of ruptured AAA as a single entity. However, patients with ruptured AAA can present on a wide spectrum, from complete hemodynamic stability to severe instability with shock parameters. The degree of hemodynamic instability is directly related to the risk of mortality with a ruptured AAA, hence, addressing all ruptured AAA as a single entity opens the possibility for significant bias when analyzing the data.

Results, conclusion, and what it means

A total of one hundred and thirty-six studies (259 267) patients - EVAR 58 273 open surgery (208 986) were analyzed. EVAR had a significantly lower peri-operative mortality than open surgical repair (OR 0.54). As for the secondary objectives, meta-regression analysis found that peri-operative mortality had decreased over time for both EVAR and open repair for ruptured AAA ($p < .001$) for both. (Institutional caseload of EVAR had a nonsignificant association to peri-operative mortality after EVAR for ruptured AAA. In contrast, the association between perioperative mortality after open repair of ruptured AAA and institutional case load of open surgical repairs per year was significant, with centers performing more open procedures having superior results.

In spite of the different possible biases in a meta-analysis study, the current study's strength is its methods of study selection and statistical analysis. The conclusion, therefore, is well-supported: EVAR is a better treatment for ruptured AAA than open repair as it carries a lower perioperative mortality risk. Furthermore, EVAR's superiority over open repair for ruptured AAA has become more pronounced over the years.

Although EVAR is established as the treatment of choice for AAA, its application in a rupture scenario requires a well-trained surgical team and institutional system

availability. The current analysis supports the wider use of EVAR for the treatment of ruptured AAA and can help drive institutions to finance and support the availability of this important service.

Comments and future research

Anatomical factors (size of the AAA, length and angle of the aneurysm “neck”, etc.) as well as clinical factors (the patient’s age, comorbidities, hemodynamic stability at presentation etc.) may have a potential impact on the outcomes of EVAR or open surgery for ruptured AAA. Further research should focus on these aspects.

i Related important publications

Badger S, Forster R, Blair PH, Ellis P, Kee F, Harkin DW. Endovascular treatment for ruptured abdominal aortic aneurysm. *Cochrane Database Syst Rev.* 2017 May 26;5(5):CD005261.

Chaikof EL, Dalman RL, Eskandari MK, Jackson BM, Lee WA, Mansour MA, Mastracci TM, Mell M, Murad MH, Nguyen LL, Oderich GS, Patel MS, Schermerhorn ML, Starnes BW. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *J Vasc Surg.* 2018 Jan;67(1):2-77.e2.

Schermerhorn ML, Buck DB, O’Malley AJ, Curran T, McCallum JC, Darling J, Landon BE. Long-Term Outcomes of Abdominal Aortic Aneurysm in the Medicare Population. *N Engl J Med.* 2015 Jul 23;373(4):328-38.

ARTICLE NUMBER 3

Comparative clinical effectiveness and cost effectiveness of endovascular strategy v open repair for ruptured abdominal aortic aneurysm: three-year results of the IMPROVE randomized trial.

J BMJ. 2017 Nov 14;359:j4859.
IMPROVE Trial Investigators.

Abstract

Objective: To assess the three-year clinical outcomes and cost effectiveness of a strategy of endovascular repair (if aortic morphology is suitable, open repair if not) versus open repair for patients with suspected ruptured abdominal aortic aneurysm.

Methods: Design - Randomized controlled trial. Setting - 30 vascular centers (29 in UK, one in Canada), 2009-16. Participants - 613 eligible patients (480 men) with a clinical diagnosis of ruptured aneurysm, of whom 502 underwent emergency repair for rupture. Interventions - 316 patients were randomized to an endovascular strategy (275 with confirmed rupture) and 297 to open repair (261 with confirmed rupture). Main outcome measures - Mortality, with reinterventions after aneurysm repair, quality of life, and hospital costs to three years as secondary measures.

Results: The maximum follow-up for mortality was 7.1 years, with two patients in each group lost to follow-up by three years. After similar mortality by 90 days, in the mid-term (three months to three years) there were fewer deaths in the endovascular than the open repair group (hazard ratio 0.57, 95% confidence interval 0.36 to 0.90), leading to lower mortality at three years (48% v 56%), but by seven years mortality was about 60% in each group (hazard ratio 0.92, 0.75 to 1.13). Results for the 502 patients with repaired ruptures were more pronounced: three-year mortality was lower in the endovascular strategy group (42% v 54%; odds ratio 0.62, 0.43 to 0.88), but after seven years there was no clear difference between the groups (hazard ratio 0.86, 0.68 to 1.08). Reintervention rates up to three years were not significantly different between the randomized groups (hazard ratio 1.02, 0.79 to 1.32); the initial rapid rate of reinterventions was followed by a much slower mid-term reintervention rate in both groups. The early higher average quality of life in the endovascular strategy versus open repair group, coupled with the lower mortality at three years, led to a gain in average quality adjusted life years (QALYs) at three years of 0.17 (95% confidence interval 0.00 to 0.33). The endovascular strategy group spent fewer days in hospital and had lower average costs of -£2605 (95% confidence interval -£5966 to £702) (about €2813; \$3439). The probability that the endovascular strategy is cost effective was >90% at all levels of willingness to pay for a QALY gain.

Conclusions: At three years, compared with open repair, an endovascular strategy for suspected ruptured abdominal aortic aneurysm was associated with a survival

advantage, a gain in QALYs, similar levels of reintervention, and reduced costs, and this strategy was cost effective. These findings support the increasing use of an endovascular strategy, with wider availability of emergency endovascular repair.

Article review and analysis

Aim of this study: In light of controversial data regarding the survival benefit of endovascular treatment versus open surgical treatment for ruptured AAA, specifically the mid-term survival, it is difficult to initiate organizational changes in order to improve endovascular services for ruptured AAA. Hence, this study aims to investigate the hypothesis that EVAR strategy is both clinically effective and cost effective compared with open surgical repair.

Methods

Pros: The study was designed as a randomized multicentric trial. The central computer-generated randomization eliminates selection bias by the treating surgeons. It is the first randomized trial comparing EVAR to open surgical repair of ruptured AAA with comprehensive mid-term clinical outcomes as well as cost effectiveness.

Cons: The randomization of patients was carried out in the ER before CTA was performed, based on clinical diagnosis of ruptured AAA. Hence, up to 10% of patients had a different diagnosis and were excluded from the trial. Another consequence of this early randomization is that approximately 40% of the patients in the EVAR group had open repair (110/259 patients) and 13% of the patients in the open repair group had EVAR (33/243 patients). These cross-overs were due to unsuitable anatomy, unavailable endovascular team/equipment and the patient's medical condition. Therefore, analyses of the full trial cohort were performed on an intention to treat basis.

Results, conclusion, and what it means:

The EVAR strategy (EVAR as the intention to treat group) patients had a significantly lower mortality rate as well as better quality of life at the midterm follow up (three years). This advantage was achieved without higher reintervention rate during the follow-up and with a significant decrease in the overall cost of treatment. This advantage in the mid-term results may be explained by the lower physiological burden of an endovascular approach compared to open surgical repair. Patients with ruptured AAA die early due to hemorrhagic shock and cardiovascular collapse, regardless of the treatment. Periprocedural coronary events, acute renal failure and respiratory complications involve long-term consequences that may increase mortality in the mid-term follow-up period.

Comments and future research

Improved mid-term survival and, no less important, the lower costs of EVAR provide support for adoption of an endovascular first strategy for patients with ruptured AAA.

ARTICLE NUMBER 4

Contemporary outcomes for ruptured abdominal aortic aneurysms using endovascular balloon control for hypotension.

J Vasc Surg. 2018 May;67(5):1389-1396.

Bath J, Leite JO, Rahimi M, Giglia J, Jain A, Shelton K, Meier GH.

Abstract

Objective: Ruptured abdominal aortic aneurysm (rAAA) continues to portend significant mortality, despite ruptured endovascular aneurysm repair (rEVAR), enhanced perioperative care, and endovascular balloon control (EBC) for hypotension. We review our academic institution's experience using a protocol of EBC for all hypotensive patients, irrespective of type of repair.

Methods: A retrospective review was conducted of 66 cases of rAAA treated at a single academic institution from 2007 to 2016 using EBC for hypotensive patients. Demographics, comorbidities, intraoperative parameters, and clinical outcomes were recorded. Patients were studied with respect to hemodynamic status, rEVAR, or ruptured open aortic repair in the setting of EBC for hypotension.

Results: rEVAR was performed in 43 patients (65%) and ruptured open aortic repair in 23 patients (35%). rAAA was treated in 51 men (77%). Mean rAAA size was 7.6 mm, and mean age of the patients was 73 years. Perioperative survival was 82%. Overall survival at 30 days, 1 year, and 5 years was 71%, 65%, and 52%. Blood transfusion and severe hypotension were significant predictors of mortality at 30 days on multivariable analysis (odds ratio of 1.2 [P = .08] and 39 [P = .03], respectively). Severe hypotension was defined as a mean arterial blood pressure <65 mm Hg and vasopressor use and was present in 59% of the cohort. Normotension was defined as an absence of these conditions and was present in 12%, with 29% of patients exhibiting moderate hypotension. There was no difference in 30-day survival between normotensive and moderately hypotensive patients. The 30-day survival for severely hypotensive patients was 61% vs 85% for moderately hypotensive patients (P = .003), with a significant difference between groups that persisted at 1 year (85% vs 51%; P = .008) and 5 years (66% vs 51%; P = .017).

Conclusions: Good midterm outcomes for moderately hypotensive and normotensive patients can be obtained using an EBC protocol for hypotension with a regionalized transport system directly to the operating room. Severely hemodynamically unstable rAAA patients still pose a significant challenge despite mitigation of hypotension by EBC, suggesting that survival may be compromised by factors other than hypotension alone. We still advocate for the use of EBC for all hypotensive patients as part of a defined rAAA protocol before definitive repair.

Article review and analysis

Aim of this study: Ruptured abdominal aortic aneurysm (rAAA) remains one of the most challenging clinical and technical scenarios in vascular surgery. Hypotension and hemodynamic instability as manifestations of massive bleeding from a ruptured aneurysm are the most acute and urgent issues to manage in such cases. Bath et al. present a retrospective study of patients with ruptured aortic aneurysm with hypotension being treated with Endovascular Balloon Control (EBC).

Of utmost importance for this review is the implementation of a standardized protocol to which they adhered, providing a common platform for surgeons to follow.

Methods

Pros: The study reviewed cases treated at a single center thus adherence of the surgeons to the protocol and accustomed supporting staff and technicians are more likely. The clarity of the definition of severe or moderate hypotension also supports the validity and implementation of the protocol.

The study included 66 patients who had been treated with EBC for hypotension, with clear differentiations in the degree of hypotension. The technique is clarified in the protocol and doing so provides a more uniform treatment.

Cons: Although the indications for activating the EBC protocol are clear, it is unclear how many intra-aortic balloons were in fact inflated during the cases since the protocol states that inflation of the balloon was at the surgeon's discretion. This poses the question of the presumed benefit of EBC, since the study lacks this information and, furthermore, raises the question of whether EBC was needed in some patients, especially for those with blood pressure between 65 mmHg and 90 mmHg.

The study does not provide a clear comparison between endovascular and open aortic occlusion for hypotension.

Results, conclusion, and what it means

The results show positive outcomes; overall survival for the entire cohort at 30 days, 1 year, and 5 years was 71%, 65%, and 52%, respectively.

The authors attribute these good results to the expeditious use of EBC for rAAA patients with hypotension. As expected, the study also shows a significant decrease in survival for patients who presented with severe hypotension. This decrease in survival is maintained at 30 days, 1 year and 5 years, portraying a 39 times risk of mortality compared to patients without severe hypotension. The need for blood transfusions also predicted an increased mortality rate, with a 20% increase after each unit of blood.

Comments and future research

Endovascular balloon control for rAAA is a growing concept and is being adopted at multiple centers since the limited trials available are reporting positive outcomes.

One must also note the difference between REBOA for trauma and balloon control for rAAA, as there are multiple differences. These are notably, the experience of vascular surgeons in endovascular techniques and the presumed decreased duration of balloon inflation in rAAA patients in which EBC is used to directly control the bleeding site, compared to multi-trauma patients in which REBOA is used for maintaining blood pressure for multiple bleeding sites.

ARTICLE NUMBER 5

Endovascular repair of ruptured abdominal aortic aneurysm is superior to open repair: Propensity-matched analysis in the Vascular Quality Initiative.*J Vasc Surg.* 2020 Aug;72(2):498-507.

Wang LJ, Locham S, Al-Nouri O, Eagleton MJ, Clouse WD, Malas MB.

Abstract

Objective: The few randomized trials comparing endovascular with open surgical repair of ruptured abdominal aortic aneurysm (rAAA) were poorly designed and heavily criticized. The short-term and midterm survival advantages of endovascular repair remain unclear. We sought to compare the two treatment modalities using a propensity-matched analysis in a real-world setting.

Methods: All ruptured cases of open surgical repair (rOSR) and endovascular aneurysm repair (rEVAR) in the Vascular Quality Initiative were analyzed (2003-2018). Raw and propensity-matched rEVAR and rOSR cohorts were compared. Primary and secondary outcomes included postoperative major adverse events (cardiovascular, pulmonary, renal, bowel or limb ischemia, reoperation) and 30-day and 1-year mortality. Univariate, multivariate, and Kaplan-Meier analyses were performed.

Results: There were 4929 rAAA repairs performed, 2749 rEVAR and 2180 rOSR. Compared with rEVAR patients, rOSR patients had higher rates of myocardial ischemic events (15% vs 10%; $P < .001$), major adverse events (67% vs 37%; $P < .001$), and 30-day death (34% vs 21%; $P < .001$). On adjusted analysis, rOSR was predictive of 30-day mortality (odds ratio, 1.8; 95% confidence interval, 1.5-2.2). After 1:1 matching, the study cohort consisted of 724 pairs of rOSR and rEVAR. The rOSR patients had twice the length of stay (median, 10 days [interquartile range, 5-19 days] vs 5 days [interquartile range, 3-10 days]; $P < .001$). Univariate analysis demonstrated persistent increased 30-day mortality after rOSR (32% vs 18%; $P < .001$) and higher rates of myocardial infarction (14% rOSR vs 8% rEVAR; $P = .002$), respiratory complications (38% vs 20%; $P < .001$), and acute kidney injury (42% vs 26%; $P < .001$). Overall major adverse event rate was higher after rOSR (68% vs 35%; $P < .001$). Multivariable regression analysis of the propensity-matched pairs demonstrated that rOSR was associated with double the 30-day mortality compared with rEVAR (odds ratio, 2.0; 95% confidence interval, 1.6-2.7). All-cause 1-year survival was 73% and 59% after rEVAR and rOSR in the propensity-matched cohort, respectively ($P < .001$).

Conclusions: This is one of the largest studies of rAAA demonstrating clear short-term and midterm survival benefits of rEVAR over rOSR that persisted after matching on all major demographic, comorbid, and anatomic variables. Furthermore, patients who survived rOSR had twice the length of stay with increased rates of complications compared with rEVAR patients. These data suggest a more aggressive endovascular approach for rAAA in patients with suitable anatomy.

Article review and analysis

Aim of this study: The debate about whether open surgical (rOSR) or endovascular repair (rEVAR) is better for ruptured abdominal aortic aneurysm (rAAA) is still ongoing. Multiple studies, including 3 big RCT, have previously addressed this issue with most concluding no major difference in outcomes between the 2 modalities. This study aims to better clarify the benefits of rEVAR using propensity-matched analysis in a contemporary, real-world setting.

Methods

Pros: A very large number of patients are included in the study. The data were collected from the Vascular Quality Initiative from 2003 through 2018. Most centers involved contributed to both the rOSR and rEVAR arms. From a technical point of view, there are clear delineations of certain anatomical factors in addition to demographic and clinical data.

Cons: Although the study offers results after propensity matching and states the results of propensity matched and unmatched groups, a major variable lies in the very large number of centers contributing to the database. Different levels of expertise at different centers could play a role in these cases.

Results, conclusion, and what it means

The results of this study show improved outcomes after rEVAR. It also states that rOSR is a significant risk factor for mortality. This poses a debate since patients who are occasionally treated with rOSR have worse preoperative conditions, are unsuitable for EVAR, and are infrequently hypotensive. Both morbidity and mortality are reported to favor rEVAR and, in such a large study, these results make a strong argument for endovascular treatment.

A lot of factors contribute to these results and one may tend to discard results that are clear based on a debated issue. However, perhaps a more endo-oriented approach to rAAA should be adopted at least in endo-oriented and equipped centers.

Comments and future research

With rAAA patients suffering from blood loss, perhaps the value of the endovascular approach in minimizing the unintentional yet inevitable blood loss is of great value and endovascular balloon occlusion of the aorta is of paramount importance in these cases. Many limitations, such as surgeon preferences, institutional capabilities and possibly ethical issues, are at times major factors in impeding the conducting of randomized controlled trials in rAAA cases. As such, this trials offers a good insight of how important a role rEVAR is playing and one that will probably increase with such favorable outcomes.

CHAPTER 17.

Embolization of non-traumatic bleeding

Authors: Anna Maria Ierardi, Elvira Stellato, Silvia Tortora and Gianpaolo Carrafiello

Introduction

Spontaneous hematoma (SH) is defined as bleeding without associated trauma, specific organ or vessel pathology (e.g., ruptured aortic or splenic artery aneurysm), or iatrogenic manipulation¹. It is characterized by a high morbidity and mortality rate due to the unspecific clinical presentation, causing diagnostic delay². Rapid blood loss without tamponade and hemorrhagic shock or complications such as compartment syndrome worsen the prognosis¹. High-risk patients are those receiving anticoagulation/antiplatelet medications or a combination of both¹. The most common sites of anticoagulant-related hemorrhage are in order of occurrence soft tissues, and the gastrointestinal and urinary tracts³.

In the past, SH was mainly managed using a conservative approach. The choice was based on the idea that a microangiopathy was the physiopathological process underlying the spontaneous bleeding. Nowadays, the approach is patient-based and transarterial embolization (TEA) is establishing itself as a valid therapeutic strategy⁴. TAE is recommended in a variety of traumatic and non-traumatic bleeding conditions, such as hemoptysis⁵, tumors^{6,7}, and iatrogenic lesions⁸.

The role of TAE in the management of patients with spontaneous bleeding is not well defined and there are no validated guidelines. Moreover, even if several studies show the efficacy and safety of TAE, this evidence is limited to retrospective studies, often monocentric and with a small sample size. Large prospective studies and/or randomized case-control studies, comparing embolization to conservative management in hemodynamically stable patients or comparing embolization to surgical intervention, are limited⁴.

In the following chapter, we are going to present an analysis of selected articles with the aims of evaluating the safety and efficacy of TAE in spontaneous bleedings; investigating the risk factors associated with the procedure and the predictors of negative outcomes; and proposing an algorithm for managing patients with SH.

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ARTICLE NUMBER 1

Multicenter retrospective study of transcatheter arterial embolisation for life-threatening haemorrhage in patients with uncorrected bleeding diathesis.

CVIR Endovasc. 2020 Dec 10;3(1):95.

Spiliopoulos S, Katsanos K, Paraskevopoulos I, Mariappan M, Festas G, Kitrou P, Papageorgiou C, Reppas L, Palialexis K, Karnabatidis D, Brontzos E.

Abstract

Background: We retrospectively investigated outcomes of emergency TAE for the management of life-threatening haemorrhage in patients with uncorrected bleeding diathesis.

Materials and methods: This multicenter, retrospective, study, was designed to investigate the safety and efficacy of percutaneous TAE for the management of life-threatening haemorrhage in patients with uncorrected bleeding disorder at the time of embolization. All consecutive patients with uncorrected coagulation who underwent TAE for the treatment of haemorrhage, between January 1st and December 31st 2019 in three European centers were included. Inclusion criteria were thrombocytopenia (platelet count < 50,000/mL) and/or International Normalized Ratio (INR) ≥ 2.0, and/or activated partial thromboplastin time (aPTT) > 45 s, and/or a pre-existing underlying blood-clotting disorder such as factor VIII, Von Willebrand disease, hepatic cirrhosis with abnormal liver function tests. Primary outcome measures were technical success, rebleeding rate and clinical success. Secondary outcome measures included patients' 30-day survival rate, and procedure-related complications.

Results: In total, 134 patients underwent TAE for bleeding control. A subgroup of 17 patients with 18 procedures [11 female, mean age 70.5 ± 15 years] which represent 12.7% of the total number of patients, presented with pathological coagulation parameters at the time of TAE (haemophilia n = 3, thrombocytopenia n = 1, cirrhosis n = 5, anticoagulants n = 7, secondary to bleeding n = 1) and were analyzed. Technical success was 100%, as in all procedures the bleeding site was detected and successfully embolised. Clinical success was 100%, as none of the patients died of bleeding during hospitalization, nor was surgically treated for bleeding relapse. Only one rebleeding case was noted (5.9%) that was successfully treated with a second TAE. No procedure-related complications were noted. According to Kaplan-Meier analysis the estimated 30-day survival rate was 84.2%.

Conclusion: TAE in selected patients with uncorrected bleeding diathesis should be considered as a suitable individualized management approach. Emergency TAE for life threatening haemorrhage in patients with coagulation cascade disorders should be used as an aid in realistic clinical decision making.

Article review and analysis

Aim of this study: This study aimed to investigate the safety and efficacy of percutaneous transcatheter arterial embolization (TAE) in the management of life-threatening hemorrhage in patients with uncorrected bleeding disorder at the time of embolization.

The primary outcome measures were technical success, defined as occlusion of bleeding site(s) with no signs of bleeding at completion of a Digital Subtraction Angiography (DSA); recurrent hemorrhage rate defined as relapse of bleeding at the same site following successful TAE; reintervention rate due to recurrent hemorrhage, and clinical success defined as the absence of bleeding-related death during hospitalization. Secondary outcome measures were patients' 30-day survival rate, rebleeding rate compared to that of patients without deranged coagulation at the time of embolization, and procedure-related complications, classified according to the CIRSE 6-grade classification system.

Methods

Pros: An important strength of this study is its multicentricity; the analysis of the data relating to the treated patients was carried out in 3 different tertiary European vascular centers.

Cons: Limitations of the study include: possible selection bias in relationship to the retrospective design; relatively small number of patients included; loss of cases discussed by multidisciplinary team for TAE but who underwent endoscopy or surgery; absence of comparative control group; absence of comparative data of rebleeding rate with the group of patients demonstrating normal coagulation profile that could be confounded by significant heterogeneity; additional conservative treatments given to patients may have increased procedural and clinical success but the study design did not allow for the assessment of the contribution of such factors to the study outcome measures.

Results, conclusion, and what it means

In clinical practice, many interventional radiologists refuse TAE for patients with uncorrected bleeding parameters; in 2019 the Society of Interventional Radiology (SIR) recommended arterial puncture $\leq 6\text{Fr}$ and embolotherapy for patients presenting with INR values between 2 and 3, and PLTs $< 50,000/\mu\text{L}$, but with no solid scientific evidence.

There are no specific recommendations for the management of bleeding diathesis prior, during, and after TAE for hemorrhage control requiring rapid decision making and intervention.

In this study, the authors selected 17 patients with uncorrected coagulation disorder at the time of embolization (PLTs $< 50,000/\mu\text{L}$ and/or INR > 2 and/or aPTT $> 45\text{s}$ and/or underlying clotting disorder) and they used 2.6 or 2.7 F microcatheters for superselective catheterization of the site of bleeding. They obtained a technical and clinical successful rate of 100% (even though they describe a rebleeding case) that proves the effectiveness and safety of TAE in the management of life-threatening hemorrhage in patients with uncorrected bleeding disorder.

The authors highlight the importance of the collaboration of the multidisciplinary team in the clinical and therapeutic management of the patients and the importance of not delaying the TAE to wait for the restoration of the correct coagulation parameters.

Comments and future research

Further studies are needed in order to better define indications for TAE in patients with uncorrected bleeding diathesis.

It could be interesting to do a comparative study with a control group of patients with normal coagulation parameters.

Related important publications

Please see the end of the chapter.

ARTICLE NUMBER 2

Predictors of Mortality from Spontaneous Soft-Tissue Hematomas in a Large Multicenter Cohort Who Underwent Percutaneous Transarterial Embolization.

Radiology. 2019 Apr;291(1):250-258.

Barral M, Pellerin O, Tran VT, Gallix B, Boucher LM, Valenti D, Sapoval M, Soyer P, Dohan A.

Abstract

Purpose: To evaluate the safety and efficacy of percutaneous transarterial embolization (PTAE) for the treatment of spontaneous soft-tissue hematomas (SSTHs) and identify variables predictive of short-term outcome.

Materials and Methods: Between 2011 and 2017, the outcome was retrospectively analyzed for 112 patients (mean age 6 standard deviation, 72 years 6 14; range, 28–92 years), including 65 women (mean age, 73 years 6 12.7; range, 39–92 years) and 47 men (mean age, 70 years 6 14.9; range, 28–91 years), with SSTH treated with PTAE. Thirty-day mortality, technical and clinical success, simplified acute physiology score (SAPS) II, anticoagulation, embolic agent, hematoma volume and location, serum hemoglobin level, hemodynamic instability, and presence of active bleeding at CT and/or angiography were recorded. Clinical success was defined as cessation of bleeding as determined by hemodynamic stability and/or serum hemoglobin level stabilization after PTAE. Univariable and multivariable analyses were performed by using a Cox model to identify variables associated with time to death.

Results: Mortality rate was 26.8% (30 of 112 patients), angiographic success rate was 95.5% (107 of 112 patients), and clinical success rate was 83% (93 of 112 patients). For surviving patients, mean SAPS II was 19.6 6 7.1 (range, 13–31) and mean hematoma volume was 862 cm³ 6 618 (range, 238–1887 cm³). For deceased patients, mean SAPS II was 42 6 13.2 (range, 18–63) and mean hematoma volume was 1419 cm³ 6 788 (range, 251–3492 cm³). SAPS II ($P = .001$), hematoma volume ($P = .01$), and retroperitoneal location ($P = .01$) were independently associated with fatal outcome.

Conclusions: Percutaneous transarterial embolization is effective for the emergency treatment of spontaneous soft-tissue hematomas. Simplified acute physiology score II, hematoma volume, and retroperitoneal location are predictors of short-term outcome.

Article review and analysis

Aim of this study: The aims of this study were to evaluate the safety and efficacy of PTAE for the treatment of SSTH in a large multicenter cohort and to identify variables that may be used as predictors of short-term outcome.

The primary clinical outcome was defined as the survival of the patient 30 days after PTAE. The secondary outcome was immediate clinical success determined by

hemodynamic and/or serum hemoglobin level stabilization (i.e., a decrease of 1 g/dL of hemoglobin serum level from baseline value) less than 3 hours after PTAE.

Methods

Pros: The important strengths of this study are its multicentricity and the large number of enrolled patients (n: 112).

The multivariable analysis proves that peritoneal location, large hematoma volume, and high SAPS II are associated with poorer outcomes.

Cons: Limitations of the study include: retrospective analysis of radiologic and clinical files; absence of a control group of patients with SSTH who did not undergo PTAE; no stratification of patients who could benefit most from PTAE; and it does not evaluate if early PTAE could improve patient outcome.

Results, conclusion, and what it means

The study reported an immediate technical and clinical success rate of 96% and 86%, respectively, which is in agreement with the current literature. The authors underlined the high mortality rate after 30 days from PTAE (27%) of patients with worse general clinical conditions (higher SAPS II, hemodynamic instability, and large hematoma volume). Important new data is the correlation between the location of the hematoma and the risk of death; in fact 73% of patients who died after 30 days had a retroperitoneal hematoma. This suggests that retroperitoneal hematomas are more difficult to treat. The results of the multivariate analysis performed in this study suggest that retroperitoneal localization, large hematoma volume, and high SAPS II values are associated with worse outcome. In this study, active bleeding was more frequently seen on CT than on angiography (88% vs 70%), which confirms that arterial phase CT should be performed before PTAE.

Comments and future research

As the authors have already suggested, it could be interesting do a prospective controlled study randomizing patients with SSTH according to their SAPS II, hematoma volume at CT, and retroperitoneal location to investigate the actual benefit of PTAE.

Related important publications

Please see the end of the chapter.

ARTICLE NUMBER 3

Spontaneous Intramuscular Hematomas of the Abdomen and Pelvis: A New Multilevel Algorithm to Direct Transarterial Embolization and Patient Management.

Cardiovasc Intervent Radiol. 2017 Apr;40(4):537-545.

Popov M, Sotiriadis C, Gay F, Jouannic AM, Lachenal Y, Hajdu SD, Doenz F, Qanadli SD.

Abstract

Purpose: To report our experience using a multilevel patient management algorithm to direct transarterial embolization (TAE) in managing spontaneous intramuscular hematoma (SIMH).

Materials and Methods: From May 2006 to January 2014, twenty-seven patients with SIMH had been referred for TAE to our Radiology department. Clinical status and coagulation characteristics of the patients are analyzed. An algorithm integrating CT findings is suggested to manage SIMH. Patients were classified into three groups: Type I, SIMH with no active bleeding (AB); Type II, SIMH with AB and no muscular fascia rupture (MFR); and Type III, SIMH with MFR and AB. Type II is furthermore subcategorized as IIa, IIb and IIc. Types IIb, IIc and III were considered for TAE. The method of embolization as well as the material been used are described. Continuous variables are presented as mean $\pm$ SD. Categorical variables are reported as percentages. Technical success, clinical success, complications and 30-day mortality (d30 M) were analyzed.

Results Two patients (7.5%) had Type IIb, four (15%) Type IIc and 21 (77.5%) presented Type III. The detailed CT and CTA findings, embolization procedure and materials used are described. Technical success was 96% with a complication rate of 4%. Clinical success was 88%. The bleeding-related thirty-day mortality was 15% (all with Type III). **Conclusion** TAE is a safe and efficient technique to control bleeding that should be considered in selected SIMH as soon as possible. The proposed algorithm integrating CT features provides a comprehensive chart to select patients for TAE.

Article review and analysis

Aim of this study: In this study, the authors report their experience using a model for patient management based on the patient's clinical condition, CT findings, presence of ACT, and the degree of dependence on ACT as well as the presence of associated coagulopathy. The safety and efficacy of TAE in the selected population were evaluated.

Methods

Pros: The strength of this article is the attempt to outline an algorithm, integrating CT findings that lead to a CT-based classification that seems to be useful for selecting patients and directing TAE procedures.

Cons: Limitations of the study include: the retrospective design of the study; the

relatively small number of patients included (SIMH remains a rare condition and only a small number are potential candidates for TAE even with their extended indication); and the absence of a comparative control group.

Results, conclusion, and what it means

In this study spontaneous intramuscular hematomas are classified into 3 groups in relation to CT characteristics (active or not bleeding) and clinical and laboratory data:

-Type I: spontaneous intramuscular hematoma with no active bleeding and hemodynamically stable patient

-Type II: spontaneous intramuscular hematoma with active bleeding and no muscular fascia rupture

-Type III: spontaneous intramuscular hematoma with active bleeding and muscular fascia rupture overlying the bleeding muscle and extending into the surrounding soft tissue (with or without coagulation dysfunction).

Type II is subcategorized into: type IIa if there is no contraindication to discontinue anticoagulant therapy; type IIb if there is a contraindication to stop anticoagulant therapy; type IIc if not related to anticoagulation or antiplatelet therapy. As there are no clear guidelines on the treatment of spontaneous intramuscular hematomas, hemodynamically stable patients are treated with conservative therapy, and hemodynamically unstable patients are treated surgically or with TAE.

The authors proposed a hematoma treatment algorithm; in particular types IIb, IIc and III are treated with TAE, especially in type III with complete rupture of the muscle fascia, due to massive bleeding and high mortality rate (29%), which should be treated with TAE immediately. For type II, conservative treatment can be adopted judiciously and by carefully monitoring the vital parameters; however, in patients in whom there is a contraindication to stopping the anticoagulant therapy (IIb) or in patients with spontaneous coagulopathy (IIc), TAE should be considered as soon as possible. The clinical success rate in the study was 96% and a 30-day mortality rate of approximately 30% is reported, which is accordance with the literature. The mortality rate was higher in patients requiring TAE in more than 2 arterial territories.

Comments and future research

Over a relatively long period of time, almost 8 years (May 2006 - January 2014), a limited number of patients were selected. The relatively limited number of patients reiterates that spontaneous intramuscular hematoma remains a rare condition and only a small number are potential candidates for TAE, even with the extended indications suggested. However, larger series are required to confirm the concept and better establish the value and the role of TAE in spontaneous intramuscular hematomas.

Related important publications

Please see the end of the chapter.

ARTICLE NUMBER 4

Transcatheter Arterial Embolization of Spontaneous Soft Tissue Hematomas: A Systematic Review.*Cardiovasc Intervent Radiol.* 2019 Mar;42(3):335-343.

Touma L, Cohen S, Cassinotto C, Reinhold C, Barkun A, Tran VT, Banon O, Valenti D, Gallix B, Dohan A.

Abstract

Background: Severe spontaneous soft tissue hematomas (SSTH) are usually treated with transcatheter arterial embolization (TAE) although only limited retrospective studies exist evaluating this treatment option. The aim of this study was to systematically assess the efficacy and safety of TAE for the management of SSTH.

Methods: Medline, EMBASE, PubMed and Cochrane Library were searched from inception to July 2017 using MeSH headings and a combination of keywords. Eligibility was restricted to original studies with patients suffering from SSTH treated with TAE. Patients with traumatic hematomas or who were treated with solely conservative or surgical management were excluded. For each publication, clinical success based on the control of the bleed, rebleeding rates and complications (including mortality) was collected, as well as technical details.

Results: Sixty-three studies met the inclusion criteria, with an aggregate total of 267 patients. Follow-up extended from 1 day to 10 years. Bleeding was mainly localized to the iliopsoas (n = 113/267, 42.3%) and anterior abdominal wall (n = 145/266, 54.7%). When information was available, 81.0% (n = 158/195) of patients were on anticoagulant therapy prior to the bleeding episode. Initial stabilization with control of the bleed was obtained in 93.1% (n = 242 patients, n = 60 studies). The most common embolic materials were coils (n = 129, 54.4%). Rebleeding was reported in 25 patients (9.4%). Only two embolization complications were reported (0.7%). The 30-day mortality was 22.7% (n = 42/185).

Conclusion: TAE represents a safe and effective procedure in the management of SSTH. We present a management algorithm based on these data, but further studies are needed to address the knowledge gap.

Article review and analysis

Aim of this study: The primary aim of this review was to investigate the efficacy and safety of TAE in SSTH. The secondary objectives were to compare Computed Tomography Angiography (CTA) and DSA results, to verify a correlation between embolization materials used and outcomes, and to evaluate the rate of recurrence and mortality of SSTH treated with TAE. Authors present a management algorithm based on these data.

Methods

Pros: Considering that there are almost only case reports and original articles with small sample size available to investigate the efficiency and safety of TAE in SSTH, this review will try to synthesize and confirm the results so far reported. The authors tried to compensate for the absence of validated guidelines proposing a structured management algorithm based on the literature.

Cons: All publications included in these reviews are of poor methodological quality, being of a retrospective nature and having small study samples. Further, only one article was found that compared TAE to alternative management.

In order to optimize a diagnostic and therapeutic protocol for patients with SSTH, it would be interesting to study all patients with SSTH rather than exclude patients who were treated solely with conservative or surgical management.

The authors underlined that the studies had a high risk of bias assessed by the Quality Rating Scheme from Oxford Centre for Evidence-based Medicine.

The heterogeneity of the reported data in each study did not allow a mathematical meta-analysis to be performed.

Many data were missed in the articles analyzed, such as the anticoagulation status, hemodynamic status, localization of recurrences, a report of non-severe complications and the embolization materials used. This required the authors to focus on a very small sample to achieve some of the objectives of the article. In many articles, similar outcomes were studied in different ways and on different timescales.

The authors considered several locations of bleeding in the same patient as being different bleeding occurring in a different patient: this method may create bias in the final considerations.

Results, conclusion, and what it means

This review validated the results reported by previous studies on SSTH: TAE is a safe and effective treatment for SSTH; clinical success was achieved in 93.1% (n=242) of patients and a low rate of complications (0.7%) was registered.

SSTH has a high mortality rate, confirming that it can be a life-threatening condition, with an all-cause 30-day mortality rate of 22.7% (n=42/185) and with a mortality rate of 50% among patients with recurrences (n=8/16).

The most common sites of SSTH were the iliopsoas muscle (42.3%; n = 113/267) and the anterior abdominal wall (54.7%; n=146/267). SSTH has a high rate of recurrence (9.4%; n=25/267) in different sites, with only one third of recurrences being in the same primary site (33%; n=3/9). 92.9% of the patients were under anticoagulation therapy (n = 13/14), underlying the elevated risk for subjects that cannot undergo reversal of anticoagulation (e.g., in patients with prosthetic heart valves). Re-embolization is an effective procedure with clinical success achieved in 75% of cases (n = 15/20).

The embolization materials used were coils alone (30.7%, n=73/238), glue alone (n =

43, 18.1%), gelfoam alone (n = 39, 16.4%) and microparticles alone (n = 14, 6.0%).

Note that no correlation seems to emerge between recurrences and the choice of embolization agent: gelfoam alone (n=5/25, 7%), gelfoam with coils (n=3, 21.4%), coils alone (n = 4, 28.6%) and glue alone (n=2, 14.3%). As such, even if the authors' purpose was to identify the optimal embolic agent, it is not possible to reach a final conclusion; they suggest the use of the material the operator is most familiar with and with which non-selective embolization is least likely. Not by chance, the most used agents were coils; this choice is probably based on its permanent embolic action and its safety, given their less likely migration compared to glue and particles.

Among stable patients who were known to have CTA prior to embolization, active bleeding was reported on CTA in 23 patients (n=23/56). These data suggest that active bleeding on CTA may help patient management even in hemodynamic stable patients. However, a bleeding artery was identified in only 47.7% of patients.

Interestingly, DSA was able to detect a larger number of cases of active bleeding from a specific vessel, reported on DSA in 85.6% (n = 220/257) of patients and on CTA in 47.7%(n=63/254), but it must be noted that this comparison was made on two different groups of patients. Moreover, active bleeding was detected in 45 stable patients on DSA and only in 23 of those on CTA. When both imaging modalities were concordant (84.4%, n=38/45), additional bleeding vessels were identified on DSA in 23.7% of this subgroup of patients. The reported higher sensibility of DSA than CTA for active bleeding detection is in contrast with the previous evidence, such as in gastrointestinal bleedings. The authors advocated that this lower CTA sensibility could be explained by the intermittent nature of the bleeding and the risk of re-bleeding after initial stabilization. Apart from the comparison between DSA and CTA, these results suggest that the decision to perform a TAE in clinical practice is not only based on the CTA detection of active bleeding in stable patients, but also on other clinical and CTA findings.

The authors proposed a management algorithm based on the data described above or reported in the studies analyzed. They defined the TAE indications that are discussed in a multidisciplinary team. They took into account clinical presentation, comorbidities and CTA findings. TAE is always performed in unstable patients. While, in hemodynamically stable patients, TAE is performed only in cases of positive CTA, namely: 1. active bleeding; 2. rupture of retroperitoneal fascia or abdominal wall with hemoperitoneum; 3. retroperitoneal localization of hematoma (as it seems more severe than rectus sheath or other localizations 4. hematoma volume; and 5. patient comorbidities (valve prosthesis requiring continued anticoagulant therapy, age and renal failure).

Comments and future research

It would be interesting to investigate the practical application of the study management algorithm and its potential impact on patient outcomes.

All the conclusions so far reported are based on retrospective and mostly monocentric studies conducted in small samples. Multicentric and larger studies are needed

to design diagnostic and therapeutic guidelines for patients with spontaneous SSH, and to identify positive and negative predictive factors. Multicentric and prospective studies are necessary to:

- Assess TAE and patient management in different clinical scenarios through multicentric case-control randomized trials. Considering that the reported studies, although of low methodological quality, argue for the efficacy and safety of TAE for patients with severe bleeding or hemodynamic instability requiring transfusion, it would be unethical to enrol these patients in such a trial. However, in patients who are hemodynamically stable and not requiring transfusion, the efficiency of TAE versus conservative management is still doubtful and predictive factors are not yet well-defined. These patients, with a less severe clinical presentation, could be the subjects of a randomized trial.
- Investigate TAE efficacy and safety on a more homogeneous sample, such as by only selecting patients who are or are not under anticoagulant therapy, or investigating just one localization of SSSH.
- Evaluate the diagnostic efficacy of CTA in identifying active bleeding in SSSH, comparing its performance with the DSA findings.
- Identify CTA findings related to poor outcomes in SSSH and, eventually, set a scale of severity in order to set a clear cut-off value (e.g., hematoma volume).
- Investigate the efficacy and safety of the embolic materials in order to identify the embolic material that is able to ensure the best clinical and technical success.
- Evaluate which anatomical, clinical, procedural and therapeutic factors are associated with the risk of recurrence, considering that the localization of recurrences was not always the same as the first SSSH and that no correlation emerged between recurrences and the embolization material used.

i Related important publications

Please see the end of the chapter.

ARTICLE NUMBER 5

Management of Spontaneous Soft-Tissue Hemorrhage Secondary to Anticoagulant Therapy: A Cohort Study.

Am J Emerg Med. 2018 Dec;36(12):2177-2181.

Menditto VG, Fulgenzi F, Lombardi S, Dimitriadou A, Mincarelli C, Rosati M, Candelari R, Pomponio G, Salvi A, Gabrielli A.

Abstract

Study objective: The optimal management of patients receiving heparin, warfarin or direct anti-coagulant therapy who experience spontaneous, severe, life-threatening soft-tissue hemorrhage (SSTH) is unclear. The purpose of this study is to investigate efficacy and safety of the interventional protocol implemented in our department.

Methods: In this retrospective cohort study, we analyzed data from 80 consecutive patients with SSTH secondary to anticoagulation therapy diagnosed by the appropriate computed tomography scan. All patients received a structured clinical pathway, including aggressive resuscitation, reversal of coagulopathy when indicated, Interventional Radiology procedures by transcatheter embolization (TE), clinical observation and repeated laboratory controls.

Results: We enrolled 80 patients from 2013 to 2017. Angiography was performed in 60 patients (75%). It revealed the bleeding site in 46 cases, and a TE was performed in all. The rates of technical success of TE, primary clinical success and bleeding control were 98% (45/46), 91% (73/80) and 89% (71/80) respectively. In 5 patients (6%) the control of the bleeding was obtained with a second TE. Short-term and 30-day mortality was 5% (4 patients) and 11% (9 patients), respectively. No adverse events were observed.

Conclusion: A structured clinical pathway, including TE seems to be an effective and safe method to manage the patients with SSTH due to anticoagulant treatment.

Article review and analysis

Aim of this study: This study aimed to investigate the efficacy and safety of the diagnostic and therapeutic protocol applied in the semi-intensive unit for the management of anticoagulant-related SSTH.

Methods

Pros: This study presents the largest cohort of patients with SSTH reported so far. It investigates the efficacy and safety of the guidelines already embraced at the referring hospital. The study includes patients who received TAE and patients who underwent different procedures. Unlike previous studies, in which evaluation is limited to intensive care units, the present study considers patients hospitalized in a semi-intensive unit. On the one hand, exclusive enrollment of patients who stopped anticoagulants before TAE procedure allowed the evaluation of a homogeneous cohort. On the other,

it did not allow an objective evaluation of the procedure for those patients for whom anticoagulants cannot be stopped (e.g., patients with prosthetic heart valves).

Cons: There is a risk of selection- or information-bias due to the retrospective nature of the study.

There are limitations to the reproducibility of the results due to the monocentric nature of the study. The study was conducted in a single third-level hospital; hence it can exclude patients with non-severe SSTH who did not require to be managed by a third-level hospital.

30-day mortality was retrospectively evaluated by telephone calls. This does not allow a thorough assessment of risk factors for a bad outcome, such as re-introduction of anti-thrombotic therapy.

Results, conclusion, and what it means

With the largest cohort so far reported, this study confirms some statements already outlined in previous articles based on a smaller case study. These are:

The progressive increase in incidence of SSTH, with a doubling of cases from twelve in 2013 to twenty-four in 2016.

The correlation between the increasing use of anticoagulants and the increasing incidence of SSTH.

Interestingly, the percentage of patients under anticoagulant treatment seems to be higher than that reported in previous studies (86-90%). This could be explained by the study setting being a third level hospital, hence anticoagulated patients with non-severe SSTH are underreported in the study group.

CTA is accurate in predicting active bleeding by means of a contrast extravasation detected in 80% of the cases and an active bleeding confirmed by angiography in 76% of target arteries catheterized.

SSTH is a life-threatening condition and despite TAE therapeutic success being achieved in 98% of cases, the postoperative and 30-day mortality is still significant, respectively 7% and 11%. Nonetheless, it should be underlined that other studies reported higher short term and 30-day mortality rates, respectively 12% and 32%.

In conclusion, although with remarkable differences between the studies' subjects and setting, the clinical choices proposed in this article seem to be effective to reduce subject mortality. These data highlight how an effective strategy for SSTH management could improve patient survival, and the need to develop validated guidelines.

Comments and future research

Despite the established role of CTA in SSTH detection, the predictivity of radiological findings on patient outcomes is yet to be defined. While some articles considered only the detection of an active bleeding as an indication for TAE, others gave great importance to several CT findings such as hematoma volume and size. Furthermore, even if the role of active bleeding detection is not established, some hospitals prioritize the

clinical presentation in the decision-making process, downplaying the importance of a contrast extravasation detection, while in other hospitals, the detection of a contrast extravasation justifies the indication to perform TAE.

It is interesting to note how various management protocols and treatment of SSTH reported in retrospective studies seem to be effective in bleeding control, but that prospective studies are necessary to validate this finding. Case-control trial should be conducted in order to compare the most effective and safe management reported in literature. In particular, given the possible intermittent nature of the bleeding and the delayed worsening of the patient's clinical condition, one important aspect to investigate is if patients treated conservatively or with an initial conservative approach have a different mortality and complication rate compared to patients with the same clinical and radiological presentation managed with a more invasive approach. Future studies should:

- Investigate TAE efficacy and safety on a more homogeneous sample, such as by only selecting patients who are or are not under anticoagulant therapy or investigating just one localization of SSTH.
- Evaluate the diagnostic efficacy of CTA in identifying active bleeding in SSTH, comparing its performance with the DSA findings.
- Identify CTA findings related to poor outcomes in SSTH and, eventually, set a scale of severity in order to set a clear cut-off value (e.g., hematoma volume).
- Investigate the efficacy and safety of the embolic materials in order to identify the embolic material that is able to ensure the best clinical and technical success.
- Evaluate which anatomical, clinical, procedural and therapeutic factors are associated with the risk of recurrence, considering that the localization of recurrences was not always the same as the first SSTH and that no correlation emerged between recurrences and the embolization material used.

i Related important publications

Please see the end of the chapter.

i Related important publications

regarding the chapter Embolization of non-traumatic bleeding:

Shi ZX, Yang J, Liang HW, Cai ZH, Bai B. Emergency transcatheter arterial embolization for massive gastrointestinal arterial hemorrhage. *Medicine* (Baltimore). 2017 Dec;96(52):e9437.

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CHAPTER 18.

Endovascular treatment of iatrogenic vascular injuries

Authors: *Veacheslav Zilbermints, Yelena Gribets-Tiosano and Neev Tchernin*

Introduction

Iatrogenic vascular injuries are uncommon, although their incidence recently has been increasing, most likely due to the growing popularity of procedures that depend on a percutaneous vascular approach. Moreover, the improvement of recent patient care is partially correlated with increasing prevalence of more advanced and radical surgical resections, which require simultaneous endovascular treatment. The number of percutaneous endovascular interventions performed worldwide has been growing rapidly due to technological advances, improved long-term clinical outcomes, and lower morbidity associated with these procedures, compared with traditional surgical approaches.

Endovascular repair of iatrogenic vascular injuries, during a surgical procedure, is uncommon since the preferred approach in this scenario is to perform an emergent surgical repair. Thus, most of the research available on this topic is based on endovascular treatment for iatrogenic endovascular percutaneous interventions.

Most such vascular complications have minimal clinical significance. However, life-threatening vascular complications exist and remain an important cause of significant morbidity and mortality.

The most frequent percutaneous iatrogenic vascular injuries include hematoma, active bleeding, pseudoaneurysm formation, arteriovenous fistula, and arterial dissection or rupture. Surgical repair has been the treatment of choice for iatrogenic vascular injuries for a long time. However, complications such as lymphocele, neuralgia, significant

blood loss and chronic lymphedema are frequent. In addition, clinical presentation and the patient's comorbidities increase the risk of systemic complications associated with surgical repair.

This significant morbidity has led to the development of new less invasive alternatives, such as endovascular treatments.

There are various treatment options in this field, depending on the underlying pathology itself, location and diameter of the injured vessel, and the personal experience of the interventional radiologist performing the procedure. The currently available tools include temporary balloon occlusion, thrombin injection, glue embolization, vascular plugs, covered stents, coil embolization, etc. However, lack of satisfactory evidence-based medicine limits the establishment of guidelines for the management of these injuries. In this chapter, we review some of the most important publications in this field. In addition, this particular topic, importantly reflecting the EVTm concept progress, is very "young". Therefore, the number of related recommended publications is limited.

ARTICLE NUMBER 1

Prospective randomized study comparing ultrasound-guided thrombin injection to compression in the treatment of femoral pseudoaneurysms.

J Endovasc Ther. 2004 Oct;11(5):570-6.
Lönn L, Olmarker A, Geterud K, Risberg B.

Abstract

Purpose: To compare in a randomized prospective study the treatment of femoral pseudoaneurysms with ultrasound-guided thrombin injection versus ultrasound-guided compression.

Methods: Thirty consecutive patients (22 men; mean age 67+/-8 years, range 53-82) with iatrogenic femoral pseudoaneurysms were randomized to treatment with either ultrasound-guided compression (n=15) or injection of bovine thrombin (n=15). The primary outcome measure was thrombosis of the pseudoaneurysm within 24 hours. Secondary outcome measures were complications and hospitalization time (LOS).

Results: Thrombosis within 24 hours was achieved in 15 (100%) patients given thrombin versus 2 (13%) in the compression group ($p<0.001$). Of 13 pseudoaneurysms failing the initial compression treatment, 7 were retreated, 4 successfully. Thus, only 6 (40%) lesions were thrombosed within 48 hours after 1 or 2 compression sessions. The other 9 cases were successfully treated with thrombin injection. LOS was 2.8+/-1.5 days and 3.5+/-2.4 days in the thrombin and compression groups, respectively ($p>0.05$). No complications were noted in either group.

Conclusions: Ultrasound-guided thrombin injection induces a fast, effective, and safe thrombosis of postcatheterization pseudoaneurysms. The technique is clearly superior to compression treatment and is recommended as the therapy of choice.

Article review and analysis

Aim of this study: Postcatheterization pseudoaneurysm (PSA) is one of the most common vascular complications of percutaneous vascular diagnostic (0.05-2%) and therapeutic (2-8%) procedures. Although the incidence is low, the increasing number of transluminal procedures being performed these days and the vast use of antiplatelets and anticoagulants, may increase the incidence. It has been suggested that PSAs may thrombose spontaneously, but the aggressive antithrombotic and dual antiplatelet therapy limits the rate of spontaneous occlusion. Until the early 1990s the only available treatment for PSAs was surgery. Since that time, ultrasound-guided compression repair (USGC), ultrasound-guided thrombin injection (UGTI), and other various modalities, such as compression devices, coil insertion, fibrin adhesives or balloon occlusion, have been used. Direct thrombin injection into the PSA to induce thrombosis has been known for almost 3-4 decades. However, this method has never been fully

evaluated in a controlled trial. The aim of this study was to compare USGC to UGTI in a prospective, open, randomized, single-center trial.

Methods

Pros: This is the first randomized controlled study that investigates the use of UGTI in the treatment of femoral pseudoaneurysms. Difference in primary success (thrombosis at 24 hours) with UGTI vs USGC was statistically significant and clearly demonstrated the superiority of UGTI, a fact that outlines a future treatment path. The follow up period was relatively long (22 ± 10 months), which is another advantage of this study.

Cons: This study has several limitations that must be taken into account. First and foremost is the relatively small cohort, which limits the power of the study and may obfuscate possible complications. The cohort could have been larger if an active screening for PSA formation was performed in all post-catheterization patients and not just on clinical suspicion. Furthermore, due to the treatment procedure visibility, this study cannot be a “classic” double blind RCT.

Results, conclusion, and what it means

Manual USGC was first introduced in 1991 as an optional treatment for postcatheterization pseudoaneurysm, with a success rate of around 60%. USGC was described as uncomfortable, painful and time-consuming, both for the patient and the operator. Patients receiving anticoagulation therapy have a low success rate and are usually not suitable for compression therapy. Thrombin injection, as an alternative treatment method, was first attempted in the mid 1980s and has been used widely since the late 1990s, with a success rate of 94-100%. This technique is associated with some adverse effects, including immunogenic response, systemic activation of the coagulation system, and intra-arterial thrombosis. On the other hand, UGTI is simple, quick, well tolerated, safe and effective. This study demonstrates well that thrombosis within 24 hours (primary outcome) was significantly better in the thrombin group, with no significant differences in length of stay and complication rate (there were no periprocedural complications in either group) in the two treatment groups.

Comments and future research

Endovascular treatment is a subject yet to be fully explored. Hence, similar or different comparative method studies with larger cohorts are required. Most of the currently existing data is based on single-center experience and one can assume that collaboration between centers would be beneficial. An important question that the present trial was not designed to answer is which patients should be offered thrombin injection; this question opens a window for planning functional studies on this matter (considering comorbidities, basic characteristics, and type of injury). Furthermore, the information that was collected in this study included the geometry and position of the lesion as

well as the number of pseudoaneurysm lobes; this information can be used in future comparative studies and treatment algorithm creation (based on this information).

A combination of different methods should also be studied prospectively (for example balloon tamponade+thrombin injection).

Due to the fact that iatrogenic PSAs have detrimental consequences, prevention techniques are worth an in-depth discussion and research (standard use of US guidance procedures/routine use of closure devices etc.).

This study supports the feasibility of thrombin injection in the treatment of iatrogenic pseudoaneurysms following percutaneous interventions. It would be of great interest to conduct future animal/human studies evaluating the effectiveness of this method in the treatment of abdominal solid organ pseudoaneurysms resulting from blunt/penetrating abdominal injury.

Related important publications

Kontopodis N, Tsetis D, Tavlas E, Dedes A, Ioannou CV. Ultrasound Guided Compression Versus Ultrasound Guided Thrombin Injection for the Treatment of Post-Catheterization Femoral Pseudoaneurysms: Systematic Review and Meta-Analysis of Comparative Studies. *Eur J Vasc Endovasc Surg.* 2016 Jun;51(6):815-23.

Dzijan-Horn M, Langwieser N, Groha P, Bradaric C, Linhardt M, Böttiger C, Byrne RA, Steppich B, Koppa T, Gödel J, Hadamitzky M, Ott I, von Beckerath N, Kastrati A, Laugwitz KL, Ibrahim T. Safety and efficacy of a potential treatment algorithm by using manual compression repair and ultrasound-guided thrombin injection for the management of iatrogenic femoral artery pseudoaneurysm in a large patient cohort. *Circ Cardiovasc Interv.* 2014 Apr;7(2):207-15.

Yang EY, Tabbara MM, Sanchez PG, Abi-Chaker AM, Patel J, Bornak A, Jones KM, Rey J. Comparison of Ultrasound-Guided Thrombin Injection of Iatrogenic Pseudoaneurysms Based on Neck Dimension. *Ann Vasc Surg.* 2018 Feb;47:121-127.

ARTICLE NUMBER 2

Covered stents for endovascular repair of iatrogenic injuries of iliac and femoral arteries.*Cardiovasc Revasc Med.* 2015 Apr-May;16(3):156-62.

Kufner S, Cassese S, Groha P, Byrne RA, Schunkert H, Kastrati A, Ott I, Fusaro M.

Abstract

Background: The growing number of complex endovascular procedures is expected to increase the risk of iatrogenic injuries of peripheral arteries. A strategy of percutaneous transluminal angioplasty (PTA) with covered stent (CS) may represent a valuable alternative to open surgery. However, systematic evaluations of CS in this setting represent a scientific gap. In the present study, we investigate the procedural and clinical outcomes associated with PTA and CS implantation to repair iatrogenic injuries of peripheral arteries.

Methods: All patients undergoing PTA with CS for endovascular repair of iatrogenic injuries of peripheral arteries between August 2010 and July 2013 at our Institution were retrospectively analyzed. The primary endpoint was the technical success. Secondary endpoints were in-hospital mortality and cumulative death, target lesion revascularization (TLR), amputation and major stroke at 12-month follow-up.

Results: During the period of observation, a total of 30 patients underwent PTA with either self-expandable (43.3%) or balloon-expandable CS (56.7%) for iatrogenic injuries of peripheral arteries. Injuries consisted of perforation/rupture (76.7%), arteriovenous fistula (16.7%) and pseudoaneurysm (6.7%) of iliac-femoral arteries. Technical success was achieved in all cases. Median follow-up was 409 days [210-907]. The incidence of in-hospital mortality was 10.0%. At 12-month follow-up, the incidence of death, TLR, amputation and major stroke was 20.0%, 17.0%, 3.3% and 6.7%, respectively.

Conclusion: The use of covered stents for endovascular repair of iatrogenic injuries of peripheral arteries shows a high technical success and may be alternative to surgery. Further studies with larger populations are needed to confirm these preliminary findings.

Article review and analysis

Aim of this study: In recent decades, the use of vascular percutaneous procedures has been consistently growing, allowing patients previously considered as “high surgical risk” to be treated with minimally invasive procedures. However, the popularity of such methods also entails increased incidence of iatrogenic vascular injuries. As the femoral artery is the most common access site, the iliac-femoral axis is the main location of iatrogenic arterial injuries.

The management of access-site complications has shifted in recent years from emergent surgery to various endovascular treatment options. Percutaneous transluminal

angioplasty (PTA) with covered stent (CS) has been proposed as a treatment option in iliac and femoral iatrogenic injuries. This study investigated procedural and clinical outcomes of patients treated with PTA with CS implantation for iatrogenic arterial injuries in a consecutive cohort of patients undergoing percutaneous procedures.

The primary endpoint in this study was technical success. Success was defined as absence of blood loss (contrast medium extravasation in the case of vessel perforation or rupture) or the complete exclusion of the pathological communication (in case of arteriovenous fistula or pseudoaneurysm), confirmed at digital subtraction angiography after CS implantation, without acute deterioration of clinical status or the need for urgent surgical conversion. Secondary endpoints were in-hospital death and cumulative death, target lesion revascularization (TLR), amputation and major stroke at 12-month follow-up.

Methods

Pros: To date, this is the largest published study evaluating the use of CS in the treatment of arterial vascular injury. The results were analyzed for the entire study population as well as separately for each injury location (above and below the inguinal ligament). Additionally, sub-analysis of mortality rates and TLR at 12-month follow-up was conducted, according to clinical setting (urgent/elective), type of CS (self-expandable/balloon expandable) and presence of peripheral artery disease.

Cons: This is a single-center, retrospective study and thus it is subject to all the possible disadvantages of this type of observational study. In addition, the paucity of data, relatively small size and its heterogeneous cohort preclude adequate evaluation of all predictors of adverse outcomes by means of a regression model. Moreover, median follow-up was limited to 12 months. Of note, this study lacks a direct comparison between endovascular and surgical repair of iatrogenic injuries of peripheral arteries. Finally, data is lacking regarding the time-intervals between initial procedure, diagnosis of arterial injury and CS implantation.

Results, conclusion, and what it means

The outcome for patients with iatrogenic peripheral artery injuries largely depends on the patient's baseline clinical status. The major findings are as follows: (1) PTA with CS is associated with 100% technical success, independently of the type and location of the injuries; (2) the clinical presentation at time of index PTA may impact in-hospital mortality. Mortality was associated with older age, high risk profile and shock; (3) the presence of PAD may impact the rates of revascularization at 12 months. Patients with PAD presented with more TLR events at 12 months as compared with patients without pre-existing PAD.

In this study, 70% of patients presenting with shock at time of PTA survived, suggesting that endovascular repair can be attempted in a broad spectrum of patients.

The results demonstrate that the use of covered stents in the treatment of peripheral

artery iatrogenic injuries may be an acceptable alternative to open surgery. RCTs and larger studies are needed to confirm these preliminary findings and to evaluate the long-term durability of covered stents.

Comments and future research

Future research dealing with PTA with CS, specifically in acute settings, can be innovative. In addition, subdivision into anatomical injury districts can also provide a basis for future comparative research. Stratification for either self-expandable or balloon-expandable stent, additionally based on vessel size, injury location, length of segment, may better define the indications for the specific type of treatment. Comparative prospective RCTs may also help evaluate which type of stent is more suitable in specific scenarios. Smaller and more flexible specifically designed stent-grafts for peripheral arteries may enable the treatment of even smaller and anatomically challenging vessels in acute or elective scenarios.

i Related important publications

Ruffino MA, Fronda M, Varello S, Discalzi A, Mancini A, Muratore P, Rossato D, Bergamasco L, Righi D, Fonio P. Emergency management of iatrogenic arterial injuries with a low-profile balloon-expandable stent-graft: Preliminary results. *Medicine (Baltimore)*. 2020 Apr;99(15):e19655.

Schahab N, Kavsur R, Mahn T, Schaefer C, Kania A, Fimmers R, Nickenig G, Zimmer S. Endovascular management of femoral access-site and access-related vascular complications following percutaneous coronary interventions (PCI). *PLoS One*. 2020 Mar 19;15(3):e0230535.

ARTICLE NUMBER 3

Ultrasound-Guided Fibrin Glue Injection for Treatment of Iatrogenic Femoral Pseudoaneurysms.

Vasc Endovascular Surg. 2020 Aug;54(6):497-503.

Gummerer M, Kummam M, Gratl A, Haller D, Frech A, Klocker J, Fraedrich G, Gruber H.

Abstract

Introduction: Arterial pseudoaneurysms (PSAs) are the most common access site complication following transarterial catheter intervention. Ultrasound-guided injection of thrombogenic substances into perfused arterial PSAs followed by compression therapy is a well-established and less invasive treatment option than surgical repair. Different agents are available to induce thrombosis including thrombin and a fibrin-based tissue glue, which is used as first-line treatment at our institution. This paper deals with our experience using ultrasound-guided fibrin glue injection (UGFI).

Materials and methods: Retrospective data analysis: all patients (55) treated for iatrogenic femoral PSA following digital subtraction angiography of the lower extremities between January 1, 2010, and December 31, 2018, were included. Data on epidemiology, PSA location and size, vascular risk factors, fibrin glue injection (fibrin glue volume), primary success rate of UFGI, and complications related to the treatment were analyzed.

Results: A total of 55 consecutive femoral iatrogenic PSAs were treated during the defined period and 32 (58.2%) of the patients were female. Imaging was performed using ultrasound in all cases. The most common PSA location (80.0%) was the common femoral artery, mean PSA size ($\pm$ SD) was 2.7 ± 1.2 cm, and neck length was 1.6 ± 1.0 cm. The dose (mean $\pm$ SD) of fibrin glue was 2.6 mL (± 1.0 ; maximum: 6 mL). Primary UGFI success rate was 87.3% and conversion rate to open surgery was 12.7%. Two (4%) patients required embolectomy for peripheral embolization after UGFI.

Conclusion: Early results achieved with UGFI for treatment of iatrogenic femoral PSA are promising. In our cohort, UGFI was a safe and effective first-line alternative to traditional open surgery, which then was unnecessary in the vast majority of PSA cases. Further prospective studies for comparison of ultrasound-guided techniques should be encouraged.

Article review and analysis

Aim of this study: Fibrin-based tissue glue, also known as fibrin sealant or fibrin tissue adhesive, is known to have a good thrombogenic effect. It is a biological type of glue that may contain fibrin alone or two different acting agents, including fibrinogen, thrombin, and factor XIII. It acts upon mixing the two components - the thrombin, as a highly specific protease, transforms fibrinogen into fibrin and forms a clot. To prevent premature degradation of fibrin, the majority of commercially available products also contain antifibrinolytic agents.

The basis of this method is the assumption that fibrin glue has a better thrombogenic effect as it creates a more stable clot faster than thrombin. The aim of this study was to evaluate the safety and efficacy of ultrasound-guided fibrin injection (UGFI) for the treatment of patients with PSA following percutaneous interventions.

This is a retrospective study performed in a single center. The study included 55 patients with iatrogenic femoral PSA following peripheral arterial interventions, treated with UGFI. The primary endpoint was complete thrombosis of the femoral PSA confirmed by ultrasound Doppler, which was performed within 24 hours after UGFI. Secondary endpoints were reintervention and complication rates.

Methods

Pros: This is the largest cohort regarding this treatment method. The authors collected data regarding patient's demographics, cardiovascular risk factors, and comorbidities, as well as puncture technique, sheath size and post-procedural anticoagulation regimen. Data on PSA size and location, first treatment option, and numbers and indications for reinterventions were also analyzed. In addition, each case of arterial embolism, which is one of the main complications of UGFI, was analyzed in detail.

Cons: One of the limitations of this study is that the indications for conversion to open repair, which occurred in seven patients, were not detailed. In addition, the treatment protocol in this study may constitute a possible confounder. The protocol included tissue glue application followed by an ultrasound-guided manual compression for 10 minutes, followed by a compression bandage for a total of 24 hours. The real contribution for hemostasis remains unclear since the manual compression may, on its own, contribute significantly to hemostasis achievement.

Another notable limitation of this study is the lack of patient follow up for assessment of the long-term results of treatment with UGFI. Moreover, the advantages of minimally invasive treatment options are specifically important in patients with high risk of perioperative morbidity and mortality, which unfortunately were not included in this article. Thus, it is impossible to conclude whether this method is feasible and safe in the patients who may gain most from this approach. Furthermore, the retrospective design of this study as an important limitation that needs to be considered when analyzing the results and drawing conclusions regarding this treatment method.

Results, conclusion, and what it means

In this study, the primary end-point success rate was 87.3% (48/55), which is relatively low compared to other methods, such as thrombin injection, as reported in the literature. However, this study demonstrates another good example of endovascular alternative treatment that may enable avoidance of open surgical repair. In addition, it demonstrates the safety of this approach even in patients with antiplatelet and/or anticoagulant therapy.

Comments and future research

Based on the existing literature, limitations restricting the use of UGFI are a short/missing PSA neck and a larger PSA sac. In the current study, the treated PSAs mean size was 2.7 ± 1.2 cm and neck length was 1.66 ± 1.0 cm. Future research should examine the success rate and safety of UGFI treatment, depending on the size and characteristics of the aneurysm.

Fibrin glue is a fairly new approach for the treatment of iatrogenic vascular injuries. Thus, it is necessary to evaluate the long-term effects of this treatment option.

RCTs comparing UGFI with other minimally invasive treatment options are also needed in order to better define the indications, feasibility, efficacy and complications of each technique.

The current data on this method is scarce, probably due to other existing safe and effective treatment alternatives (thrombin injection, coils, stents, etc.). In addition, it is important to note that tissue glues are expensive and thus their use must be considered from a cost-effective point of view. However, with the development of new technologies and the rising popularity of UGFI-based treatments, costs may decrease in the future. We hope that this study will inspire and promote further future research on this method and its possible use in different iatrogenic injuries, such as arteriovenous fistula formation, bleeding and perforation.

i Related important publications

Kurzwski J, Janion-Sadowska A, Sadowski M. A novel minimally invasive method of successful tissue glue injection in patients with iatrogenic pseudoaneurysm. *Br J Radiol.* 2018 Jul;91(1087):20170538.

Matson MB, Morgan RA, Belli AM. Percutaneous treatment of pseudoaneurysms using fibrin adhesive. *Br J Radiol.* 2001 Aug;74(884):690-4.

Aytekin C, Firat A, Yildirim E, Kirbas I, Boyvat F. Ultrasound-guided glue injection as alternative treatment of femoral pseudoaneurysms. *Cardiovasc Intervent Radiol.* 2004 Nov-Dec;27(6):612-5.

ARTICLE NUMBER 4

Percutaneous coil embolization of postcatheterization arterial femoral pseudoaneurysm.*J Vasc Surg.* 2002 Jul;36(1):127-31.

Kobeiter H, Lapeyre M, Becquemin JP, Mathieu D, Melliere D, Desgranges P.

Abstract

Study design: This study was a prospective monocentric study to assess the safety and effectiveness of percutaneous embolization with coils of postcatheterization femoral pseudoaneurysm (PCFP).

Patients and methods: Seventeen PCFPs of 32-mm mean diameter in 16 patients were embolized while anticoagulant or antiplatelet therapy was maintained. Ultrasound scan-guided compression repair failed at least one time in 13 cases and was contraindicated in the four remaining cases. With ultrasound-Doppler scan guidance, the PCFPs were percutaneously punctured with a 16-gauge intravenous catheter. An angiogram was performed through the catheter to ensure its location within the sac. Stainless steel spring coils with synthetic fibers were introduced within the PCFP with fluoroscopic control. Successful thrombosis was checked with ultrasound-Doppler scan and was repeated at days 1, 30, and 180 when possible.

Results: All PCFPs of 32-mm mean diameter were successfully treated with two to nine coils. After embolization, gentle additional compression was necessary for complete occlusion, with a mean duration of 6.3 minutes (range, 0 to 15 minutes), except in one case with treatment with abciximab in which it was 45 minutes. All procedures were uneventful and painless. The mean follow-up period was 9.5 months (range, 1 to 21 months). Two recurrences (11.7%) were observed, and one was successfully treated with a second embolization.

Conclusions: Percutaneous embolization with coils appears to be a safe and effective method for treatment of PCFP. It may be performed in patients undergoing anticoagulant or antiplatelet therapy and must be attempted when ultrasound scan-guided compression repair has failed or is contraindicated.

Article review and analysis

Aim of this study: The treatment of postcatheterization femoral artery pseudoaneurysm (PSA) has undergone major changes during recent years. Acceptable treatment has moved from a surgical approach to a wide variety of non-surgical treatment options as mentioned previously. A fairly new technique is direct percutaneous coil embolization. This study aimed to assess the feasibility and clinical outcome of this treatment method.

Methods

Pros: Utilization of coils is well known and established in the treatment of vascular aneurysms. However, this is one of the first attempts to use this technique in the treatment of iatrogenic vascular injury and one of the first studies to report results of this new and innovative approach. An important strength of this study is its prospective design, which is unique and relatively rare in this field.

Cons: This study was performed in a single center with a small sample size of only 16 patients. It is therefore difficult to evaluate the true benefits and drawbacks of this method.

Furthermore this is a single-arm study with no comparison group. Another limitation of this study that needs to be taken into account is the relatively variable follow-up period, which ranged from between 1 and 21 months. When considering the long-term results reported in this study, it is important to note that several patients underwent short follow-up and may have developed complications or recurrences that were not recorded and reported in the study.

Results, conclusion, and what it means

The results of this study show that coil embolization is a fast technique with a very high success rate and only relatively minor complications.

The results have been analyzed separately regarding early and late results. The early results show 100% success rate of embolization. Similarly, XU H, et al. reported a 94.1% success rate with this technique. Regarding the need for post-procedural local compression, mean compression time, until achievement of full embolization as confirmed by US-Doppler, was 6.3 min. All the patients were discharged within 24 hours. These are both important advantages of this technique when compared to other techniques such as local compression alone which necessitates longer compression time and prolonged hospital stay.

During the follow-up period (mean 9.5 months), only 2 patients (11.7%) suffered from a recurrence, one who needed re-embolization by coil and another who underwent surgical repair. Coil embolization appears to be a safe, fast and effective approach for treatment of iatrogenic pseudoaneurysms. However, to date, there are not enough large studies that support the routine use of this method.

Comments and future research

Even though coil embolization is a well-known and established technique, very few studies regarding its use in iatrogenic injury have been published. An interesting possibility for future research is a comparison of the clinical outcome of patients with postcatheterization artery pseudoaneurysm treated with different approaches. For example, a comparison of patients treated with coiling and those with thrombin or fibrin injection is necessary in order to evaluate which method is superior and which should be used in different patients and various clinical scenarios.

i Related important publications

Xu H, Jing C, Zhou J, Min X, Zhao J, Yang L, Ren Y. Clinical efficacy of coil embolization in treating pseudoaneurysm post-Whipple operation. *Exp Ther Med.* 2020 Nov;20(5):37.

ARTICLE NUMBER 5

Balloon Tamponade Repair after Inadvertent Subclavian Artery Catheterization.

J Vasc Access. 2015 Mar-Apr;16(2):152-7.
Dunham GM, Vaidya SS.

Abstract

Purpose: The approach to repair inadvertent subclavian artery catheterization has evolved to increasingly less invasive modalities. Most recently, endovascular balloon tamponade has become the preferred initial approach. We report our experience and review the technique.

Methods: Eleven patients underwent primary treatment with balloon tamponade from 2001 to 2012. Using either femoral or brachial approach, an appropriately sized balloon was placed directly adjacent to the site of hemorrhage and inflated for 5-25 min on the basis of operator preference and repeated as needed. Primary technical success defined as hemostasis was achieved with balloon tamponade.

Results: Technical success was achieved in nine of 11 patients. The mean follow-up time was 10.8 months. Two deaths were reported, both unrelated to catheter placement and removal. Of the successful cases, five achieved hemostasis with one inflation and four required two inflations. One patient developed a small thrombus at the thyrocervical trunk of no clinical significance. No other complications occurred. One of the nine patients had a double wall injury. The two patients with unsuccessful hemostasis underwent two & four inflations, respectively. Both patients had a double wall injury. One of the patients had a complication of distal ischemia and stroke.

Conclusions: In patients with inadvertent subclavian artery catheterization, balloon tamponade is an effective first step in management, with primary technical success approaching 100% in cases of single lumen injury. It appears less effective in patients with double lumen injury. However, the ease of transition from balloon tamponade to stent placement supports an initial attempt at hemostasis with tamponade prior to placement of a permanent stent.

Article review and analysis

Aim of this study: Subclavian artery injuries are associated with high morbidity and may be life-threatening. The treatment of these injuries is a challenge and has shifted in recent years from an open surgical approach to endovascular methods. This study aimed to evaluate the results of primary balloon tamponade in the hybrid treatment of subclavian artery injuries.

Methods

Pros: This is one of the first studies to report the results of endovascular balloon tamponade in patients with iatrogenic subclavian artery injury.

Cons: This is a retrospective small cohort, including 11 patients in two medical centers, treated with endovascular balloon tamponade. Due to the small sample size of this study, it is difficult to evaluate the true benefits and complications of this method. In addition, balloon size and the duration of balloon inflation varied greatly among the patients in this study, as these were according to the treating physician's decision. Moreover, other aspects of this study included patients being treated in a wide range of clinical settings, from acute care in trauma to outpatient elective surgery. Another limitation of this study that needs to be considered is the relatively wide-ranging follow-up period (7 days to 44 months). When considering the long-term results reported in this study, it is important to note that several patients had a relatively short follow-up or died shortly after the procedure (due to causes other than the inadvertent arterial catheter insertion and the endovascular treatment).

Results, conclusion, and what it means

This study has found endovascular balloon tamponade to be a fast procedure (mean time to full hemostasis of 9.4 minutes) with a high success rate in 9 out of 11 patients. The authors reported lower success rate for patients with double lumen injuries, as only one of three patients with such injury was successfully treated with balloon tamponade.

Comments and future research

The current treatment approach for subclavian artery injury due to inadvertent insertion of a catheter varies greatly and includes open repair, stent placement, insertion of a closure device, and balloon tamponade. Future studies may compare balloon tamponade and other techniques, such as stent placement and/or insertion of a closure device, in order to evaluate the advantages and disadvantages of each method as well as better define the appropriate clinical setting for each approach. In addition, as the treatment of double wall injuries remains a challenge, further studies investigating the treatment results in these patients are needed in order to evaluate the appropriate approach in such scenarios.

Related important publications

Yu H, Stavas JM, Dixon RG, Burke CT, Mauro MA. Temporary balloon tamponade for managing subclavian arterial injury by inadvertent central venous catheter placement. *J Vasc Interv Radiol.* 2011 May;22(5):654-9.

Nicholson T, Ettles D, Robinson G. Managing inadvertent arterial catheterization during central venous access procedures. *Cardiovasc Intervent Radiol.* 2004 Jan-Feb;27(1):21-5.

CHAPTER 19.

Endovascular and hybrid approach in elective surgery

Authors: *Haddad Riad, Levy Hagar and Abbou Benyamine*

Introduction

The endovascular approach was first utilized in modern medicine in the setting of war, when resuscitative endovascular balloon occlusion of the aorta (REBOA) was used in order to treat exsanguination caused by intra-abdominal injuries. However, it was only several decades later that this technique started expanding further into the whole field of trauma surgery as a useful tool for temporary bleeding control. REBOA has since been introduced in non-trauma patients with hemorrhagic shock, where its placement has shown promising results in gaining control over active hemorrhage.

The potential of REBOA and other endovascular techniques to limit bleeding by using them as prophylactic tools is an effective and quite novel approach that is now being investigated in different fields of surgery. Although previous data indicate some possible related complications of this method, its use for elective surgeries, where prior preparation is possible and real time imaging is accessible, may alter previous results and end-up minimizing these potential risks. In this chapter, we provide some of the latest publications to review this approach and its safety. The diversity of surgeries that can benefit from the use of a hybrid operating room and endovascular embolization is already wide and amazing. We hope this chapter will inspire our colleagues from different fields of specialization to dare to investigate this approach further in each of our readers fields of interests.

ARTICLE NUMBER 1

Intraoperative balloon occlusion of the aorta for blood management in sacral and pelvic tumor resection: A systematic review and meta-analysis.

Surg Oncol. 2020 Dec;35:156-161.

Bailey AJ, Lee A, Li HO, Glen P.

Abstract

Background: Neoplasms of the sacrum and pelvis are challenging to manage due to their complex vascularity and size and are at high risk of bleeding during resection. Intra-aortic balloon occlusion (IABO) has been used in trauma to control massive blood loss, but its efficacy and safety in oncologic sacral and pelvic surgery are unknown. The primary objective of this systematic review and meta-analysis was to assess the effectiveness of IABO in providing hemorrhage control during resection of sacral and pelvic tumors.

Methods: This PROSPERO pre-registered study meta-analyzed all studies reporting on the use of IABO in the setting of pelvic and sacral tumor resection, in accordance with the PRISMA guidelines. The primary outcome of the meta-analysis was intraoperative blood loss, with secondary outcomes consisting of transfusion volume, post-operative blood loss, operative time, complication rate, and mortality.

Results: Across studies, IABO was associated with a large, significant reduction in intraoperative blood loss (SMD -0.81, 95% CI -1.01 to -0.60, $P < 0.0001$) and transfused red blood cell volume (SMD 0.92, 95% CI -1.30 to -0.53, $P < 0.0001$). Two studies reported that complication rates were comparable between patients receiving IABO and patient receiving conventional surgery (Odds ratio = 1.29, 95% CI: 0.59 to 2.83, $P = 0.52$). All studies descriptively reported improved visualization of the operative field with IABO.

Conclusions: Our findings demonstrated that IABO is an effective technique to decrease blood loss and transfusion requirements during sacral and pelvic tumor surgery. Future clinical trials should be conducted to establish the safety of this method and explore potential contraindications.

Article review and analysis

Aim of this study: Neoplasms of the sacrum and pelvis are well-known for their high and complex vascularity. Since resection of such tumors may involve extensive intraoperative and postoperative blood loss, and are associated with high morbidity rates, a novel approach to reduce blood loss by using IABO prophylactically during resection was examined. The aim of this study was to review and analyze existing data regarding the effects of IABO on blood loss in elective sacral and pelvic tumor surgery.

Methods

Pros: This meta-analysis is the result of a thorough literature review, made according to the PRISMA statement, starting from 710 articles and ending up with just 4 articles matching the inclusion criteria. A total of 433 patients were enrolled in all four selected studies and 210 of them comprised the experimental group. All the studies included were required to report comparative results, which included and yet were not limited to intraoperative, postoperative and total blood loss, total transfusion volume, operative time, balloon-related complications, and patient morbidity and mortality. Apart from adverse effects, all measured outcomes were objective and therefore less prone to bias.

Cons: The main limitation of the included studies lies in their retrospective design. Furthermore, all studies were defined as having a moderate risk of bias as no control for potential confounding factors was performed, two studies had non-random selection, and there were no blinded studies. In addition, two out of four studies did not report the measurement technique of intraoperative blood loss, even though this was considered as the primary measured outcome. Regarding some of the investigated secondary outcomes, such as operative time and postoperative blood loss, since high heterogeneity was demonstrated a definitive conclusion, could not be determined. Lastly, adverse effects were reported to resolve under treatment in all four studies, nevertheless most adverse effects and the way they were treated were not specified.

Results, conclusion, and what it means

The most significant impact of this study is the demonstration of the possible favorable outcomes of IABO and the relative safety of its use as a prophylactic tool to avoid excessive blood loss in the setting of elective surgery. IABO use successfully managed to reduce blood loss intraoperatively by approximately 40% and showed a significant reduction of approximately 50% in total RBC transfusion volume and therefore may help decrease the risk of transfusion-related complications. All four studies reported that IABO subjectively improved the identification of the tumor edges and facilitated en bloc resection. Lastly, the results of this meta-analysis may suggest that the use of IABO is safe, with zero perioperative mortality and similar complication rates between the groups.

Comments and future research

To date, there is not sufficient data to determine the exact appropriate use of IABO, nor well established indications and contraindications to assist the selection of the optimal patients who can benefit most from this method. Further investigation, preferably prospective, is required to determine the short and long-term side effects of the use of IABO in order to establish such indications. Another suggested query would be the effect of IABO use on recurrence and metastases as well as other surgical outcomes and complications. As one study reported no significant difference in prognosis

between the compared groups at three years, this meta-analysis demonstrated a significant improvement of field visualization when using IABO, and this outcome, along with better characterization of patients, may indeed suggest better surgical outcomes. Certainly, this hypothesis warrants further studies to be conducted in order for it to be established.

i Related important publications

Tang X ,Guo W ,Yang R ,Tang S ,Dong S .Use of aortic balloon occlusion to decrease blood loss during sacral tumor resection .J Bone Joint Surg Am 2010 .Jul .1747-53:(8)92;21

Zhang Y ,Guo W ,Tang X ,Yang R ,Yan T ,Dong S ,Wang S ,Zaphiros N .Can Aortic Balloon Occlusion Reduce Blood Loss During Resection of Sacral Tumors That Extend Into the Lower Lumbar Spine ?Clin Orthop Relat Res2018 . Mar.490-498:(3)476;

Zhou M, Yang H, Chen K, Wang G, Lu J, Ji Y, Wu C, Chen C, Hu H. Surgical treatment of giant cell tumors of the sacrum and spine combined with pre-operative transarterial embolization. Oncol Lett. 2013 Jul;6(1):185-190.

ARTICLE NUMBER 2

Laparoscopic partial nephrectomy following tumor embolization in a hybrid room. Feasibility and clinical outcomes.

*Surg Oncol.*377-381:(4)26;2017 .

Panayotopoulos P, Bouvier A, Besnier L, Rousselet MC, Nedelcu C, Baize N, Beydon L, Aubé C, Azzouzi AR, Bigot P.

Abstract

Purpose :In order to limit ischemia and operative bleeding during and after partial nephrectomy we developed a clampless laparoscopic technique ,in a hybrid operating room ,immediately after super-selective arterial embolization of the renal tumor .We evaluated feasibility and morbidity of this new approach of zero ischemia in partial nephrectomy .

Methods: We included prospectively 50 consecutive patients treated in a hybrid operating room by this new technique for a localized renal tumor in a university hospital between May 2015 and January 2017. We evaluated perioperative data, postoperative complications, surgical margin and modification of renal function one month after surgery. Renal tumor complexity was evaluated by the R.E.N.A.L. score.

Results: We included 30 (60%) men and 20 (40%) women with a median age of 61 years (32-84) and a median BMI of 26.85 kg/m² (20.1-46.4). Tumors were at low, median and high complexity in respectively 11 (22%), 32 (64%) and 7 (14%) cases. Median endovascular and surgical procedures durations were 43 min (16-120) and 80 min (32-150). Median blood loss was 100 mL (10-850). Two Clavien II complications occurred. Median length of hospital stay was 3 days (2-7). Renal function was not modified one month after partial nephrectomy. Median tumor size was 3 cm (1.2-8). Forty tumors (80%) were malignant and surgical margins were positive in one (2%).

Conclusions: Clampless laparoscopic partial nephrectomy in a hybrid operating room without pedicular dissection after previous tumoral embolization is a technically safe and carcinologically efficient mini-invasive alternative for the management of localized renal tumors

Article review and analysis

Aim of this study: Partial nephrectomy is considered the treatment of choice in patients with localized renal tumors of less than 7 cm. However, since this method involves arterial clamping, high rates of peri-operative morbidity and post-operative complications have been previously documented. In this study a combination of a surgical and endovascular approach in one room and setting, with the notion of zero ischemia, was evaluated for its feasibility and ability to spare morbidity when performing laparoscopic partial nephrectomy.

Methods

Pros: This prospective study included a relatively large number of patients, treated by the hybrid approach. Among the patients enrolled, different complexities of tumors, evaluated by the R.E.N.A.L score, were identified, making the data collected relevant for patients with low as well as median and high complexity tumors. The procedures protocol is highly detailed, systematic and reproducible. Specific adjustments for specified tumor characteristics, such as endophytic tumor or adherent renal fat, were predefined and applied accordingly, when needed. The protocol was carried out by the same two persons, a surgeon and an interventional radiologist, which further contributes to its systematic design. Conducting post-operative follow-up allows crucial data collection regarding the safety and long-term outcomes of this new alternative approach. An additional significant advantage of this study is the consistent use of validated and acceptable scores and classifications, such as the Clavien-Dindo scale for the classification of surgical complications and the MDRD criteria to evaluate renal function during follow-up, which minimizes results bias.

Cons: Although the results seem promising, a comparative analysis with the current standard treatment is needed to establish the advantages of the clampless laparoscopic technique. This technique may be used for very selected patients, requires special training, and hence may only be applicable in very high volume centers. In this study, all procedures were performed by the same two highly skilled professionals, which may suggest the results are very much operator dependent and therefore the feasibility of this new technique may in fact be much more limited. Furthermore, the reported follow-up lasted only up to 6 months, which is insufficient from an oncological point of view in this type of tumor. Additionally, such a relatively short follow-up period cannot provide data concerning long-term effects, such as cardiovascular adverse events, which were previously shown to be associated with partial and radical nephrectomy.

Results, conclusion, and what it means

In this study, the authors attempted to improve an existing method, making it more specific and accurate, and super-selective, by using the resources of the hybrid room. According to the R.E.N.A.L score, 7 (14%), 32 (64%) and 11 (22%) tumors were of high, moderate and low complexity, respectively. Each and every patient's tumor was scanned and the exact arteries to be embolized were determined individually: in 31 cases (62%) only one subsegmental artery was embolized, whereas 15 cases (30%), 3 cases (6%), and 1 case (2%) required the embolization of 2, 3 and 4 arteries, respectively. Median laparoscopic operating time was 80 minutes, which is relatively long compared with previous similar data. However, median blood loss was 100 mL, a much more favorable outcome compared with 500 mL in other studies with "zero ischemia" procedures without clamping. Final hemostasis of the resection bed was achieved by using hemostatic sutures and hemostatic agents, yet no clamping was needed. Median hospital post-operative stay was 3 days, similar to the results of a large series previously

conducted. No major perioperative or postoperative complications occurred, five complications were reported and treated, and none of them were specific to the technique. No patient had post-op renal failure. In terms of pathological results, 10 benign tumors (20%) were identified, 40 (80%) were malignant, and one surgical margin was positive. These results show a fine example of how a procedure can be personalized, with efficiency, safety and promising outcomes. The main conclusion of the authors is that partial nephrectomy after super-selective arterial embolization is a safe and reproducible minimally invasive procedure for the treatment of localized renal tumors.

Comments and future research

Additional studies are needed in order to confirm the results of this study and establish the advantages of this new technique when compared with LPN. Prospective studies should be conducted in order to evaluate perioperative outcomes as well as long-term outcomes, and show that perioperative morbidity and long term cardiovascular adverse events are not similar for the two methods. A longer follow-up period is necessary in order to assess oncologic outcomes and determine whether this technique shows an advantage in terms of lower recurrence rate and 5-year overall survival. Once its benefits and safety are established, it would be interesting to try utilizing this new technique in other fields of surgical oncology.

i Related important publications

Simone G, Gill IS, Mottrie A, Kutikov A, Patard JJ, Alcaraz A, Rogers CG. Indications, techniques, outcomes, and limitations for minimally ischemic and off-clamp partial nephrectomy: a systematic review of the literature. *Eur Urol.* 2015 Oct;68(4):632-40.

Simone G, Papalia R, Guaglianone S, Carpanese L, Gallucci M. Zero ischemia laparoscopic partial nephrectomy after superselective transarterial tumor embolization for tumors with moderate nephrometry score: long-term results of a single-center experience. *J Endourol.* 2011 Sep;1443-6:(9)25;

ARTICLE NUMBER 3

The role of interventional radiology in the management of abnormally invasive placenta :a systematic review of current evidences.

Quant Imaging Med Surg 2020 .Jun.1370-1391:(6)10;

Soyer P, Barat M, Loffroy R, Barral M, Dautry R, Vidal V, Pellerin O, Cornelis F, Kohi MP, Dohan A.

Abstract

Abnormally invasive placenta (AIP) is a potentially severe condition. To date, arterial embolization in women with postpartum hemorrhage due to AIP is the treatment option for which highest degrees of evidence are available. However, other techniques have been tested, including prophylactic catheter placement, balloon occlusion of the iliac arteries and abdominal aorta balloon occlusion. In this systematic review, we provide an overview of the currently reported interventional radiology procedures that are used for the treatment of postpartum hemorrhage due to AIP and suggest recommendations based on current evidences. Owing to a high rate of adverse events, prophylactic occlusion of internal iliac arteries should be used with caution and applied when the endpoint is hysterectomy. On the opposite, when a conservative management is considered to preserve future fertility, uterine artery embolization should be the preferred option as it is associated with a hysterectomy rate of 15.5% compared to 76.5% with prophylactic balloon occlusion of the internal iliac arteries and does not result in fetal irradiation. Limited data are available regarding the application of systematic prophylactic embolization and no comparative studies with arterial embolization are available.

Article review and analysis

Aim of this study: Abnormally invasive placenta may result in excessive post-partum bleeding and is thus considered a potentially life-threatening condition. The aim of this systematic review is to gather accumulated data on different existing techniques for the management of such bleeding and to enlighten the readers with information regarding the currently reported prophylactic interventional radiology procedures, which were previously not considered. Despite the fact that most articles that influence our everyday practice are well designed prospective studies, we think that this recently published review is very important as it summarizes the growing experience in this field, and truly reflects the advances of the EVTm concept.

Methods

Pros: This systematic review is the result of a thorough literature scan, with over 900 papers screened and 54 papers selected for the analysis. The overview provides a comprehensive, wide-angled view of the management of post-partum hemorrhage (PPH) due to AIP through existing data regarding several different techniques, prophylactic as well as non-prophylactic, and their efficacy in the management of this complicated condition. Collected data are diverse and include: choice of embolic agent, radiation dose delivered to the fetus, complications, and even some long-term possible outcomes. Studies reporting AIP that could not be individualized from a more general group of abnormal placentation were excluded, hence, the results concerning each technique are more specific and less prone to bias. Moreover, all the main characteristics of the studies included in the analysis are listed in a very systematic and accessible manner, and include number of AIP patients, AIP type (Accreta/Increta/Percreta), type of intervention, rate of hysterectomy, estimated blood loss, complication rate, radiation dose and other major points of interest. Suggested recommendations are plausible, given the vast amount of data collected and reviewed.

Cons: One concern to consider is the length of time over which data was collected. The overview includes articles published between the years 2008 and 2019 and provides a great deal of data, nevertheless some if it may be irrelevant, or at least not updated, due to changes and progress that have occurred during this time period. Past and recent results were presented without referring to the increasing progress in performing such procedures and the experience gained, leading to higher skills and improved outcomes. Updated results maybe should have been given more importance in the analysis. In addition, a closer examination of the studies included in the analysis reveals that the majority of them had a relatively low number of patients, effortlessly meeting the inclusion criteria of at least 10 women with AIP in the study population. An inconsistency regarding the results of the use of prophylactic balloon catheter placement in the iliac arteries may be attributed to the fact that most articles that found no advantage for this technique had a small study population and were less up to date. Well-designed studies discussing this technique are missing in this overview, and only one RCT with just 27 patients was included. Therefore any conclusions regarding this method are doubtful. Lastly, in spite of the wide coverage of data, there is still a lot of data missing making it difficult to better define the most appropriate patient for each procedure. Such additional data might include demographics, sonographic findings, angiogram features of the patients and any additional information, which may perhaps promote a better understating of which technique carries a personalized beneficial effect for each patient.

Results, conclusion, and what it means

For several decades, arterial embolization has been the common practiced interventional method for post-partum hemorrhage control. A lot of experience in this method has been gained and today it is being performed by well-trained interventional radiologists with fair results. However, in this systemic review we learn of the need to investigate other interventional techniques and the process of searching for new methods that are feasible, safe and result in even better outcomes. Four different techniques to control post-partum hemorrhage due to AIP were presented in this systematic review: arterial embolization, prophylactic uterine artery catheterization and/or prophylactic embolization, prophylactic balloon catheter placement in the iliac arteries, and prophylactic balloon occlusion of the abdominal aorta. Arterial embolization, the most practiced and investigated technique, has shown high technical success. Repeat embolization may be necessary in order to achieve optimal results, yielding an overall clinical success of approximately 90% in most of the studies reviewed and low rates of need for hysterectomy. This technique is considered safe, in accordance with the large experience of its use. Performing this procedure after cesarean delivery and before hysterectomy carries the benefit of not exposing the fetus to radiation, which is inevitable in prophylactic procedures. Another important advantage of this method is its non-prophylactic character which spares unnecessary involvement in cases of AIP without PPH. Uterine artery embolization may also be used in addition to prophylactic balloon placement techniques, and may improve final outcomes. Prophylactic procedures involving catheter placement were investigated with anticipation, leading to a large amount of data accumulated in a relatively short period of time. Still, their use remains debated since the results are often inconsistent and there is far from consensus regarding their safety. In this review, the use of a prophylactic uterine artery catheter has shown conflicting results in terms of hysterectomy rates and blood loss. Some adverse events, such as transient buttock pain, uterine necrosis, peritonitis and endometritis, were described as a result of this procedure, all of them sporadic and hence not conclusive. Prophylactic balloon occlusion of the iliac arteries remains debated, with data suggesting high rates of complications in comparison with embolization. This technique has been investigated mostly through uncontrolled studies and has shown a variety of results, some showing a clear advantage in reducing bleeding and hysterectomy rates, while other articles showed no benefit at all. Existing evidence regarding the potential benefits of this technique seem weak and not conclusive, yet accumulated evidence regarding its safety, including several vascular complications (e.g., acute limb ischemia, common and external iliac artery thrombosis, bilateral pseudoaneurysms, unilateral arterial rupture), do raise some concerns regarding the use of this method. The use of prophylactic balloon occlusion of the aorta, however, shows much more favorable results including reduced blood loss resulting in lower need for blood transfusions, low rates of hysterectomy, and less complications or adverse events in comparison with iliac balloon. When comparing all prophylactic techniques, the one that is most safe and effective is prophylactic balloon occlusion of the aorta. Data collected

from 10 studies, with 445 women treated with this technique, demonstrated a pooled hysterectomy rate of 12.1%, which is quite similar to the results of the much more commonly practiced arterial embolization. This may suggest that more practice and experience in performing prophylactic aortic balloon occlusion in women with AIP before elective cesarean section may eventually yield superiority of this method over the current standard treatment. However, the biggest disadvantage of the prophylactic approach is that previous data shows that 50% of women with AIP do not need any interventional procedure, and hereby any prophylactic systematic approach may give rise to more damage than benefit by exposing the fetus to radiation and exposing the patients, unnecessarily, to the potential risks of this approach. Treating patients with AIP, especially when fertility preservation is required, remains a challenge. Although it currently seems that arterial embolization should be the preferred option for such patients, the use of a sole prophylactic technique or a combination of balloon catheter placement with arterial embolization should be furthered investigated in order to achieve a better understanding of its potential success in prevention of hysterectomy. Prophylactic application of balloon catheter, specifically aortic, expedites treatment in cases of uncontrolled bleeding and is a feasible method which may be used successfully. The greatest impact of this article, though, is not necessarily attributed to its results, but to its conceptual impact. It introduces the readers to the process of investigating an endovascular and hybrid approach, in which experience is constantly being gained and is generating a feasible option for different fields of surgery, where advance prevention of an expected major bleed remains a major issue. This review reflects the progress being made with endovascular techniques in the management of abnormally invasive placenta, still the veracity of results arising from the vast amount of research and collected data indicates that at least some of it may not reliably reflect the advantages or disadvantages of each technique. Hence, only further research, especially comparative, can truly accomplish solid conclusions and create a new set of tools for treating PPH caused by AIP.

Comments and future research

Different interventional radiology techniques have been investigated and widely described; however, well-designed comparative studies are missing and should be conducted in order to demonstrate the efficacy and safety of each technique, and to better define the patients who may benefit most from a prophylactic procedure. Further investigation is needed in order to explore whether the characteristics of each patient with AIP may suggest a beneficial effect of one technique over the other, in terms of applicability, safety and effectiveness. Although randomized trials are considered less prone to bias, such a study design would not necessarily be a suitable option, as it may not express the personalization effect made possible with interventional radiology techniques. Finally, the potential of aortic balloon occlusion, especially in comparison with arterial embolization, should be the focus point of future research, as it appears to be the most promising prophylactic option.

i Related important publications

Chen L, Wang X, Wang H, Li Q, Shan N, Qi H. Clinical evaluation of prophylactic abdominal aortic balloon occlusion in patients with placenta accreta: a systematic review and meta-analysis. *BMC Pregnancy Childbirth*. 2019 Jan 15;19(1):30.

Ordoñez CA, Manzano-Nunez R, Parra MW, Rasmussen TE, Nieto AJ, Herrera-Escobar JP, Fernandez P, Naranjo MP, García AF, Carvajal JA, Burgos JM, Rodriguez F, Escobar-Vidarte MF. Prophylactic use of resuscitative endovascular balloon occlusion of the aorta in women with abnormal placentation: A systematic review, meta-analysis, and case series. *J Trauma Acute Care Surg*. 2018 May;84(5):809-818.

ARTICLES NUMBER 4 & 5

Compliant endovascular balloon reduces the lethality of superior vena cava tears during transvenous lead extractions.

Heart Rhythm. 2017 Sep;14(9):1400-1404.
Azarrafiy R, Tsang DC, Boyle TA, Wilkoff BL, Carrillo RG.

Abstract

Background: Superior vena cava (SVC) lacerations have been identified as the most lethal complication encountered during cardiac implantable electronic device lead extraction. The case fatality rate of these events approximates 50% due to rapid exsanguination. A novel, compliant balloon specifically designed for use in the SVC may provide hemostasis in the event of endovascular perforation.

By temporarily occluding the compromised vessel, the endovascular balloon should delay hemodynamic collapse, provide a more controlled surgical field for repair, and thereby reduce the mortality of SVC tears complicating transvenous lead extraction.

Objective: To assess the early impact of the compliant endovascular balloon on the management of SVC tears and survival outcomes.

Methods: We searched a publicly available, United States Food and Drug Administration–maintained database for adverse events from 1 manufacturer of lead extraction tools. Reports from July 1, 2016, to December 31, 2016 were reviewed by 2 physicians to identify instances of SVC tears. Extracting physicians were contacted for further case details. Confirmed SVC tears were analyzed for patient demographics, repair strategies, and index hospitalization mortality.

Results: Of the complications reported, 35 cases of surgically confirmed SVC tears were identified. One hundred percent of patients (9/9) were discharged alive when the endovascular balloon was properly utilized, compared to 50% of patients (13/26) when the device was not used (P 5 .0131). Differences between all other variables analyzed were statistically insignificant.

Conclusion: During the study period, we observed a reduction in mortality in patients who suffered SVC tears while undergoing lead extraction when treatment included an endovascular balloon.

Long-term outcomes of prophylactic placement of an endovascular balloon in the vena cava for high-risk transvenous lead extractions.

Heart Rhythm. 2017 Dec;14(12):1833-1838.

Tsang DC, Azarrafiy R, Pecha S, Reichenspurner H, Carrillo RG, Hakmi S.

Abstract

Background: Many clinicians use the strategy of prophylactically placing an endovascular balloon before transvenous lead extraction, yet there are no data regarding this practice.

Objective: This study assesses long-term outcomes of prophylactic placement of an endovascular balloon in the venae cavae of patients during transvenous lead extraction.

Methods: From April 1, 2016 to March 31, 2017 data were prospectively collected at 2 international cardiovascular centers on patients who had the balloon prophylactically placed in the venae cavae. Patients were monitored for a minimum of 3 months to capture any associated adverse events.

Results: Twenty-one patients had the balloon prophylactically placed in the venae cavae during lead extraction. Sixteen patients were male (76%); the mean age was 57.6 $\pm$ 18.7 years; and the mean body mass index was 26.1 $\pm$ 4.4 kg/m². The mean lead dwell time was 11.2 $\pm$ 8.3 years, with an average of 2.2 $\pm$ 1.1 leads per case, and most indications for extraction were noninfectious (62%).

Two minor complications (10%, pocket hematomas) and 1 major complication (5%, cardiac tamponade) occurred during the procedure. All cases (100%) were procedural successes, and all patients (100%) were discharged alive. On follow-up (6.8 $\pm$ 3.7 months), all patients were alive and reported no adverse events related to prophylactic balloon placement, such as pulmonary emboli or deep venous thrombi.

Conclusion: During the study period, we observed no acute or long-term adverse outcomes associated with prophylactic placement of an endovascular balloon in the venae cavae of patients undergoing transvenous lead extraction.

Article review and analysis

Aim of these studies: Here we present two complementary articles. The first, a pioneering work evaluating the feasibility of the technique previously only described in animal models, followed by a single case series. The second article, which was published after the enrollment of a larger number of patients, described late adverse events of the technique after long-term follow-up. Since Superior Vena Cava (SVC) lacerations have been identified as the most lethal complication encountered during cardiac implantable electronic device lead extraction, with a case fatality rate of approximately 50%, an adequate solution to improve outcomes was needed.

A novel approach of prophylactic positioning of an endovascular balloon at the SVC, ready for rapid deployment in the case of a hypotensive crisis, was developed. In the first article, data were collected retrospectively. All of the reported complications from a single lead extraction tool manufacturer from July 1, 2016 to December 31, 2016 were identified using the Manufacturer and User Facility Device Experience (MAUDE) database. Two physicians independently reviewed the MAUDE database to classify events as SVC tears or non-SVC tears and to record survival outcomes. Cases were subsequently stratified into two cohorts: tears in which an endovascular balloon was used according to manufacturer guidelines and tears in which an endovascular balloon was either not used or improperly used.

The second study prospectively collected data at two international cardiovascular centers from April 1, 2016 to March 31, 2017 on patients who had the balloon prophylactically placed in the vena cava. Patients were monitored for a minimum of 3 months to capture any associated adverse events.

Methods

Pros: The work presented was a pioneering piece of work to evaluate the feasibility of the technique which, until publication, had only been described in swine and in a case series. By gathering enough cases and analyzing their data, the authors could conclude the feasibility and efficacy of the technique.

While in the first article the data was collected retrospectively, the second was a prospective work assessing the feasibility of the approach, adverse events in acute time, and had the major advantage of follow-up and recording of late adverse events.

Cons: There is a lack of data concerning the physiological state of the patients during deployment of the endovascular balloon, size of the venous defect, amount of blood lost, number of blood products, time to balloon deployment, and time before start of surgical interference. Moreover, in the first study there was no information regarding patients' comorbidities. This decreases the strength of the comparison between the deceased and the survivals. The data in the first article was collected from a registry of a single lead manufacture, thus lacking the complication rate and survival rates of patients having other manufacturer's intravenous leads.

As mentioned in the methods, in the first article the patients were divided into two groups: the first group included patients in whom an endovascular balloon was used, and in the second group an endovascular balloon was either not used or improperly used. The grouping together of cases with misuse and non-usage of balloon causes misinterpretation of the data, since misuse of the balloon is still a usage (intention to treat).

Results, conclusion, and what it means

One hundred percent of the patients treated with endovascular balloon occlusion of the SVC survived the lethal complication of SVC tear. The first article included nine

patients and the second publication describes the experience of 21 patients. It is not clear whether there was some possible overlap. Mortality rates were up to 50% in the untreated group. However, as mentioned in the cons of the methodology, we believe that patients who underwent improper use of the balloon should be accounted for in the intervention group, thus leading to lower success rates of the technique.

The second article dealt with adverse events and not only feasibility of the procedure. No major adverse events were recorded during the perioperative period nor during the follow-up period, thus concluding that the procedure is safe both in real time and afterwards.

The authors also made an effort to define which patients are in need of prophylactic placement of a SVC balloon. In the first article, characteristics of a high-risk patient were concluded to be: female gender, low BMI score, patients with implantable cardioverter-defibrillators, and those having had leads for a prolonged term (9.62 years). In the following prospective article, patients were classified as high risk and considered for prophylactic balloon placement if they had any of the following characteristics: female gender, low BMI, leads older than 6 years, dual-coil implantable cardioverter-defibrillator (ICD) leads, or currently prescribed steroid therapy. However, the analysis of the demographic features of the 21 patients undergoing prophylactic placement of balloon showed that the majority of the patients were male (76%) with a normal BMI (26). Characteristics which correlated with earlier definitions were dual coil device (62% had ICD or CRTD) and mean lead dwell time of 11.2 years.

Comments and future research

Due to the very promising results of this new endovascular approach, especially compared with previous treatment, it may be assumed that prophylactic SVC balloon placement may be considered a future standard practice during transvenous leads extraction. However, this procedure might be associated with complications due to femoral vein access and SVC balloon placement

More comprehensive work and future studies are needed. First, the validation of this approach requires a significantly larger numbers of patients. Better clarified characteristics of high-risk patients are warranted as well as development of strict usage protocols. In addition, it will be very interesting to evaluate the additional benefits of the hybrid room usage in selected patients. Another future study may better define the appropriate training needed for the utilization of this technique.

i Related important publications

Hauser RG, Katsiyannis WT, Gornick CC, Almquist AK, Kallinen LM. Deaths and cardiovascular injuries due to device-assisted implantable cardioverter-defibrillator and pacemaker lead extraction. *Europace*. 2010 Mar;12(3):395-401.

Fu HX, Huang XM, Zhong LI, Osborn MJ, Asirvatham SJ, Espinosa RE, Brady PA, Lee HC, Greason KL, Baddour LM, Sohail RM, Acker NG, Hodge DO, Friedman PA, Cha YM. Outcomes and Complications of Lead Removal: Can We Establish a Risk Stratification Schema for a Collaborative and Effective Approach? *Pacing Clin Electrophysiol*. 2015 Dec;38(12):1439-47.

Bontempi L, Vassanelli F, Cerini M, Inama L, Salghetti F, Giacomelli D, Gargaro A, Raweh A, Curnis A. Predicting the difficulty of a transvenous lead extraction procedure: Validation of the LED index. *J Cardiovasc Electrophysiol*. 2017 Jul;28(7):811-818.

Wazni O, Wilkoff BL. Considerations for cardiac device lead extraction. *Nat Rev Cardiol*. 2016 Apr;13(4):221-9.

Wilkoff BL, Love CJ, Byrd CL, Bongiorno MG, Carrillo RG, Crossley GH 3rd, Epstein LM, Friedman RA, Kennergren CE, Mitkowski P, Schaerf RH, Wazni OM; Heart Rhythm Society; American Heart Association. Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management: this document was endorsed by the American Heart Association (AHA). *Heart Rhythm*. 2009 Jul;6(7):1085-104.

ARTICLE NUMBER 6

Precision image-guided colonic surgery: proof of concept for enhanced preoperative and intraoperative vascular imaging.*Surg Endosc.* 2021 Feb;35(2):962-970.

Forgione A, Barberio M, Agnus V, Swanström L, Marescaux J, Diana M, Gallix B.

Abstract

Background: Colorectal surgery has benefited from advances in precision medicine such as total mesorectal resection, and recently, mesocolon resection, fluorescent perfusion imaging, and fluorescent node mapping. However, these advances fail to address the variable quality of mesocolon dissection and the directed extent of vascular dissection (including high ligation) or pre-resection anastomotic perfusion mapping, thereby impacting anastomotic leaks. We propose a new paradigm of precision image-directed colorectal surgery involving 3D preoperative resection modeling and intraoperative fluoroscopic and fluorescence vascular imaging which better defines optimal dissection planes and vascular vs. anatomy-based resection lines according to our hypothesis.

Methods: Six pigs had preoperative CT with vascular 3D reconstruction allowing for the preoperative planning of vascular-based dissection. Laparoscopic surgery was performed in a hybrid operating room (OR). Superselective arterial catheterization was performed in branches of the superior mesenteric artery (SMA) or the inferior mesenteric artery (IMA). Intraoperative boluses of 0.1 mg/kg or a continuous infusion of indocyanine green (ICG) (0.01 mg/mL) were administered to guide fluorescent-based sigmoid and ileocecal resections. Fluorescence was assessed using proprietary software at several regions of interest (ROI) in the right and left colon.

Results: The approach was feasible and safe. Selective catheterization took an average of 43 min. Both bolus and continuous perfusion clearly marked pre-identified vessels (arteries/veins) and the target colon segment, facilitating precise resections based on the visible vascular anatomy. Quantitative software analysis indicated the optimal resection margin for each ROI.

Conclusion: Intra-arterial fluorescent mapping allows visualization of major vascular structures and segmental colonic perfusion. This may help to prevent any inadvertent injury to major vascular structures and to precisely determine perfusion-based resection planes and margins. This could enable tailoring of the amount of colon resected, ensure good anastomotic perfusion, and improve oncological outcomes.

Article review and analysis

Aim of this study: Colon cancer is the second most prevalent malignancy in women, and the third in men. Surgical treatment remains the cornerstone and the standard care for this type of malignancy in cases of localized or regional disease, and even in

generalized metastatic disease in select patients. The quality of surgical resection has a crucial impact on the accuracy of staging and oncologic outcomes. The concept of complete meso-colic excision (CME), which includes detachment of vessels from their origin and an extensive lymphadenectomy, has been gaining progress in recent years. Although several recent articles indicate a lower recurrence rate and higher survival rates, this concept remains controversial. According to previous data, the surgical specimen often does not meet the CME criteria and occasionally not even the standards of oncologic resection. Fluorescence imaging-guided surgery techniques, which make use of injected indocyanine green and involve the use of an optical system equipped with a near infrared camera, have been used in the past several years in colon surgeries in order to improve the identification of the anatomy and to evaluate the organs' perfusion. The aim of this study was to present an integrated hybrid approach model, which includes surgical resection in a fluorescence imaging-guided surgery technique when a selective arterial ICG injection is performed. The purpose of the model is to improve the surgical field's anatomy demonstration and, by these means, to achieve a more precise surgical resection, which in turn may lead to lower complication rates and improved oncologic outcomes.

Methods

Pros: This is a pioneering study aiming to demonstrate the feasibility of the proposed paradigm. The study was conducted in six pigs with the utilization of an identical endovascular surgical technique. Anatomical identification was assessed quantitatively by using a software analysis which mapped the regions of interest and quantified the fluorescence intensities within each scene. Additional qualitative assessment was obtained from the operating room staff, who assessed image quality and the surgical value achieved by the use of this method.

Cons: In this study, the experimental method was examined in six healthy pigs. IMA and SMA catheterization was performed in all subjects, of which, three subjects were injected with ICG directly into the relevant artery. However, the protocol was changed during the experimental process, and the other three subjects were additionally injected with intravenous ICG in different doses. All six subjects underwent sigmoid and ileocecal resection. It appears that, in order to investigate a number of procedures, several different procedures were conducted simultaneously on the same subject, generating protocols that perhaps are less proper for human subjects. Although the main purpose of the study focused on demonstrating feasibility, the use of several protocols and procedures may yield results that are less conclusive, particularly in such a small group of subjects. Additionally, no assessment was performed to substantiate the quality of surgical resection and the question of whether the resected specimens met the CME principles remained unanswered. Indeed, the main aim of the current phase of the study is a simple proof of concept. However, in the absence of such investigation, the necessity of this paradigm, even if feasible, is doubted.

Results, conclusion, and what it means

The main conclusion of this study is that the use of the proposed method improves the anatomical identification of the colorectal targets, including the IMA, IMV and the colon segments, which are supplied and not supplied by the IMA. The best results were achieved with a combination of local arterial injection and an intravenous systemic injection. The findings were observed and assessed by a qualitative and an objective quantitative analysis. The authors of the study concluded that this approach is feasible and hence further research should be performed in order to confirm its utility. We agree that the endovascular and hybrid approach may improve the surgical outcomes and that further investigation is warranted. This approach may be useful in other surgical procedures, such as surgical resection of the rectum with TME or in cases of massive GI bleeding, by better defining the optimal dissection planes and vascular mapping of selected regions of interest. Although these conclusions are held with anticipation, they are limited to a single, primary study conducted in an animal model, and may vary greatly when conducted in human subjects. First, in contrast to the healthy pigs which were chosen for this study, most patients with colon malignancy are elderly and suffer from vascular diseases and, sometimes, with occluded IMA. Additionally, collateral vessels may also affect blood supply, as may the presence of the malignant process itself, which may cause angiogenesis with altered vascularization. Adverse events as a result of arterial catheterization were not assessed in this current study and should be investigated in future research. Additionally, the potential benefits of this method should be considered versus the potential risks. Since the study aimed to improve surgical outcomes, evaluation of the quality of resection should be carried out and also refer to the oncologic outcomes and the rates of surgical complications (vascular injuries, anastomotic leaks, etc.). Moreover, the potential of this method to improve survival should ultimately be established. Another important point to consider is the aspect of cost-effectiveness of this method, as it is certainly more resource demanding in comparison to the current surgical approach.

Comments and future research

This study explores an interesting approach, which holds the potential to generate a significant advancement in the field of surgical oncology in colorectal cancer. As mentioned above, further research should be conducted in human subjects in order to evaluate the efficacy of this paradigm in terms of the surgical resection quality, complication rate and potential influence on overall survival. Lastly, the promising results of the hybrid approach in this study should encourage the introduction and exploration of this method in other fields of surgery.

i Related important publications

Liu YY, Pop R, Diana M, Kong SH, Lègner A, Beaujeux R, Marescaux J. Real-time fluorescence angiography by intra-arterial indocyanine green injection to identify obscure gastrointestinal bleeding territory: proof of concept in the porcine model. *Surg Endosc*. 2016 May;30(5):2143-50.

Heiliger C, Piecuch J, Frank A, Andrade D, Von Ehrlich-Treuenstätt V, Schiergens T, Rentsch M, Werner J, Karcz K. Intraarterial indocyanine green (ICG) fluorescence augmentation by marking embryonal resection areas in colorectal surgery: a feasibility study in a porcine model. *Minim Invasive Ther Allied Technol* 2019 .Dec .321-325;(6)28;

CHAPTER 20.

Endovascular complications

Authors: *Federico Cocolini, Silvia Strambi and Massimo Chiarugi*

Introduction

The endovascular treatment of traumatic arterial injuries is considered a less invasive but effective alternative to open surgical treatment. It has recently become widespread, especially in the past decade, due to both technical improvements and encouraging results coming from the literature. However, the use of endovascular techniques, such as REBOA, is not homogeneous across the world, both in terms of indications, practice of use (to date, there is no universally recognized certification for REBOA positioning that pertain to different emergency specialists) and type of device, which varies between continents.

In the literature, complications that burden the endovascular treatment are difficult to extrapolate, as published papers are mainly retrospective studies based on multicentric registries or on small case series, without a specific focus on complications and outcome.

However, the complications should be divided into systemic and procedure-related: the first are logically also partly due to the high degree of associated injury to which the severely traumatized patients are subject, which vary from ischemia of the lower limbs, acute kidney failure, pulmonary failure, SIRS/sepsis and MOF. On the other hand, the endovascular procedure-related complications seem to decrease significantly with the use of smaller introducer catheters for REBOA (e.g., 7 Fr, compared to traditional 12-14 Fr) as reported in a Japanese series, and with the use of partial (pREBOA) or intermittent (iREBOA) insufflation, although further prospective studies with standardized protocols are needed to better assess the outcome of these methods. We have carried out a literature search of the past five years and we hereby report the most significant articles reviewed, underlining their strengths and limitations.

ARTICLE NUMBER 1

Utilization of endovascular and open surgical repair in the United States: A 10-year analysis of the National Trauma Databank (NTDB).

Am J Surg. 2019 Dec;218(6):1128-1133.

Romagnoli AN, Zeeshan M, Joseph B, Brenner ML.

Abstract

Purpose: Endovascular therapy provides a less invasive alternative to open surgery for critically ill patients who have sustained arterial injuries. The purpose of this study was to evaluate recent trends in the management of arterial injuries in the United States with specific reference to the use of endovascular strategies and to examine the outcomes of endovascular vs open therapy for the treatment of civilian arterial traumatic injuries.

Methods: We performed a 10-year (2004-2014) analysis of ACS-NTDB and identified all adult trauma patients who had arterial injuries. Data regarding demographics, injury parameters, endovascular or open vascular repair and outcomes were extracted. Cochran-Armitage trend analysis and multivariate logistic regression analysis were performed.

Results: A total of 111,061 patients with arterial injuries were identified and included in our analysis.

Mean age was 39 ± 19 years, 82% were male and 79% were white. The most common artery injured was iliac artery followed by brachial artery and thoracic aorta. Overall 6.7% (7434) patients underwent endovascular repair while 38.8% (42,495) had open vascular repair. The rate of endovascular repair increased from 3.1% to 8.9% while the incidence of open vascular repair decreased from 47% to 32% over the study period. Patients in endovascular group had lower ISS compared to patients in open vascular repair group (17.10 vs 24.10 , $p < 0.001$). Patients who underwent endovascular repair had shorter hospital length of stay (days: 10.17 vs 11.15 , $p < 0.001$), lower mortality (8% vs 14%, $p = 0.01$). On multivariate regression analysis after controlling for confounding variables, endovascular repair was independently associated with improved survival (OR: 2.45, $p = 0.01$).

Conclusions: The use of endovascular modalities to repair arterial injuries in the setting of acute trauma is increasing in a dramatic fashion. Endovascular repair of trauma arterial injuries is associated with shorter length of stay and improved survival compared to open vascular procedures.

Article review and analysis

Aim of this study: This study analyzes data relating to the management of traumatic

arterial injuries in the United States over the past 10 years, in order to verify whether, as hypothesized, there is an increase in the use of endovascular repair.

The authors conducted a retrospective (2004-2014) analysis of traumatic arterial injuries in adults that had been registered in the American College of Surgeons (ACS) National Trauma Databank (NTDB). Patients with concomitant venous injuries or unspecified arterial injuries were excluded. The following data were collected for each patient: general demographics, comorbidities, injury parameters (mechanism of injury, ISS, AIS of each body region, location of arterial injury), vital signs at admission (SBP, HR, GCS, intensive care unit (ICU) admission, ICU length of stay (LOS)), hospital LOS, in-hospital complications, mortality and discharge disposition. Data regarding open surgical repair (OSR) or endovascular repair (EVR), discriminated using ICD-9-CM procedure codes, were compared.

Methods

Pros: The NTDB is the largest registry of trauma patients in the United States; in fact, the sample of the study is wide, with 111,061 involved patients. All data in the NTDB, which includes more than 100 data points, are subject to continuous screening, logistic checks, and audits to improve the quality of the databank.

Cons: Given the retrospective nature of the study, some data were missing and thus they were treated as missing at random (MAR). Variables with missing data included: age (2.9% of patients), ED Systolic Blood Pressure (4.8%), ED heart rate (4.7%), ED GCS (4.3%) and time to procedure (6.9%). Authors performed multiple imputations (using the Markov Chain Monte Carlo method) to account for the missing values. Moreover, in the database, the description of the vascular injury is not detailed and any need for reintervention in the same patient is not contemplated, making it difficult to reach specific conclusions.

Results, conclusion, and what it means

Only 45% (49,929) of the patients underwent a definitive repair of their arterial injuries during hospitalization: 7434 (6.7%) underwent endovascular repair while 42,495 (38.3%) underwent open surgery.

There was a significant increase in the use of EVR over the study period (from 3.1% in 2004 to 8.9% in 2014); meanwhile, the number of patients undergoing OSR decreased significantly from 47% in 2004 to 32% in 2014. This is likely due to both the improvement of endovascular techniques as well as to the FDA approval of TEVAR stent-grafts in 2005. The thoracic aorta (48%) was the most common injured artery treated in the EVR group, followed by the iliac (31%) and femoral (20%) arteries, while the brachial (34%) artery was the most common artery treated in the OSR group, followed by the femoral (28%) and popliteal (21%) arteries. The mean time to repair was 50% shorter in the EVR versus OSR groups (4h vs 8h) and this is difficult to interpret as specific chronological criteria are lacking.

Regarding complications, patients in the EVR group had statistically significantly lower rates (19% vs 24%), primarily surgical site infections and pneumonia. EVR patients were also less likely to be admitted to the ICU, had a shorter hospital length of stay, and a lower mortality rate (8.8% vs 14.2%), but we must consider that this group of patients had a lower overall injury burden with lower Injury Severity Scores (ISS). Furthermore, there are limited details regarding the patient's clinical course, making it impossible to determine whether described complications are related to the primary injury, to the vascular intervention, or are completely unrelated.

On regression analysis, after controlling for confounding variables (demographics, comorbidities, admission vitals, injury parameters, ISS), EVR was independently associated with lower odds of complications and higher odds of survival compared to OSR. However, it is important to note that there are still some anatomical areas better suited to open treatment; for example, the smaller caliber of the infrageniculate and infrabrachial vessels makes them at high risk of in-stent thrombosis.

The study, within its limitations, demonstrates an increasing utilization of endovascular treatment in the US over the past 10 years and associates it with an overall improved survival.

Comments and future research

A specific database that analyzes the vascular injury in a circumstantial way, such as the American Association of Surgery for Trauma Prospective Observational Vascular Injury Treatment registry (AAST-PROOVIT), would provide more detailed information regarding vascular complications and outcomes. Moreover, considering that intra-vascular stents and TEVAR grafts only obtained initial FD approval in the 1990s and 2000s respectively, data regarding the long-term patency in young patients, in whom in-stent thrombosis has the potential to be particularly severe, need to be updated.

i Related important publications

Morrison JJ, Madurska MJ, Romagnoli A, Ottochian M, Adnan S, Teeter W, Kuebler T, Hoehn MR, Brenner ML, DuBose JJ, Scalea TM. A Surgical Endovascular Trauma Service Increases Case Volume and Decreases Time to Hemostasis. *Ann Surg*. 2019 Oct;270(4):612-619.

DuBose JJ, Savage SA, Fabian TC, Menaker J, Scalea T, Holcomb JB, Skarupa D, Poulin N, Chourliaras K, Inaba K, Rasmussen TE; AAST PROOVIT Study Group. The American Association for the Surgery of Trauma PROspective Observational Vascular Injury Treatment (PROOVIT) registry: multicenter data on modern vascular injury diagnosis, management, and outcomes. *J Trauma Acute Care Surg*. 2015 Feb;78(2):215-22; discussion 222-3.

ARTICLE NUMBER 2

Resuscitative Endovascular Balloon Occlusion of the Aorta in trauma: a systematic review of the literature.

World J Emerg Surg. 2017 Aug 29;12:42.

Gamberini E, Coccolini F, Tamagnini B, Martino C, Albarello V, Benni M, Bisulli M, Fabbri N, Hörer TM, Ansaloni L, Coniglio C, Barozzi M, Agnoletti V.

Abstract

Purpose: Resuscitative endovascular balloon occlusion of the aorta has been a hot topic in trauma resuscitation during these last years. The aims of this systematic review are to analyze when, how, and where this technique is performed and to evaluate preliminary results.

Methods: The literature search was performed on online databases in December 2016, without time limits. Studies citing endovascular balloon occlusion of the aorta in trauma were retrieved for evaluation.

Results: Sixty-one articles met the inclusion criteria and were selected for the systematic review. Overall, they included 1355 treated with aortic endovascular balloon occlusion, and 883 (65%) patients died after the procedure. In most of the included cases, a shock state seemed to be present before the procedure. Time of death and inflation site was not described in the majority of included studies. Procedure-related and shock-related complications are described. Introducer sheath size and comorbidity seems to play the role of risk factors.

Conclusions: Resuscitative endovascular balloon occlusion of the aorta is increasingly used in trauma victim resuscitation all over the world, to elevate blood pressure and limit fluid infusion, while other procedures aimed to stop the bleeding are performed. High mortality rate is probably due to the severity of the injuries. Time and place of balloon insertion, zone of balloon inflation, and inflation cutoff time are very heterogeneous.

Article review and analysis

Aim of this study: In a systematic review, the authors analyze the use of REBOA in order to understand whether there is a real benefit in the category of trauma patients in terms of overall reduction of mortality, since previously reported data are controversial (range varies from 0 to 100). They also analyze complications in order to understand if these are due to the insertion, to the blood pressure increase upstream from the occlusion, or to the failure of the technique itself.

The Medline literature search was performed in December 2016, with no time limit. All studies concerning REBOA use in trauma were retrieved and analyzed. Review articles, systematic reviews, interventional trials, case series and reports were considered

eligible for inclusion in this systematic review. Only trauma victims who underwent REBOA during emergency department (ED) and operating room (OR) resuscitation phase were considered.

Methods

Pros: The authors retrospectively analyzed the results of 28 studies concerning the use of REBOA exclusively in a trauma context during the resuscitation phase, excluding non-traumatic hemorrhage, such as obstetric, gastrointestinal or ruptured aneurysm bleeding. Cases in which REBOA was positioned in order to prevent shock (in critical but hemodynamically stable patients at admission) were also excluded. Mortality, procedure-related and shock-related complications were collated for all the papers involved.

Cons: The study includes a large sample (1355) of adult patients, with a huge heterogeneity in patient selection due to different inclusion criteria for each paper. Regarding mortality, there is a lack of temporal discrimination (e.g., within or after 24h from admission), which would allow better understanding of whether it was REBOA-related or not. Complications were also expressed as a percentage of total cases, although there was a clear variability in procedures regarding procedure time and environment, involved Zone (I, II or III) and balloon deflation cut-off time.

Results, conclusion, and what it means

Despite a huge heterogeneity in its employment, REBOA is commonly used in trauma patients to limit blood loss, elevate blood pressure and allow for subsequent treatments. The most common site of insertion is by femoral artery access with a 10 to 12 Fr introducer. High mortality rate is a feature of severely multiple-injured patients. The main risk factors are comorbidity (high body mass index, thrombocytopenia, use of anti-platelet drugs) and large introducer sheath size, since complications seem to significantly reduce with a 7-Fr catheter. The main reported systemic complications were distal ischemia/thromboembolic events (with eventual need for amputation), kidney failure, and intracranial massive hemorrhage. Direct REBOA-related complications seem to have a minor role in mortality and are limited to local vascular injuries (e.g., pseudoaneurysm in the access site, arterial injury caused by puncture, and insertion site infection). The REBOA role as an effective and safe bridge to final bleeding control has been increasingly acknowledged during the past 10 years all over the world.

Comments and future research

Different Trauma System benchmarks will be the way to better understand and perform resuscitation in severe hemorrhagic trauma. Also the creation of a universally recognized certification for REBOA positioning will make it possible to establish homogeneous procedural competence. The role of pre-hospital REBOA in trauma victim resuscitation, “prophylactic” REBOA insertion in selected cases, partial or intermittent

balloon inflation and resuscitative endovascular balloon occlusion of inferior vena cava to treat injuries in this site, should be interesting issues for the near future.

Related important publications

Tsurukiri J, Akamine I, Sato T, Sakurai M, Okumura E, Moriya M, Yamanaka H, Ohta S. Resuscitative endovascular balloon occlusion of the aorta for uncontrolled haemorrhagic shock as an adjunct to haemostatic procedures in the acute care setting. *Scand J Trauma Resusc Emerg Med.* 2016 Feb 9;24:13.

DuBose JJ, Scalea TM, Brenner M, Skiada D, Inaba K, Cannon J, Moore L, Holcomb J, Turay D, Arbabi CN, Kirkpatrick A, Xiao J, Skarupa D, Poulin N; AAST AORTA Study Group. The AAST prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: Data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). *J Trauma Acute Care Surg.* 2016 Sep;81(3):409-19.

ARTICLE NUMBER 3

The complications associated with Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA).*World J Emerg Surg.* 2018 May 11;13:20.*Ribeiro Junior MAF, Feng CYD, Nguyen ATM, Rodrigues VC, Bechara GEK, de-Moura RR, Brenner M.***Abstract**

Non-compressible torso hemorrhage (NCTH) remains a significant cause of morbidity and mortality in the field of trauma and emergency medicine. In recent times, there has been a resurgence in the adoption of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for patients who present with NCTH. Like all medical procedures, there are benefits and risks associated with the REBOA technique. However, in the case of REBOA, these complications are not unanimously agreed upon with varying viewpoints and studies. This article aims to review the current knowledge surrounding the complications of the REBOA technique at each step of its application.

Article review and analysis

Aim of this study: The authors review complications of REBOA at each stage of its application, using a combination of literature review and clinical experience.

A Medline search was conducted including keywords such as REBOA, resuscitation, hemorrhage, and shock; the results were collected and analyzed. The research also includes studies performed in animal models.

Methods

Pros: The authors describe the various complications that can arise in each specific phase of the procedure: insertion and balloon positioning, balloon inflation, balloon occlusion time, balloon deflation, sheath removal and post-operative management of REBOA. This analysis, addressing all the specific phases, allows the readers to better understand all the potential complications and, thus, take adequate measures in their clinical practice to prevent them.

Cons: This is a registry-based and retrospective study conducted by analyzing the literature concerning the use of REBOA for non-compressible torso hemorrhage (NCTH), regardless of the etiology of the bleeding. The heterogeneity of the cohort does not allow precise indications for the use of REBOA to be obtained; although this would have been useful for the reader, it is actually beyond the scope of this paper.

Results, conclusion, and what it means

The major REBOA complications related to arterial access and balloon positioning are vessel injuries (aortic dissection, rupture, and perforation), embolization, air emboli

and peripheral ischemia. In particular, the use of large-sized sheaths for REBOA can be a critical risk factor for lower extremity ischemia. The use of a smaller (7 Fr) introducer device may be a safe and effective alternative and may remain in place during the post-procedure resuscitative phase without sequelae. The REBOA balloon should be inflated until the blood pressure is augmented and contralateral femoral pulse is stopped, avoiding not over-inflating the balloon, as this would lead to the rupture of the balloon or of the blood vessel. Various complications can occur during the balloon occlusion phase, such as misplacement of the wire/balloon within the arterial system, creation of dissection flaps or other arterial injury, development of clots, lactic acidosis and organ dysfunction. It is important to avoid a long occlusion time (exceeding 40 min), as this can result in irreversible organ injury and death. REBOA balloon deflation and subsequent reperfusion can lead to cardiovascular complications, such as hemodynamic collapse, due to the rapid release of ischemic metabolites; in this event, immediate reinflation of the balloon must be considered. In an attempt to minimize distal ischemia and extend the duration of use of REBOA, studies have led to the development of partial REBOA (pREBOA), whereby the balloon is deflated slightly, allowing a degree of flow beyond the balloon. After completion of the procedure, both the REBOA balloon catheter and the wire should be removed ensuring there is no clot in the sheath. Vigilant assessment of abdominal end organ and distal extremity perfusion is critical, and imaging the access sites within 24–48 h of sheath removal is prudent. These results provide the readers with information that can be practically applied in order to limit possible complications. Although REBOA is an effective, less-invasive and safe option for treatment of non-compressible torso hemorrhage, further understanding of the potential complications that can arise during all stages must be recognized before further spreading its clinical practice.

Comments and future research

The exact indications for REBOA remain uncertain and further knowledge of the potential complications that can aggravate all stages is required. Future studies should focus on which patient populations are suitable for receiving REBOA, as well as identifying the timeframe at which REBOA is most effective. Significant research, including the role of partial REBOA (pREBOA), will help refine its use for a wide variety of clinical scenarios.

i Related important publications

Biffi WL, Fox CJ, Moore EE. The role of REBOA in the control of exsanguinating torso hemorrhage. *J Trauma Acute Care Surg.* 2015 May;78(5):1054-8.

Davidson AJ, Russo RM, Reva VA, Brenner ML, Moore LJ, Ball C, Bulger E, Fox CJ, DuBose JJ, Moore EE, Rasmussen TE; BEST Study Group. The pitfalls of resuscitative endovascular balloon occlusion of the aorta: Risk factors and mitigation strategies. *J Trauma Acute Care Surg.* 2018 Jan;84(1):192-202.

ARTICLE NUMBER 4

Aortic balloon occlusion (REBOA) in pelvic ring injuries: preliminary results of the ABO Trauma Registry.*Updates Surg.* 2020 Jun;72(2):527-536.

Coccolini F, Ceresoli M, McGreevy DT, Sadeghi M, Pirouzram A, Toivola A, Skoog P, Idoguchi K, Kon Y, Ishida T, Matsumura Y, Matsumoto J, Reva V, Maszkowski M, Fugazzola P, Tomasoni M, Cicuttin E, Ansaloni L, Zaghi C, Sibilla MG, Cremonini C, Bersztel A, Caragounis EC, Falkenberg M, Handolin L, Oosthuizen G, Szarka E, Manchev V, Wannatoop T, Chang SW, Kessel B, Hebron D, Shaked G, Bala M, Ordoñez CA, Hibert-Carius P, Chiarugi M, Nilsson KF, Larzon T, Gamberini E, Agnoletti V, Catena F, Hörer TM.

Abstract

EndoVascular and Hybrid Trauma Management (EVTM) has been recently introduced in the treatment of severe pelvic ring injuries. This multimodal method of hemorrhage management counts on several strategies such as the REBOA (resuscitative endovascular balloon occlusion of the aorta). Few data exist on the use of REBOA in patients with a severely injured pelvic ring. The ABO (aortic balloon occlusion) Trauma Registry is designed to capture data for all trauma patients in hemorrhagic shock where management includes REBOA placement. Among all patients included in the ABO registry, 72 patients presented with severe pelvic injuries and were the population under exam. 66.7% were male. Mean and median ISS were respectively 43 and 41 (SD $\pm$ 13). Isolated pelvic injuries were observed in 12 patients (16.7%). Blunt trauma occurred in 68 patients (94.4%), penetrating in 2 (2.8%) and combined in 2 (2.8%). Type of injury: fall from height in 15 patients (23.1%), traffic accident in 49 patients (75.4%), and unspecified impact in 1 patient (1.5%). Femoral access was gained pre-hospital in 1 patient, in emergency room in 43, in operating room in 12 and in angio-suite in 16. REBOA was positioned in zone 1 in 59 patients (81.9%), in zone 2 in 1 (1.4%) and in zone 3 in 12 (16.7%). Aortic occlusion was partial/periodical in 35 patients (48.6%) and total occlusion in 37 patients (51.4%). REBOA associated morbidity rate: 11.1%. Overall mortality rate was 54.2% and early mortality rate ($\leq$ 24 h) was 44.4%. In the univariate analysis, factors related to early mortality ($\leq$ 24 h) are lower pH values ($p = 0.03$), higher base deficit ($p = 0.021$), longer INR ($p = 0.012$), minor increase in systolic blood pressure after the REBOA inflation ($p = 0.03$) and total aortic occlusion ($p = 0.008$). None of these values resulted significant in the multivariate analysis. In severe hemodynamically unstable pelvic trauma management, REBOA is a viable option when utilized in experienced centers as a bridge to other treatments; its use might be, however, accompanied with severe-to-lethal complications.

Article review and analysis

Aim of this study: Since the EVTm concept has been introduced, several studies in the literature concerning the use of REBOA in small case series or in animal models

have been reported, but a study that specifically investigated the use of REBOA for the management of hemodynamic instability due to traumatic pelvic bleeding was lacking. The authors, therefore, decided to publish the preliminary data of the ABO Trauma Registry covering 31 accredited centers from all over the world.

After approval by their ethics committees, the participating centers included their data anonymously via the website. Collected data pertained to pre-treatment conditions (patient demographics, mechanism of injury, vital signs, BMI, GCS, laboratory tests, ISS, systolic blood pressure (SBP) before REBOA inflation), REBOA phase (puncture technique, specialty obtaining access, number of access attempts, zone of occlusion, inflation time, SBP after REBOA inflation), REBOA technique (divided in continuous occlusion (CO) or non-continuous occlusion (NCO) ones, such as partial or intermittent inflation), and to complications and outcome (defined as 30-day mortality). In particular, complications were divided into REBOA-related (such as balloon migration/rupture, aortic rupture, puncture site hemorrhage, extremity compartment syndrome and distal embolus) or general complications, such as organ failure.

Methods

Pros: The study reports a consistent and homogenous case series of patients and analyzes both the characteristics of the patient, the type of trauma, the data relating to the insertion of the REBOA and its effect, in addition to the relative and systemic complications. A detailed analysis of these data allows the reader to obtain useful information about the endovascular management of severe pelvic trauma and of potential complications of this technique.

Cons: As often happens with retrospective studies, some data are missing; for example, some data regarding duration time of inflation are lacking and the diameter of the catheter used for REBOA introduction is not specified. In addition, for some parameters, the sample is not large enough to allow a multivariate analysis. A comparison with the data concerning patients treated for traumatic pelvic bleeding without the use of REBOA would also have been interesting.

Results, conclusion, and what it means

Regarding epidemiological data, there are no particular results to underline. Of 72 reported cases, only 12 patients had isolated lesions of the pelvic ring. REBOA positioning was associated with laparotomy in 46.3% of cases, and to external fixation in 15.7%, pre-peritoneal pelvic packing in 2.0%, thoracotomy in 20.8%, aortic clamping in 15.7%, angiography in 61.1% and to brain surgery in 11.1% of cases. It is, therefore, clear that the use of REBOA is part of a complex multidisciplinary context and that it cannot be considered in isolation from the anatomical and physiopathological issues arising from multiple lesions in a single patient.

Aortic occlusion was partial/periodical in 35 patients (48.6%) and total in 37 (51.4%); regarding the patients who survived over 24 hours, 15 (37.5%) had undergone total

occlusion, while 25 (62.5%) had undergone partial occlusion. Partial REBOA was statistically associated with survival in the univariate analysis (even if not confirmed in the multivariate analysis), whereas complete occlusion was associated with early mortality. Thus, in accordance with the current literature, this confirms the potential benefit of using partial REBOA, opening up for further interesting studies.

It is interesting to underline that, even if the lesion was in the pelvic ring, REBOA was inflated in Zone 1 in the majority of patients (59), and in the remaining cases in Zone 3, except for one case of Zone 2 positioning, with adjustment of balloon position being necessary in 22 cases (31%).

REBOA-related morbidities occurred in 8 patients (11.1%): 5 cases of embolization/extremity ischemia, 1 case of aortic/iliac perforation, 1 case of hematoma in the access site, 2 balloon ruptures and 4 cases of renal failure.

General complications were multiorgan failure (16.7%), pulmonary failure (8.3%) and SIRS/sepsis (8.3%).

Overall the mortality rate was 54.2% with an early mortality rate (within 24 h) of 44.4%. It is important to remember that the selected population is one of severely injured patients and this high mortality peak in the first 24 hours is in line with what is generally described in the severe trauma population.

In the univariate analysis, lower pH values, higher base deficit, longer INR, minor increase in systolic blood pressure after the REBOA inflation, and total aortic occlusion (as previously stated) were significantly associated with early mortality (≤ 24 h), but none of these risk factors was confirmed in the multivariate analysis.

The data demonstrates that REBOA is a valid tool in the temporary management of severe hemodynamically unstable pelvic bleeding when used in trained centers and, even if still associated with significant complications, can surely improve survival of severely injured patients.

Comments and future research

It would be interesting to have dedicated analyses regarding the results of partial REBOA (pREBOA, where the balloon volume is reduced to permit a level of flow-through) and intermittent occlusion (iREBOA, where the balloon is deflated entirely at regular intervals). Various techniques of REBOA inflation may be combined differently with the other hemorrhage control methods in pelvic trauma. This may allow us to find more effective solutions.

i Related important publications

Matsumura Y, Matsumoto J, Kondo H, Idoguchi K, Ishida T, Kon Y, Tomita K, Ishida K, Hirose T, Umakoshi K, Funabiki T; DIRECT-IABO Investigators. Fewer REBOA complications with smaller devices and partial occlusion: evidence from a multicentre registry in Japan. *Emerg Med J.* 2017 Dec;34(12):793-799.

Coccolini F, Stahel PF, Montori G, Biffi W, Horer TM, Catena F, Kluger Y, Moore EE, Peitzman AB, Ivatury R, Coimbra R, Fraga GP, Pereira B, Rizoli S, Kirkpatrick A, Leppaniemi A, Manfredi R, Magnone S, Chiara O, Solaini L, Ceresoli M, Allievi N, Arvieux C, Velmahos G, Balogh Z, Naidoo N, Weber D, Abu-Zidan F, Sartelli M, Ansaloni L. Pelvic trauma: WSES classification and guidelines. *World J Emerg Surg.* 2017 Jan 18;12:5.

ARTICLE NUMBER 5

Smaller introducer sheaths for REBOA may be associated with fewer complications.*J Trauma Acute Care Surg. 2016 Dec;81(6):1039-1045.**Teeter WA, Matsumoto J, Idoguchi K, Kon Y, Orita T, Funabiki T, Brenner ML, Matsumura Y.***Abstract**

Purpose: Large arterial sheaths currently used for resuscitative endovascular balloon occlusion of the aorta (REBOA) may be associated with severe complications. Smaller diameter catheters compatible with 7Fr sheaths may improve the safety profile.

Methods: A retrospective review of patients receiving REBOA through a 7Fr sheath for refractory traumatic hemorrhagic shock was performed from January 2014 to June 2015 at five tertiary-care hospitals in Japan. Demographics were collected including method of arterial access; outcomes included mortality and REBOA-related access complications.

Results: Thirty-three patients underwent REBOA at Zone 1 (level of the diaphragm). Most patients were male (70%), with a mean age ($\pm$ SD) 50 ± 18 years, mean BMI 23 ± 4 , and a median [IQR] ISS of 38 [34, 52]. Ninety-four percent of patients presented after sustaining injuries from blunt mechanisms. Twenty-four percent underwent CPR before arrival, and an additional 15% received CPR after admission. Percutaneous arterial access without ultrasound or fluoroscopy was achieved in all patients. Systolic blood pressure increased significantly following balloon occlusion (mean 62 ± 36 to 106 ± 40 mm Hg, $p < 0.001$). Median total duration of complete initial occlusion was 26 [range 10-35] minutes. Sixteen patients (49%) survived beyond 24 hours, and 14 patients (42%) survived beyond 30 days. Twenty-four-hour and 30-day survival were 48% and 42%, respectively. Of the patients surviving 24 hours ($n = 16$), median duration of sheath placement was 28 [range 18-45] hours with all removed using manual pressure to achieve hemostasis. Of 33 REBOAs, 20 were performed by Emergency Medicine practitioners, 10 by Emergency Medicine practitioners with endovascular training, and 3 by Interventional Radiologists. No complication related to sheath insertion or removal was identified during the follow-up period, including dissection, pseudoaneurysm, retroperitoneal hematoma, leg ischemia, or distal embolism.

Conclusions: 7Fr REBOA catheters can significantly elevate systolic blood pressure with no access-related complications. Our results suggest that a 7Fr introducer device for REBOA may be a safe and effective alternative to large-bore sheaths, and may remain in place during the post-procedure resuscitative phase without sequelae.

Article review and analysis

Aim of this study: The use of smaller (7 Fr) sheath-compatible catheters for REBOA balloon has been widely used in Japan since 2013 with encouraging results. The

authors report a Japanese case series concerning the use of 7 Fr catheters in traumatic bleeding, underlying their possible benefits and complications, in order to spread their application to the clinical practice of other countries.

The authors conducted a retrospective review of adult patients who underwent REBOA through a 7Fr sheath for refractory traumatic hemorrhagic shock from January 2014 to June 2015 at five tertiary-care hospitals in Japan. They analyzed demographic data, mechanism of trauma, ISS, time to arrival/arrival to occlusion and arrival to hemostatic procedure, vital signs on arrival, CPR before REBOA and its duration time, associated procedures to achieve hemodynamic stability, and blood product utilization in the first 24 hours.

Regarding the REBOA procedure, they reported: location of placement (prehospital/emergency department/angiography suite) and operator specialty and experience, access site, type of device, placement procedure (blind arterial/US guided-access), type of occlusion (partial vs total), zone of inflation, duration of aortic occlusion, vascular access complications. Outcomes, clinical course, and general complications of survivor patients were recorded separately from patients who expired in the first 24 hours after REBOA inflation.

Methods

Pros: This is the first paper that reports data exclusively regarding a 7Fr compatible device for REBOA placement. In the involved centers, a partial occlusion technique was carried out with the goal of keeping SBP over 90 mm Hg to allow distal perfusion. Thus, in order to understand if partial occlusion could allow safe and longer time of occlusion, duration time of aortic occlusion has been reported as “duration of initial occlusion” representing the time of the first complete occlusion, “duration of partial occlusion” representing the total time the balloon was partially inflated, and “total duration of complete occlusion” representing the total time of any aortic occlusion (sum of the duration of complete and partial occlusions).

As is well known, there is no recognized certification concerning REBOA insertion and management, but the authors specified which professional (emergency medicine physicians/ interventional radiologist/EM with cross-training) had carried out the procedure and their level of expertise (attending/fellow/senior resident), in order to understand to what extent the procedure is operator dependent.

Cons: Since partial occlusion was regulated as necessary to maintain an adequate SBP, the volume and/or diameter of the balloon were not recorded in each step and this would have been useful for obtaining technical procedural information. Although in the literature Zone 1 inflation is commonly recommended for exsanguinating hemorrhage below the diaphragm or for severe retroperitoneal hemorrhage, in Japanese clinical practice REBOA is initially inflated in Zone 1, regardless of the specific site of bleeding; the possible need to reposition to Zone 3 is assessed after initial resuscitation. Thus, these data cannot be applied to general populations.

Moreover, there was no scheduled follow-up protocol for identifying vascular-related access complications in all involved hospitals; complications were identified on the basis of clinical suspicion and also any diagnostic investigations performed for other reasons.

Results, conclusion, and what it means

33 patients received a REBOA through a 7Fr sheath. The mean time from arrival to aortic occlusion was 32 minutes, time from arrival to surgery was 35 minutes and time from arrival to angioembolization was 64 minutes. Even if ultrasonography has been demonstrated in the literature as a useful tool, especially in cases of low SBP, all 33 REBOAs in the cohort were positioned by blind-percutaneous arterial access, probably because all the reported patients were anatomically compliant, with an average BMI of 23 kg/m². SBP before REBOA was 62 mmHg and was significantly improved to 106 mmHg after aortic occlusion. REBOA in all 33 patients was initially inflated in Zone 1 and only 1 was then repositioned to Zone 3. No balloon rupture occurred, but migration was encountered in two cases; smaller devices, being less rigid, are probably more prone to migration due to the pressure of aortic blood flow after aortic occlusion. Smaller diameter catheters achieved effective aortic occlusion and initial complete aortic occlusion had a median duration of 17 minutes in patients surviving over 24 hours and 29 minutes in those who did not.

20 out of 33 procedures were carried out by EM practitioners, suggesting that after an adequate formal training they may routinely use REBOA. Of the 16 patients surviving over 24 hours, mean duration of sheath placement was 25 hours, and the sheath was connected to continuous flush in order to avoid thrombosis. Unlike other cohorts previously reported in the literature, there were no thromboembolic or ischemic complications. This finding is potentially explained by the diameter reduction, which may reduce intimal injury and turbulence within the artery with an improved distal flow to the lower extremities.

Once hemorrhage control is obtained and coagulopathy corrected (by assessing laboratory coagulation parameters), all catheters were safely removed using manual compression to achieve hemostasis, without the need for surgical arterial repair and no removal-related complications.

Among systemic complications, acute reversible kidney injury occurred in one patient, while respiratory failure requiring mechanical ventilation occurred in 12 patients. Of the 17 patients who did not survive beyond 24 hours, 13 (39%) died from hemorrhagic shock and 4 (12%) due to traumatic brain injury sequelae.

Although limited to a Japanese multicentric experience, these results suggest that 7Fr introducer systems for REBOA can be percutaneously placed in selected patients with a significant improvement in patient hemodynamics after inflation, and can be safely removed with manual compression, without any access-related complications.

Comments and future research

As unnecessarily prolonged sheath placement should be avoided to prevent access-related complications, specific protocol to assess coagulopathy and advanced coagulation monitoring (such as thromboelastography) may contribute to identification of the ideal timing for sheath removal. A predetermined follow-up protocol would also be useful for early identification of access-related complications.

i Related important publications

Moore LJ, Brenner M, Kozar RA, Pasley J, Wade CE, Baraniuk MS, Scalea T, Holcomb JB. Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage. *J Trauma Acute Care Surg.* 2015 Oct;79(4):523-30; discussion 530-2.

DuBose JJ, Scalea TM, Brenner M, Skiada D, Inaba K, Cannon J, Moore L, Holcomb J, Turay D, Arbabi CN, Kirkpatrick A, Xiao J, Skarupa D, Poulin N; AAST AORTA Study Group. The AAST prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: Data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). *J Trauma Acute Care Surg.* 2016 Sep;81(3):409-19.

CHAPTER 21.

Anesthesia in patients with rAAA, rTAA and Endovascular Aortic Repair (EVAR)

Authors: *Peter Hilbert-Carius and Arie Eden*

Introduction

Welcome to the world behind the curtain, where the anesthetist takes care of the critically ill patients. EVAR is an accepted approach for patients presenting with ruptured aortic aneurysm and suitable anatomy. The effect of the different anesthesia modalities on mortality outcomes has not yet been well-described and data from big randomized controlled trials are still lacking. For EVAR, there are generally three different anesthesia modalities that are suitable (possible):

1. General anesthesia (GA), which is mandatory in most patients with open aneurysm surgery and still the preferred modality in many cases of TAA.
2. Regional anesthesia (RA), such as spinal or epidural anesthesia, which can be used for EVAR and in some patients with open surgery for abdominal aortic aneurysm and in TEVAR.
3. Local anesthesia (LA), which is only suitable for EVAR and TEVAR.

Besides the surgical approach to the often critically ill patients with ruptured aortic aneurysm, open surgery or EVAR, which might have a potential impact on outcome, the anesthesia modality used might also have an impact on outcome after EVAR. Data regarding the impact of anesthesia modality on outcomes after endovascular aneurysm repair (EVAR) are rare and have been assessed mainly in the elective setting (1).

New studies are focusing on the impact of anesthesia modality on outcome in patients mainly with rAAA and EVAR.

Independent of the possible surgical approach and the center promoting a close cooperation between anesthetist and vascular surgeon, achieving the best possible outcome in this highly critical patient group requiring emergency surgery for rAAA or rTAA is of utmost importance. Mortality in this patient group is still high and further improvement is only possible if all team members are pulling on the same side of the rope. What is needed is a team approach, taking the patient's condition, the planned or possible surgical approach, and the different possible anesthesia modalities into consideration in order to achieve the best outcome for the patient.

Regarding the different anesthesia modalities, such as LA, RA, GA and possible different types of GA, such as total intravenous anesthesia or balanced anesthesia, the current literature is very limited to the comparison of LA vs GA, LA vs RA and RA vs GA in patients with rAAA. Only two current studies were found for patients comparing GA + epidural anesthesia vs GA alone in patients with AAA or TAA (2, 3). Despite better pain relief, no other outcome relevant improvement was found for the combination of GA + epidural anesthesia. No current paper was found studying the different types of GA in patients who needed vascular surgery.

ARTICLE NUMBER 1

Locoregional anesthesia is associated with lower 30-day mortality than general anesthesia in patients undergoing endovascular repair of ruptured abdominal aortic aneurysm.

*J Vasc Surg. 2019 Dec;70(6):1862-1867.e1.
Bennett KM, McAninch CM, Scarborough JE.*

Abstract

Objective: The objective of this study was to compare 30-day postoperative mortality for patients undergoing endovascular repair of ruptured abdominal aortic aneurysm (rAAA) using locoregional vs general anesthesia. Unlike the open approach, endovascular repair of rAAA can be performed using either locoregional or general anesthesia. We hypothesize that mortality after endovascular repair of rAAA is lower when locoregional rather than general anesthesia is used.

Methods: Propensity score matching techniques were used to compare the 30-day postoperative outcomes of patients from the 2007 to 2015 American College of Surgeons National Surgical Quality Improvement Program database who underwent endovascular repair of rAAA under locoregional vs general anesthesia.

Results: Of the 1382 endovascular rAAA repair procedures in our overall study population, 132 (9.5%) were performed using locoregional anesthesia. Our propensity score matching algorithm yielded a cohort of 130 general anesthesia patients who were well matched with their locoregional anesthesia counterparts for known patient and procedure characteristics. The 30-day postoperative mortality rates for patients in the matched cohort were 14.6% for patients in the locoregional anesthesia group compared with 29.2% for patients in the general anesthesia group ($P = .002$).

Conclusion: Locoregional rather than general anesthesia is associated with a significantly lower 30-day mortality after endovascular repair of rAAA. The designs of future trials comparing endovascular and open rAAA repair should include stratification of endovascular procedures by anesthesia modality.

Article review and analysis

Aim of this study: The aim was to compare 30-day postoperative mortality for patients undergoing endovascular repair of rAAA using locoregional vs general anesthesia.

Retrospective data analysis of the American College of Surgeons National Surgical Quality Improvement Program from 2007 to 2015 was performed, including patients who had undergone emergency endovascular repair for rAAA. The primary interest was anesthesia modality (locoregional vs general). The primary outcome measure was 30-day mortality, secondary outcome measures were overall postoperative morbidity and nonhome discharge status. Propensity score matching was used to match every locoregional anesthesia to a general anesthesia patient. The propensity score matching

is the strength of the study, making it possible to compare general anesthesia patients with well-matched locoregional anesthesia counterparts for known patient and procedure characteristics.

Methods

Pros: Despite the limitation of this being a retrospective registry study, the use of locoregional anesthesia for EVAR in rAAA is likely to result in a significant survival benefit. The use of locoregional anesthesia in patients with EVAR in rAAA seems to be quite low in this American study and there seems to be potential for further improvement.

Cons: This is a retrospective registry study with a low number of procedures (only 9.5%) using locoregional anesthesia. The National Surgical Quality Improvement Program does not contain information regarding hemodynamic, transfusion requirement, important lab results (e.g., hemoglobin, pH, etc.) or number of patients where conversion from locoregional anesthesia to general anesthesia was necessary.

Results, conclusion, and what it means

The overall study sample included 1382 patients of which 132 (9.5%) received locoregional anesthesia. The unadjusted 30-day mortality was 15.2% in the locoregional group and 24.4% in the general anesthesia group ($p=0.017$). The 30-day postoperative morbidity was 12.9% for locoregional anesthesia vs 29.2% for general anesthesia ($p<0.005$), whereas the incidence of nonhome discharge was 25.5% for locoregional vs 36.5% for general anesthesia ($p=0.033$). The propensity score matching of 130 locoregional vs 130 general anesthesia patients revealed a lower mortality (14.6% vs 29.2%; $p=0.002$), lower postoperative morbidity (12.3% vs 23.9%; $p=0.025$) and a lower non-home discharge (25.8% vs 38.5%; $p=0.012$) in favor of locoregional anesthesia.

Comments and future research

This study demonstrates that it is not only the surgeon and the surgical procedure used for rAAA that have potential impacts on patient outcome, but the anesthetist and the anesthesia modality also have an impact on patient outcome. To underline the possible role of the anesthetic modality regarding mortality, randomized controlled clinical trials comparing the influence on mortality and morbidity are urgently needed.

Related important publications

Please see the end of the chapter.

ARTICLE NUMBER 2

Decreased mortality with local versus general anesthesia in endovascular aneurysm repair for ruptured abdominal aortic aneurysm in the Vascular Quality Initiative database.

J Vasc Surg. 2019 Jul;70(1):92-101.e1.

Faizer R, Weinhandl E, El Hag S, Le Jeune S, Apostolidou I, Shafii SM, Lee CJ, Rosenberg MS, Reed A, Fanola CL.

Abstract

Background: Endovascular aneurysm repair (EVAR) is an accepted approach for patients presenting with ruptured abdominal aortic aneurysm (rAAA) and suitable anatomy. The effect of anesthesia modality on mortality outcomes in rAAA has not been well described. Using the Vascular Quality Initiative database, this study compares local anesthesia (LA) vs general anesthesia (GA) in EVAR for rAAA.

Methods: The Vascular Quality Initiative database was queried for patients presenting with rAAA managed with open surgical repair, EVAR under LA (rEVAR-LA), and EVAR under GA (rEVAR-GA) between 2003 and 2017. Patients were observed until the earlier end point of either death or 1-year follow-up. Kaplan-Meier event rates are presented at 30 days and 1 year. Cox proportional hazards regression was used to model risk of death, with adjustment for demographic and clinical factors. Additional multivariate Cox hazards analyses were used to assess effect modifiers for 1-year mortality for the different repair methods.

Results: A total of 3330 patients (77.4% male) met the inclusion criteria (1594 [47.9%] To open surgical repair, 226 [6.8%] rEVAR-LA, and 1510 [45.3%] rEVAR-GA). Patients treated with rEVAR-LA compared with rEVAR-GA had decreased intraoperative time, number of intraoperative blood transfusions, intraoperative crystalloid administration, intensive care unit length of stay, and postoperative pulmonary complications. Mortality rates with rEVAR-LA were lower compared with rEVAR-GA at 30 days (15.5% vs 23.3%; adjusted hazard ratio [AHR], 0.70; 95% confidence interval [CI], 0.49-0.99; $P = .04$) and at 1 year (22.5% vs 32.3%; AHR, 0.71; 95% CI, 0.53-0.96; $P = .02$). Patients undergoing EVAR who were <75 years old and those without preoperative hypotension had the greatest survival benefit from LA compared with GA (both factors: AHR, 0.14 [95% CI, 0.03-0.57]; single factor: AHR, 0.57 [95% CI, 0.36-0.91]).

Conclusion: This study demonstrates that rEVAR-LA for rAAA may be a safe alternative to rEVAR-GA for certain patients, with lower morbidity and improved mortality. Further prospective study is warranted to confirm mortality benefit in rEVAR-LA for rAAA.

Article review and analysis

Aim of this study: The aim was to compare 30-day postoperative and 1-year mortality in patients presenting with rAAA who underwent EVAR using local anesthesia (LA) vs general anesthesia (GA).

Methods

Pros: This was a retrospective data analysis from the Vascular Quality Initiative (VQI) database, a registry of 18 regional quality groups, comprising > 450 centers in the United States. Patients of the VQI were stratified into three treatment groups: EVAR under LA, EVAR under GA, and open repair under GA. Baseline characteristics were examined by treatment group using chi-square test for continuous factors, differences in means were assessed with t-test and unadjusted mortality with log-rank test. Adjusted differences were subsequently assessed using Cox proportional hazards regression. Potential heterogeneity in the association of mortality with LA and GA in those who underwent EVAR was assessed.

Cons: This is a retrospective registry study with a low number (only 6.8%) of patients receiving LA and there may be inherent selection bias and unmeasured confounders that contributed to anesthesia decision. A separate analysis regarding the hybrid anesthesia approach in which LA was converted to GA could not be performed. This may have favored the results of EVAR under LA when sicker patients required conversion to GA. Nonfatal postoperative outcomes might be incompletely ascertained.

Results, conclusion, and what it means

During the study period, 3494 patients in the VQI database underwent surgical procedure for rAAA. 164 patients were excluded from the analysis due to missing data. Of the remaining 3330 patients, 6.8% of repairs were performed with EVAR under LA, 45.3% with EVAR under GA and 47.9% with open repair. Unadjusted mortality (30 days; 1 year) was significantly lower for EVAR under LA (15.5%; 22.5%) compared to EVAR under GA (23.3%; 32.3%) and to open repair (33.9%; 41.1%). Adjusted hazard ratio after 30 days was significant lower with EVAR under LA (0.7) vs EVAR under GA. After one year, the adjusted hazard ration for EVAR under LA (0.71) was significantly lower vs EVAR under GA (1.0) and vs open repair (1.22). Patients <75 years old or without preoperative hypotension had the greatest survival benefit. The following parameters were significantly reduced when EVAR was performed under LA vs GA: return to operating room, length of ICU stay, postoperative pulmonary complications, intraoperative blood transfusion, and crystalloid fluid volume.

Comments and future research

For rAAA, EVAR under LA may have benefit over general anesthesia for some patients and this benefit is greatest in those who are young or stable at presentation. This study highlights the low number of EVAR performed under LA in American centers.

This American registry study shows a clear trend, despite all the limitations, that EVAR performed in patients with rAAA under LA anesthesia has the potential to decrease mortality in these critically ill patients. Further studies, especially randomized controlled trials, are needed to prove the possible decreased mortality in patients with use of LA. Due to the possible positive influence on mortality, LA should be used in a higher number of patients.

i Related important publications

Please see the end of the chapter.

ARTICLE NUMBER 3

Local anaesthesia for endovascular repair of ruptured abdominal aortic aneurysm.*Br J Surg.* 2019 Jan;106(1):74-81.*Mouton R, Rogers CA, Harris RA, Hinchliffe RJ.***Abstract**

Background: Case series and a post hoc subgroup analysis of a large randomized trial have suggested a potential benefit in treating ruptured abdominal aortic aneurysms (rAAAs) using endovascular aneurysm repair (EVAR) with local anaesthesia (LA) rather than general anaesthesia (GA). The uptake and outcomes of LA in clinical practice remain unknown.

Methods: The UK National Vascular Registry was interrogated for patients presenting with rAAA managed with EVAR under different modes of anaesthesia between 1 January 2014 and 31 December 2016. The primary outcome was in-hospital mortality. Secondary outcomes included: the number of centres performing EVAR under LA; the proportion of patients receiving this technique; duration of hospital stay; and postoperative complications.

Results: Some 3101 patients with rAAA were treated in 72 hospitals during the study: 2306 underwent on open procedure and 795 had EVAR (LA, 319; GA, 435; regional anaesthesia, 41). Overall, 56 of 72 hospitals (78 per cent) offered LA for EVAR of rAAA. Baseline characteristics and morphology were similar across the three EVAR subgroups. Patients who had surgery under LA had a lower in-hospital mortality rate than patients who received GA (59 of 319 (18.5 per cent) versus 122 of 435 (28.0 per cent)), and this was unchanged after adjustment for factors known to influence survival (adjusted hazard ratio 0.62, 95 per cent c.i. 0.45 to 0.85; $P = 0.003$). Median hospital stay and postoperative morbidity from other complications were similar.

Conclusion: The use of LA for EVAR of rAAA has been adopted widely in the UK. Mortality rates appear lower than in patients undergoing EVAR with GA.

Article review and analysis

Aim of this study: The IMPROVE (Immediate Management of the Patient with Rupture: Open Versus Endovascular repair) trial (6) demonstrated a significantly reduced 30-day mortality rate for patients operated on under LA compared with surgery under GA after adjustment for potential confounding. The aim of this study was to quantify the uptake of LA for rEVAR across all UK vascular centers and evaluate whether the benefit of LA observed in the IMPROVE trial has been replicated in everyday clinical practice. During the study period, 3101 patients with rAAA were treated in 72 hospitals, of which 2306 underwent on open procedure and 795 had EVAR; 319 (40.1%) patients under LA, 435 (54.7%) patients under GA, and 41 (5.1%) under regional anaesthesia. The 56

hospitals (78%) that used LA for rEVAR were the higher-volume centers carrying out a median of 47.0 EVAR and 15.2 rAAA procedures each year, compared with a median of 26.7 EVAR and 7.9 rAAA procedures in the non-LA centers. Mean age was 79 years in the LA and RA groups and 77 years in the GA group, and the majority of patients were men. The in-hospital mortality rate was 28% in the GA group, followed by 18.5% in the LA group and 15% in the RA group. After adjustment, the risk of death in patients having rEVAR under LA was 38% lower than the risk under GA (adjusted hazard ratio 0.62, $p = 0.003$). The estimated mortality rate from the Kaplan–Meier curves at 30 days was 39.5% with GA compared with 34% with LA. The risk with all three modes of anaesthesia (GA, LA and RA) was less than the risk of death with open repair of rAAA. The complication rates were similar in both groups: 54.4% in the LA group had no reported complications compared with 56.4% in the GA group.

Methods

Pros: Compared to the two above mentioned American studies, a rate of 40% of EVAR performed under LA is quite high in this UK study. LA was mainly used by higher-volume centers with more expertise in EVAR. Mortality was lower in the LA group and this study provides further evidence of the benefit of LA for patients undergoing emergency EVAR for rAAA, despite a comparable rate of postoperative complications.

Cons: Any registry is limited by the completeness and quality of its data. The NVR was established as part of the National Clinical Audit and Patient Outcomes Program, and was not designed primarily for research. The NVR does not identify procedures that were initiated under LA only but then converted to GA (or RA) later in the procedure. This may favor EVAR in LA results when sicker patients required conversion to GA.

Results, conclusion, and what it means

During the study period, 3101 patients with rAAA were treated in 72 hospitals, of which 2306 underwent on open procedure and 795 had EVAR; 319 (40.1%) patients under LA, 435 (54.7%) patients under GA, and 41 (5.1%) under regional anaesthesia. The 56 hospitals (78%) that used LA for rEVAR were the higher-volume centers carrying out a median of 47.0 EVAR and 15.2 rAAA procedures each year, compared with a median of 26.7 EVAR and 7.9 rAAA procedures in the non-LA centers. Mean age was 79 years in the LA and RA groups, and 77 years in the GA group, and the majority of patients were men. The in-hospital mortality rate was 28% in the GA group, followed by 18.5% in the LA group, and 15% in the RA group. After adjustment, the risk of death in patients having rEVAR under LA was 38% lower than the risk under GA (adjusted hazard ratio 0.62, $p = 0.003$). The estimated mortality rate from the Kaplan–Meier curves at 30 days was 39.5% with GA compared with 34% with LA. The risk with all three modes of anaesthesia (GA, LA and RA) was less than the risk of death with open repair of rAAA. The complication rates were similar in both groups: 54.4% in the LA group had no reported complications compared with 56.4% in the GA group.

Comments and future research

A prospective larger case number study is needed.

i Related important publications

Please see the end of the chapter.

ARTICLE NUMBER 4

Type of Anesthesia for Endovascular Abdominal Aortic Aneurysm Repair.

J Cardiothorac Vasc Anesth. 2019 Feb;33(2):462-471.

Armstrong RA, Squire YG, Rogers CA, Hinchliffe RJ, Mouton R.

Abstract

Objective: Endovascular aneurysm repair (EVAR) is used increasingly in the management of patients with abdominal aortic aneurysms (AAAs), including in the emergency setting for ruptured AAA. The lower mortality among patients undergoing emergency EVAR under local anesthesia (LA) observed in the Immediate Management of Patients with Rupture: Open Versus Endovascular Repair trial has sparked renewed interest in the anesthesia choice for EVAR. This systematic review evaluates the effect of mode of anesthesia on outcomes after EVAR.

Design: The review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines. The primary outcome was in-hospital/30-day mortality, and both emergency and elective EVAR were included. The relative risk of death was estimated for each individual study without adjustment for potential confounding factors.

Setting: Hospitals.

Participants: A total of 39,744 patients from 22 nonrandomized studies were included in the analysis.

Interventions: None.

Measurements and main results: Sixteen studies in 23,202 patients compared LA to general anesthesia (GA) and reported in-hospital/30-day mortality. The unadjusted risk of death after emergency EVAR with LA was lower than with GA. Trends in elective surgery were less clear.

Conclusion: There is some evidence across both emergency and elective settings to suggest that mode of anesthesia may be associated with improved outcomes. In particular, LA appears to have a positive effect on outcome after emergency EVAR. Because of the lack of randomized trial data, a significant risk of confounding remains. The optimal mode of anesthesia for EVAR should be investigated further and the reasons why particular anesthesia techniques are chosen for particular patients identified.

Article review and analysis

Aim of this study: This systematic review evaluates the effect of mode of anesthesia on outcome after EVAR.

A systematic review was carried out according to the Preferred Reporting Item for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. A systematic electronic search of the MEDLINE, Excerpta Medic (EMBASE), Web of Science, and Cochrane

Library databases up to March 2018, was performed supplemented by a hand search of material not published by commercial publishers. The primary outcome measure was 30-day, in-hospital mortality for both elective and emergency EVAR surgery. Risk of bias was assessed using the Scottish Intercollegiate Guidelines Network (SIGN) checklists.

Methods

Pros: The authors have provided an up-to-date summary of all the available evidence on the effect of different modes of anesthesia on outcomes after both emergency and elective EVAR. Emergency EVAR has been studied less extensively, but there is some evidence to suggest LA may be associated with reduced early mortality compared with GA. However, with no randomized trial data specifically comparing mode of anesthesia available, a significant risk of confounding remains.

Cons: The meta-analysis only reports unadjusted mortality and it was not possible to report adjusted risks. The medical literature, as it currently stands, does not report sufficient detail on the definitions of anesthetic techniques employed, nor by whom they were administered. Many studies in the review did not report conversion from LA or RA to GA. Finally, all data are observational, with a SIGN grading of 2, and the decision on whether an individual patient receives LA, RA, or GA is determined by a myriad of factors.

Results, conclusion, and what it means

Between 1996 and 2018, 22 studies met the inclusion criteria and were included in the review. According to SIGN, all were classified as level 2, indicating that they carry a significant risk of selection bias or confounding. Regarding the comparison of the different anesthesia modalities with reference to mortality, the meta-analysis found:

In an emergency setting, a benefit was shown favoring LA over GA with an estimated relative risk (RR) of death that ranged from 0.4 to 0.68. In the elective setting, the estimated RR ranged from 0.08 to 1.53, with most studies favoring LA, but the range of the confident intervals (CI) was wide.

When comparing RA vs GA in the elective setting, the estimated RR of death ranged from 0.17 to 0.65 favoring RA, but in all studies the CI were wide and close to 1. Only one study focused on the emergency setting with a RR of 0.52 favoring LA, but the CI were close to 1.

Comparing LA vs RA, the study's results are inconclusive with RR ranging from 0.57 to 3.91 and with a wide range of CI.

Comments and future research

This well-designed systematic review and meta-analysis nicely summarizes the current evidence regarding potential improvement in mortality after EVAR for AAA when using LA or RA anesthesia. Future reviews should focus on the different anesthetic

modalities in the context of the patient's condition, comorbidity and surgical procedure, to help the anesthesiologist select the best mode of anesthesia in the individual patient.

Related important publications

Please see the end of the chapter.

ARTICLE NUMBER 5

Anaesthetic Management for Endovascular Repair of the Thoracic Aorta.*Anesthesiol Clin. 2019 Dec;37(4):593-607.**Cheruku S, Huang N, Meinhardt K, Aguirre M.***Abstract**

Thoracic endovascular aneurysm repair (TEVAR) is fast becoming the primary treatment of thoracic aortic aneurysms, thoracic aortic dissections, acute aortic injuries, and other conditions affecting the thoracic aorta. Patients scheduled for TEVAR tend to have a host of comorbid conditions, including coronary artery disease, diabetes, and chronic obstructive pulmonary disease. Intraoperative management should optimize end-organ perfusion, facilitate neuromonitoring, and adjust hemodynamic management. Complications include spinal cord injury, peripheral vascular injury, contrast-induced nephropathy, postimplantation syndrome, and endoleaks. Patients who undergo TEVAR require care in a postoperative environment where these complications can be rapidly detected and aggressively treated.

Article review and analysis

Aim of this study: The aim was to give a brief overview of the pathophysiology, surgical considerations, anesthetic consideration and postoperative care in patients with endovascular repair of the thoracic aorta.

This is a brief review that provides the anesthesiologist with basic knowledge of the risk factors and pathophysiology of aneurysmal diseases and the surgical consideration, including diagnosis, indications and endovascular procedures. Anesthetic considerations, such as preoperative evaluation of the cardiovascular, pulmonary, neurological and renal system, are discussed as is intraoperative management regarding the different anesthetic modalities, hemodynamic monitoring, transoesophageal echocardiography, neuromonitoring, kidney protection and cerebrospinal fluid drainage. Finally, the postoperative care is discussed.

Methods

Pros: This article gives a brief overview of surgical and anesthetic considerations regarding TEVAR and should be read by anesthesiologists involved in the care of patients scheduled for TEVAR. It summarizes the most important aspects that are needed to give basic knowledge.

Cons: The article is an overview and does not include any meta-analysis of different studies.

Results, conclusion, and what it means

TEVAR has become the treatment of choice for acute type B dissections, complex thoracic aneurysm repair, and acute traumatic injuries of the thoracic aorta. Patients scheduled for TEVAR tend to have a host of comorbid conditions. The preoperative evaluation should be as comprehensive as possible. General anesthesia is currently the most popular anesthetic technique for TEVAR because it provides a secure airway with controlled ventilation, facilitates transesophageal echocardiography monitoring, and ensures immobility. The use of RA and LA for TEVAR is possible in selected patients. Evoked potential monitoring is used to test the integrity of spinal cord pathways, and both motor-evoked potentials and somatosensory-evoked potentials are sensitive monitors for spinal cord ischemia (SCI) in patients undergoing TEVAR. SCI is a devastating complication that can result in transient or permanent paraplegia after TEVAR. Strategies to prevent TEVAR include increasing mean arterial pressure and cerebrospinal fluid drainage to optimize spinal cord perfusion pressure. Endoleaks are relatively common complications following TEVAR; they require lifetime surveillance and, when indicated, aggressive intervention. Postoperative care includes transfer to an intensive care unit or similar environment, adequate hemodynamic management, close neurological monitoring, pain relief detection and treatment of post-implantation SIRS and endoleaks.

Comments and future research

Research on anesthesia-related issues in patients with TEVAR is still very limited and future studies are urgently needed to define the best mode of anesthesia in patients scheduled for TEVAR. All that has been written above with regard to EVAR in patients with AAA also applies to future research in patients with TAA.

i Related important publications regarding Anesthesia in patients with rAAA, rTAA and EVAR

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CHAPTER 22.

Extracorporeal Cardiopulmonary Resuscitation (ECPR) and Extracorporeal Membrane Oxygenation (ECMO)

Authors: *Emmanuel Rozenberg and Oscar Thabouillot*

Introduction

Cardiac arrest is one of the biggest challenges for an emergency physician that requires having a quick response team, experienced doctors, and well-organized in and out-of-hospital emergency departments. Conventional resuscitation is based on chest compression, defibrillation, and specific treatment of the cause of cardiac arrest. Despite this, survival of out-of-hospital cardiac arrest is less than 10% at discharge, and less than 20% for in-hospital cardiac arrest. In this context, guidelines are changing, and extracorporeal circulation has acquired a place in cardiopulmonary resuscitation. The principle of the extracorporeal circulation, during the cardiopulmonary resuscitation, is to maintain efficient circulation until the cause is treated.

In this chapter, we selected and analyzed 5 recent studies about Extracorporeal CardioPulmonary Resuscitation (ECPR).

Despite most of the meta-analyses having been based on observational studies, it seems that ECPR is more efficient than conventional cardio-pulmonary resuscitation. In our opinion, ECPR will never replace an efficient care system. For ECPR to have its place, all the other links in the chain must already be functioning at their maximum efficiency. ECPR should be included in an already effective cardiac arrest management system.

ECPR: Extracorporeal CardioPulmonary Resuscitation

CCPR: Conventional CardioPulmonary Resuscitation

IHCA: In-Hospital Cardiac Arrest

OHCA: Out-of-Hospital Cardiac Arrest

ARTICLE NUMBER 1

Comparing extracorporeal cardiopulmonary resuscitation with conventional cardiopulmonary resuscitation: A meta-analysis.

Resuscitation. 2016 Jun;103:106-116.

Kim SJ, Kim HJ, Lee HY, Ahn HS, Lee SW.

Abstract

Introduction: The objective was to determine whether extracorporeal cardiopulmonary resuscitation

(ECPR), when compared with conventional cardiopulmonary resuscitation (CCPR), improves outcomes in adult patients, and to determine appropriate conditions that can predict good survival outcome in ECPR patients through a meta-analysis.

Methods: We searched the relevant literature of comparative studies between ECPR and CCPR in adults, from the MEDLINE, EMBASE, and Cochrane databases. The baseline information and outcome data (survival, good neurologic outcome at discharge, at 3–6 months, and at 1 year after arrest) were extracted.

Beneficial effect of ECPR on outcome was analyzed according to time interval, location of arrest (out-of-hospital cardiac arrest (OHCA) and in-hospital cardiac arrest (IHCA)), and pre-defined population inclusion criteria (witnessed arrest, initial shockable rhythm, cardiac etiology of arrest and CPR duration) by using Review Manager 5.3. Cochran's Q test and I² were calculated.

Results: 10 of 1583 publications were included. Although survival to discharge did not show clear superiority in OHCA, ECPR showed statistically improved survival and good neurologic outcome as compared to CCPR, especially at 3–6 months after arrest. In the subgroup of patients with pre-defined inclusion criteria, the pooled meta-analysis found similar results in studies with pre-defined criteria.

Conclusion: Survival and good neurologic outcome tended to be superior in the ECPR group at 3–6 months after arrest. The effect of ECPR on survival to discharge in OHCA was not clearly shown. As ECPR showed better outcomes than CCPR in studies with pre-defined criteria, strict indications criteria should be considered when implementation of ECPR.

Article review and analysis

Aim of this study: The aim of this study was to determine whether ECPR results in better outcome than CCPR, regardless of time interval and location of arrest. The secondary objective was to determine adequate predictors of better outcome in ECPR versus CCPR through subgroup analysis.

Methods

Pros: The authors conducted a meta-analysis, including observational studies of whether ECPR, compared with CCPR, improves survival outcome and good neurological outcome (CPC1, 2) in adult patients with cardiac arrest, according to time interval after arrest (at discharge, 3–6 months, and 1 year).

Studies were included in this meta-analysis if they included adult (age ≥ 16 years) patients, who had suffered either in-hospital or out-of-hospital cardiac arrest, comparative study data between ECPR as the intervention group and CCPR as the control group, and reported outcomes (survival and neurological outcome at discharge, 3–6 month, and 1 year after arrest). This study excluded cardiac arrest after cardiac surgery and pediatric cardiac arrest.

This study has been conducted rigorously, and all the articles, including 3 databases (MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials (CENTRAL)), were analyzed. Studies that were duplicates of the same patient cohort were not included.

The authors included only comparative studies in their meta-analysis. Any studies that contained only non-comparative outcomes of either ECPR or CCPR were not included.

Cons: All the studies analyzed were only observational. There was no randomized trial. Moreover, the meta-analysis included patients from the years 2000 to 2013. In 2005 and 2010, resuscitation guidelines were changed and improved, which could have changed the survival of the patients.

Results, conclusion, and what it means

14 studies have been analyzed, all were observational, and none was a randomized trial. Overall survival tended to be higher in ECPR than CCPR, especially at 3–6 months (RR 2.60, 95% CI 1.57–4.30) in the studies using propensity-matched data (RR 1.86, 95% CI 0.99–3.50 at discharge; and RR 1.96, 95% CI 1.00–3.87 at 1 year). Overall good neurologic outcome at discharge, at 3–6 months and at 1 year was higher in ECPR than CCPR (RR 3.12, 95% CI 1.46–6.66; RR 4.65, 95% CI 2.00–10.81; RR 2.63, 95% CI 1.11–6.21). These results favor the superiority of ECPR over CCPR.

Comments and future research

Despite the results of this meta-analysis being in favor of a superiority of the ECPR over CCPR, this study has several limitations, such as the small number of observational studies with the possibility of unbalanced confounders.

The next step, in order to clearly determine the superiority of ECPR over CCPR, is to conduct a randomized trial. A randomized trial will overcome the biases linked to the differences in the study populations.

i Related important publications

Reynolds JC, Frisch A, Rittenberger JC, Callaway CW. Duration of resuscitation efforts and functional outcome after out-of-hospital cardiac arrest: when should we change to novel therapies? *Circulation*. 2013 Dec 3;128(23):2488-94.

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ARTICLE NUMBER 2

Extracorporeal Cardiopulmonary Resuscitation for Cardiac Arrest: A Systematic Review. Resuscitation. 2018 Oct;131:91-100.

Holmberg MJ, Geri G, Wiberg S, Guerguerian AM, Donnino MW, Nolan JP, Deakin CD, Andersen LW; International Liaison Committee on Resuscitation's (ILCOR) Advanced Life Support and Pediatric Task Forces.

Abstract

Aim: To assess the use of extracorporeal cardiopulmonary resuscitation (ECPR), compared with manual or mechanical cardiopulmonary resuscitation (CPR), for out-of-hospital cardiac arrest (OHCA) and in-hospital cardiac arrest (IHCA) in adults and children.

Methods: The PRISMA guidelines were followed. We searched Medline, Embase, and Evidence-Based Medicine Reviews for randomized clinical trials and observational studies published before May 22, 2018. The population included adult and pediatric patients with OHCA and IHCA of any origin. Two investigators reviewed studies for relevance, extracted data, and assessed the quality of studies using the ROBINS-I tool. Outcomes included short-term and long-term survival and favorable neurological outcome.

Results: We included 25 observational studies, of which 15 studies were in adult OHCA, 7 studies were in adult IHCA, and 3 studies were in pediatric IHCA. There were no studies in pediatric OHCA. No randomized trials were included.

Results from individual studies were largely inconsistent, although several studies in adult and pediatric IHCA were in favor of ECPR. The risk of bias for individual studies was overall assessed to be critical, with confounding being the primary source of bias. The overall quality of evidence was assessed to be very low. Heterogeneity across studies precluded any meaningful meta-analyses.

Conclusions: There is inconclusive evidence to either support or refute the use of ECPR for OHCA and IHCA in adults and children. The quality of evidence across studies is very low.

Article review and analysis

Aim of this study: The aim was to assess the use of extracorporeal cardiopulmonary resuscitation (ECPR) compared with the classic medicalized cardiopulmonary resuscitation (CPR). This study deals with out-of-hospital and in-hospital cardiac arrest, both in adults and children.

Methods

Pros: The authors conducted a meta-analysis and selected twenty-five observational studies. No randomized clinical trials were identified. The authors did not pool all the patients from the different studies and no global relative risk between ECPR and classic CPR has been calculated.

The authors conducted a very large screening of all the studies concerning ECPR and classic CPR. They did not include studies with less than 5 patients receiving ECPR or studies that did not report the timing of ECPR.

Cons: Despite a large screening of various databases, no randomized clinical trials were found. Only observational studies were analyzed. Even if the analyses were carried out in multivariate, observational retrospective studies have a low level of evidence.

Results, conclusion, and what it means

The authors conclude that there is inconclusive evidence to either support or refute the use of ECPR for out-of-hospital and in-hospital cardiac arrest in adults and children, because the quality of evidence across the studies is very low.

This means that this meta-analysis does not confirm or deny the potential interest in ECPR versus classic RCP.

Comments and future research

This study could be interesting because it deals with different situations of cardiac arrest: in-hospital, out-of-hospital, adult, pediatric, but the studies are very different from each other.

The authors did not pool the results from the different studies. This study is inconclusive, and did not support or refute the use of ECPR or classic CPR.

Future research should involve the creation of a large randomized study of ECPR and classic CPR, and separate in-hospital cardiac arrest and out-of-hospital cardiac arrest. Since the prognosis of in-hospital cardiac arrest and out-of-hospital cardiac arrest is very different, ECPR vs classic CPR should be analyzed separately in this two different situations.

i Related important publications

Conrad SA, Broman LM, Taccone FS, Lorusso R, Malfertheiner MV, Pappalardo F, Di Nardo M, Belliato M, Grazioli L, Barbaro RP, McMullan DM, Pellegrino V, Brodie D, Bembea MM, Fan E, Mendonca M, Diaz R, Bartlett RH. The Extracorporeal Life Support Organization Maastricht Treaty for Nomenclature in Extracorporeal Life Support. A Position Paper of the Extracorporeal Life Support Organization. *Am J Respir Crit Care Med*. 2018 Aug 15;198(4):447-451.

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ARTICLE NUMBER 3

A Pre-Hospital Extracorporeal Cardio Pulmonary Resuscitation (ECPR) strategy for treatment of refractory out hospital cardiac arrest: An observational study and propensity analysis.

Resuscitation. 2017 Aug;117:109-117.

Lamhaut L, Hutin A, Puymirat E, Jouan J, Raphalen JH, Jouffroy R, Jaffry M, Dagron C, An K, Dumas F, Marijon E, Bougouin W, Tourtier JP, Baud F, Jouven X, Danchin N, Spaulding C, Carli P.

Abstract

Background: Out of hospital cardiac arrest (OHCA) mortality rates remain very high with poor neurological outcome in survivors. Extracorporeal cardiopulmonary resuscitation (ECPR) is one of the treatments of refractory OHCA. This study used data from the mobile intensive care unit (MOICU) as part of the emergency medical system of Paris, and included all consecutive patients treated with ECPR (including pre-hospital ECPR) from 2011 to 2015 for the treatment of refractory OHCA, comparing two historical ECPR management strategies.

Methods: We consecutively included refractory OHCA patients. In Period 1, ECPR was indicated in selected patients after 30 min of advanced life support; in- or pre-hospital implementation depended on estimated transportation time and ECPR team availability. In Period 2, patient care relied on early ECPR initiation after 20 min of resuscitation, stringent patient selection, epinephrine dose limitation and deployment of ECPR team with initial response team. Primary outcome was survival with good neurological function Cerebral Performance Category score (CPC score) 1 and 2 at ICU discharge or day 28.

Findings: A total of 156 patients were included. (114 in Period 1 and 42 in Period 2). Base-line characteristics were similar. Mean low-flow duration was shorter by 20 min ($p < 0.001$) in Period 2. Survival was significantly higher in Period 2: 29% vs 8% ($P < 0.001$), as confirmed by the multivariate analysis and propensity score. When combining stringent patient selection with an aggressive strategy, the survival rate increased to 38%. Pre-hospital ECPR implementation in itself was not an independent predictor of improved survival, but it was part of the strategy in Period 2.

Interpretation: Our data suggest that ECPR in specific settings in the management of refractory OHCA is feasible and can lead to a significant increase in neurological intact survivors. These data, however, need to be confirmed by a large RCT.

Article review and analysis

Aim of this study: The aim of the study was to compare ECPR as an option or as the standard care for pre-hospital cardiac arrest.

The authors conducted a before-after study, comparing ECPR as a choice by each emergency physician during the first period, and ECPR as the standard for resuscitation of cardiac arrest during the second period. The study concerned both IHCA and OHCA.

Methods

Pros: The study compared two periods. The first period, from 2011 to 2015, concerned the use of ECPR for cardiac arrest resuscitation as a choice by each physician. The ECPR was initiated both in hospital and out-of-hospital. Patients who received the ECPR were eligible if they had received at least 30 minutes of advanced life support, and if they could reach the hospital in under 20 minutes.

During the second period, from 2015, patients were eligible for ECPR if they had received 20 minutes of advanced life support, were aged less than 70 years, and had suffered a witnessed OHCA. During the second period, ECPR was the default strategy for these patients.

The primary outcome was survival rate and good neurological function at discharge and at 28 days.

The comparison between classic resuscitation with an aggressive resuscitation, including ECPR as a standard, is interesting. It compares the “real life” of an emergency department with a new implementation.

Cons: This is a “before-after” type study.

In period 2, patients who received ECPR were better selected than in period 1: the low flow was significantly higher during period 1, more patients had signs of life before ECPR during period 2, and more patients received more than 5 mg of epinephrine in period 1 than in period 2.

Results, conclusion, and what it means

Survival was significantly higher in period 2 compared to period 1: 29% vs 8% ($p < 0.001$), respectively.

Survival was strongly correlated with the presence of signs of life prior to ECPR ($p < 0.001$) and was not different between the two periods if the patient did not have vital signs during the advanced life support. The survival was similar in patients with pre-hospital vs in-hospital ECPR, both periods combined, when implementation could be carried out within the 60 min.

Comments and future research

This study is very interesting because it is, according to our knowledge, the first study to include out-of-hospital ECPR. Moreover, it compared classic care with ECPR as an option with an aggressive strategy where ECPR is the standard. It has shown that an aggressive strategy with ECPR is better than classic advanced life support. Despite this, survival was strongly correlated with the presence of signs of life. In the period with the aggressive ECPR strategy, none of the patients who had no signs of life survived.

For the selected patients, the use of ECPR may lead to survival rates similar to those of patients with ROSC. ECPR should be considered as a second line of treatment and not only as a rescue therapy. So, before implementing ECPR therapy in an out-of-hospital emergency department, basic life support and advanced life support must be first fully mastered.

In our opinion, the next step is to compare two populations that are strictly similar, to prove or refute the interest in an aggressive strategy with ECPR as a standard.

Another interesting study could compare in-hospital ECPR with pre-hospital ECPR.

i Related important publications

Shin TG, Choi JH, Jo IJ, Sim MS, Song HG, Jeong YK, Song YB, Hahn JY, Choi SH, Gwon HC, Jeon ES, Sung K, Kim WS, Lee YT. Extracorporeal cardiopulmonary resuscitation in patients with inhospital cardiac arrest: A comparison with conventional cardiopulmonary resuscitation. *Crit Care Med.* 2011 Jan;39(1):1-7.

Le Guen M, Nicolas-Robin A, Carreira S, Raux M, Leprince P, Riou B, Langeron O. Extracorporeal life support following out-of-hospital refractory cardiac arrest. *Crit Care.* 2011;15(1):R29.

ARTICLE NUMBER 4

Extracorporeal membrane oxygenation for refractory cardiac arrest: a retrospective multicenter study.

Intensive Care Med. 2020 May;46(5):973-982.

Lunz D, Calabrò L, Belliato M, Contri E, Broman LM, Scandroglio AM, Patricio D, Malfertheiner M, Creteur J, Philipp A, Taccone FS, Pappalardo F.

Abstract

Purpose: The aim of this study was to assess the neurologic outcome following extracorporeal cardiopulmonary resuscitation (ECPR) in five European centers.

Methods: Retrospective database analysis of prospective observational cohorts of patients undergoing ECPR (January 2012-December 2016) was performed. The primary outcome was 3-month favorable neurologic outcome (FO), defined as the cerebral performance categories of 1-2. Survival to ICU discharge and the number of patients undergoing organ donation were secondary outcomes. A subgroup of patients with stringent selection criteria (i.e., age $\leq$ 65 years, witnessed bystander CPR, no major co-morbidity and ECMO implemented within 1 h from arrest) was also analyzed.

Results: A total of 423 patients treated with ECPR were included (median age 57 [48-65] years; male gender 78%); ECPR was initiated for OHCA in 258 (61%) patients. Time from arrest to ECMO implementation was 65 [48-84] min. Eighty patients (19%) had favorable neurological outcome. ICU survival was 24% (n = 102); 23 (5%) non-survivors underwent organ donation procedures. Favorable neurological outcome rate was lower (9% vs. 34%, $p < 0.01$) in out-of-hospital than in-hospital cardiac arrest and was significantly associated with shorter time from collapse to ECMO. The application of stringent ECPR criteria (n = 105) resulted in 38% of patients with favorable neurologic outcome.

Conclusions: ECPR was associated with intact neurological recovery in 19% of unselected cardiac arrest victims, with 38% favorable outcome if stringent selection criteria would have been applied.

Article review and analysis

Aim of this study: Mortality from cardiopulmonary arrest is very high and survivors most often have severe disabling sequelae. Survival depends in particular on the time taken to initiate resuscitation maneuvers and the duration of resuscitation before recovery of circulatory activity. When this duration exceeds 30 minutes, cardiorespiratory arrest is considered refractory and the probability of survival without sequelae is almost zero. The management of refractory cardiac arrest by ECPR is currently developing more and more, and could prove to be effective according to certain published data. However, there are only very heterogeneous and small-size cohorts among the data where the possibility of carrying out an organ donation in the event of unfavorable

developments is reported. The objective of this study was to retrospectively evaluate the outcome of cardiac arrests treated with ECPR over a large cohort.

Methods

Pros: This study presents retrospective data collected over five years, from five intensive care units, each of different nationalities, concerning all the patients who had presented after a cardiac arrest treated by ECPR. It allows the evaluation of this therapy on a first large international cohort.

The criterion for evaluating the efficiency of the use of ECPR (evaluation of survival with good neurological outcome at 3 months) is highly relevant. The possibility of performing an organ donation after ECPR is also particularly interesting data which is, in this article, studied for the first time.

Cons: Several limitations in the interpretation of this study exist. The population is certainly large but nevertheless very disparate, which makes it difficult to compare it with other studies. First, although five resuscitations centers were included, the vast majority of patients (391/423, 92%) came from three of them, with the other two centers having included only 13 and 19 patients, respectively. ECPR is currently reserved for specialized centers and the small number of patients included by two centers (between 2 and 4 patients per year) does not allow reliable analogies to be made with the data from expert centers. On the other hand, only 61% of the cardiorespiratory arrests included in this study were of out-of-hospital origin, a factor associated with an unfavorable prognosis in the literature.

Furthermore, the qualification of cardiac arrest as “refractory” is not currently consensual and, among the population studied, the indication for the implementation of arteriovenous ECMO is not detailed. For example, a number of patients benefited from an arteriovenous ECMO within 20 minutes of the onset of cardiac arrest, de facto modifying the prognosis.

On the other hand, the level of expired CO₂ and the existence or not of signs of life during resuscitation, conventionally described as factors of a good prognosis, are not reported. Likewise, if an initial shockable rhythm is well-identified, the persistence of an abnormal ventricular rhythm during the establishment of the arteriovenous ECMO is not reported.

Finally, the frequency of use of thermal control during resuscitation of cardiac arrest is not reported, although it seems to modify the prognosis of patients. It is recommended in many countries.

Results, conclusion, and what it means

This study describes, for the first time, an international multicenter cohort including the epidemiology of patients who have benefited from the use of ECPR in the management of cardiorespiratory arrest.

The establishment of an arteriovenous ECMO is a complicated therapy and is the

responsibility of specialized centers. This technique cannot, therefore, be offered for all cardiac arrests and a specific number of criteria making it possible to refine the indications for its use are necessary.

Although retrospective, the comparison of the patients who survived with a good neurological prognosis with those whose progress was not favorable makes it possible to highlight the importance of several prognostic factors: patient age, absence of no flow, and short duration of low flow before circulatory assistance. Survival with a good neurological prognosis reached 38% in this study. Patients fulfilling such criteria are therefore likely to benefit from ECPR.

In addition, 10% of the patients included in this study whose fate was unfavorable were candidates for organ donation.

Comments and future research

The use of ECPR is becoming more and more frequent, therefore it must be rationalized. Patients with “good prognosis” criteria must be identified as early as possible and, in particular, referred to centers with this resource. The attention of the teams caring for patients in the initial phase must be aimed at reducing as much as possible the time before the start of circulatory assistance.

Related important publications

Richardson AS, Schmidt M, Bailey M, Pellegrino VA, Rycus PT, Pilcher DV. ECMO Cardio-Pulmonary Resuscitation (ECPR), trends in survival from an international multicentre cohort study over 12-years. *Resuscitation*. 2017 Mar;112:34-40.

Le Guen M, Nicolas-Robin A, Carreira S, Raux M, Leprince P, Riou B, Langeron O. Extracorporeal life support following out-of-hospital refractory cardiac arrest. *Crit Care*. 2011;15(1):R29.

Sandroni C, D'Arrigo S, Callaway CW, Cariou A, Dragancea I, Taccone FS, Antonelli M. The rate of brain death and organ donation in patients resuscitated from cardiac arrest: a systematic review and meta-analysis. *Intensive Care Med*. 2016 Nov;42(11):1661-1671.

ARTICLE NUMBER 5

Advanced reperfusion strategies for patients with out-of-hospital cardiac arrest and refractory ventricular fibrillation (ARREST): a phase 2, single centre, open-label, randomised controlled trial.

Lancet. 2020 Dec 5;396(10265):1807-1816.

Yannopoulos D, Bartos J, Raveendran G, Walser E, Connett J, Murray TA, Collins G, Zhang L, Kalra R, Kosmopoulos M, John R, Shaffer A, Frascione RJ, Wesley K, Conterato M, Biros M, Tolar J, Aufderheide TP.

Abstract

Background: Among patients with out-of-hospital cardiac arrest (OHCA) and ventricular fibrillation, more than half present with refractory ventricular fibrillation unresponsive to initial standard advanced cardiac life support (ACLS) treatment. We did the first randomized clinical trial in the USA of extracorporeal membrane oxygenation (ECMO)-facilitated resuscitation versus standard ACLS treatment in patients with OHCA and refractory ventricular fibrillation.

Methods: For this phase 2, single center, open-label, adaptive, safety and efficacy randomized clinical trial, we included adults aged 18-75 years presenting to the University of Minnesota Medical Center (MN, USA) with OHCA and refractory ventricular fibrillation, no return of spontaneous circulation after three shocks, automated cardiopulmonary resuscitation with a Lund University Cardiac Arrest System, and estimated transfer time shorter than 30 min. Patients were randomly assigned to early ECMO-facilitated resuscitation or standard ACLS treatment on hospital arrival by use of a secure schedule generated with permuted blocks of randomly varying block sizes. Allocation concealment was achieved by use of a randomization schedule that required scratching off an opaque layer to reveal assignment. The primary outcome was survival to hospital discharge. Secondary outcomes were safety, survival, and functional assessment at hospital discharge and at 3 months and 6 months after discharge. All analyses were done on an intention-to-treat basis. The study qualified for exception from informed consent (21 Code of Federal Regulations 50.24). The ARREST trial is registered with ClinicalTrials.gov, NCT03880565.

Findings: Between Aug 8, 2019, and June 14, 2020, 36 patients were assessed for inclusion. After exclusion of six patients, 30 were randomly assigned to standard ACLS treatment (n=15) or to early ECMO-facilitated resuscitation (n=15). One patient in the ECMO-facilitated resuscitation group withdrew from the study before discharge. The mean age was 59 years (range 36-73), and 25 (83%) of 30 patients were men. Survival to hospital discharge was observed in one (7%) of 15 patients (95% credible interval 1.6-30.2) in the standard ACLS treatment group versus six (43%) of 14 patients (21.3-67.7) in the early ECMO-facilitated resuscitation group (risk difference 36.2%, 3.7-59.2; posterior probability of ECMO superiority 0.9861). The study was terminated at the

first preplanned interim analysis by the National Heart, Lung, and Blood Institute after unanimous recommendation from the Data Safety Monitoring Board after enrolling 30 patients because the posterior probability of ECMO superiority exceeded the pre-specified monitoring boundary. Cumulative 6-month survival was significantly better in the early ECMO group than in the standard ACLS group. No unanticipated serious adverse events were observed.

Interpretation: Early ECMO-facilitated resuscitation for patients with OHCA and refractory ventricular fibrillation significantly improved survival to hospital discharge compared with standard ACLS treatment.

Article review and analysis

Aim of this study: Out-of-hospital cardiac arrest (OHCA) is a frequent cause of death worldwide. Among the few survivors of OHCA, most present with an initial shockable rhythm, but half of these patients present with a refractory ventricular fibrillation (unresponsive to at least three electric shocks) leading to a longer resuscitation time. However, a long resuscitation time (more than 30 minutes) is strongly correlated with poor survival rate.

In order to improve the survival of OHCA, a lot of early veno-arterial extracorporeal membrane oxygenation (ECMO) programs are being currently developed. Observational studies are suggesting an improvement in survival but, at the time of publication, no randomized trial has been performed.

The aim of this study was to show an improvement in discharge mortality in OHCA with refractory ventricular fibrillation treated with veno-arterial ECMO compared with standard advanced cardiac life support (ACLS), in a first randomized trial.

Methods

Pros: First, the outcome measure used (survival at discharge from hospital) is particularly strong and appropriate for the subject of the study.

This is the first prospective study to be conducted on the subject. Randomization was carried out on arrival at the hospital, thus ruling out any bias linked to pre-hospital care.

The inclusion criteria were also relatively broad, making it impossible to over-select a population with a good prognosis.

Cons: The implementation of an arteriovenous ECMO in the management of refractory ventricular fibrillation is technically very specialized care, under the responsibility of the referral hospitals. Several different methods of cannulation also exist (percutaneous, surgical approach). Given the very specialized nature of the treatment and the different technical methods of implementation, a multicenter study including several centers would have had even more impact. It is also regrettable that the type of cannulation used in this study has not been described.

A limitation of the interpretation of this study, although unsolvable in such a study, is the open nature of the study, which in essence induces several biases.

Finally, if all the patients presented with an initial shockable rhythm, it would have been interesting to know how many who presented with a severe ventricular arrhythmia on arrival still had this at discharge. It would also have been interesting to know how many patients showed signs of life during CPR in each group.

Results, conclusion, and what it means

The main strength of this study is that it confirms, for the first time in a prospective comparative study, the benefit of ECPR vs CCPR.

The survival of patients in the ECPR group was 43% compared to 7% in the CCPR group. For ethical reasons, the study was stopped early because of these good results.

Comments and future research

The results of this study suggest that any patient without major comorbidity and presenting in cardiopulmonary arrest due to a refractory severe ventricular arrhythmia with short no-flow duration should be eligible for an arteriovenous ECMO as soon as possible (ECMO was in place in 59 minutes in this study). The technique must therefore be spread sufficiently so that it can be used whenever necessary.

The study was conducted in the US, where the pre-hospital care system does not include a doctor. It is also interesting to observe that only 30% (9/30) of the patients included were intubated before arriving at the hospital. Consideration should probably, therefore, be given to areas where a doctor is sent to out-of-hospital cases, in order to ensure that no time is wasted before the implementation of circulatory assistance. It would also be interesting to know whether the prognosis of refractory ventricular fibrillations treated with CCPR would be the same in the case of out-of-hospital medicalization.

In the future, due to the particularly encouraging results presented in this study, it probably does not seem ethically reasonable to conduct a new randomized study to compare against standard treatment; however, it could nevertheless be interesting to compare the prognosis of patients according to the methods of cannulation. Likewise, the comparison of the results of different centers is probably relevant.

Finally, it would likely be very interesting to conduct a study similar to this one focusing on cardio-respiratory arrests without shockable rhythm but with similar delays (no or almost zero no-flow, low flow less than 60 minutes) in order to know if a generalization of the technique would be justified.

i Related important publications

Bartos JA, Carlson K, Carlson C, Raveendran G, John R, Aufderheide TP, Yannopoulos D. Surviving refractory out-of-hospital ventricular fibrillation cardiac arrest: Critical care and extracorporeal membrane oxygenation management. *Resuscitation*. 2018 Nov;132:47-55.

Yannopoulos D, Kalra R, Kosmopoulos M, Walser E, Bartos JA, Murray TA, Connett JE, Aufderheide TP. Rationale and methods of the Advanced R²Eperfusion STrategies for Refractory Cardiac Arrest (ARREST) trial. *Am Heart J*. 2020 Nov;229:29-39.



The authors of this book have carefully identified just over 100 key scientific articles in the field of EndoVascular resuscitation and Trauma Management (EVTM). To each article follows a commentary written by clinically active medical physicians from around the world, all leading experts within their field.

The EVTm concept combines a wide range of multidisciplinary expertise so both hybrid open surgical and endovascular procedures can be used for resuscitation and management of major traumatic and/or non-traumatic hemorrhagic emergencies. As the body of published research in this field has grown considerably over the past years, we hope that this book will help the readers, both experienced physicians as well as residents and trainees, improve their knowledge on each subject and that it may inspire to continued development to identify a clear approach to hemorrhagic emergencies. Finally, this book epitomizes the main purpose of EVTm... “no ego, just good science and cooperation”!

nanos gigantium humeris insidentes

If I have seen further it is by standing on the shoulders of Giants



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