Journal of Endovascular Resuscitation and Trauma Management

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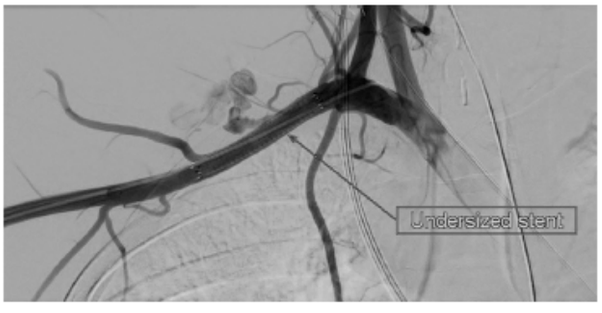

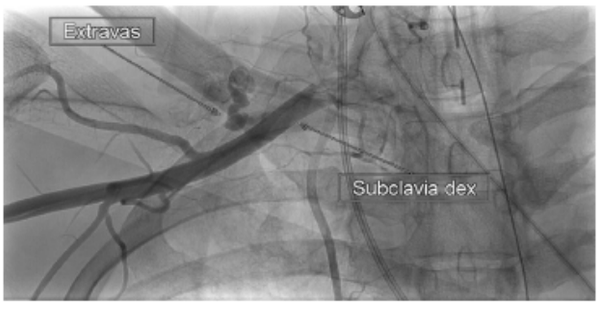

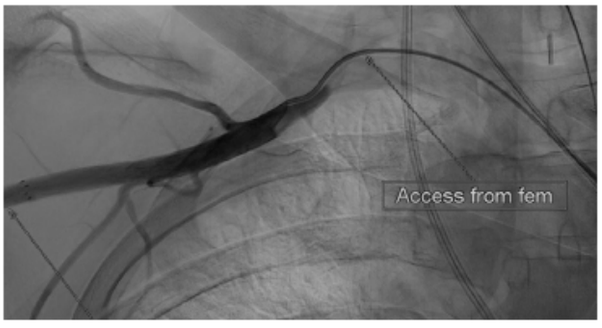

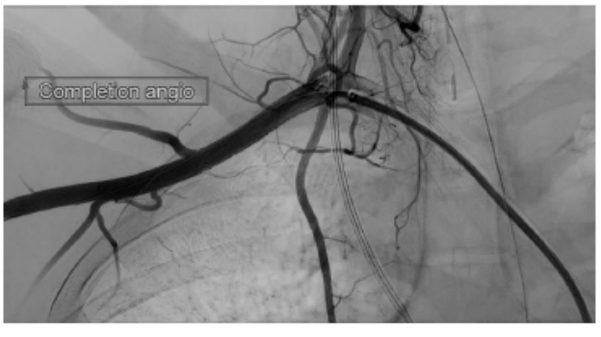

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This is the *Journal of Endovascular Resuscitation and Trauma Management*. We want to provide a truly Open Access platform for the dissemination of knowledge and peer-reviewed research in the field of endovascular and hybrid hemorrhage control.

To achieve this, we do not wish to be bound by medical discipline, country, resource or even the conventional rules of medical publishing. To achieve this goal, we have assembled an Editorial Board of clinicians and scientists who are experts within the field. This project is generously supported by a grant from Örebro University Hospital Research Unit.

We are keen to receive manuscript submissions that present new original findings, review important topics or educate our readers on any aspect of hemorrhage control, where an endovascular technique has been employed. This can either be in isolation or in combination with open surgical techniques (hybrid surgery). For further information for authors, please see *www.jevtm.com*.

As the subject of hemorrhage and resuscitation is a common problem across many medical disciplines, we encourage submissions from all specialties: vascular, trauma, acute care, obstetrics, emergency medicine, to mention a few.

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In cooperation with Örebro University Hospital and Örebro University, Sweden.

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This should consist of text in 12 pts, double spaced with a justified margin, written in US English. While each article type has specified headings, the use of sub-headings is encouraged to aid clarity. These should be formatted as follows:

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Short article managed and written by residents (no senior authors) with educational value (max word count 1500)

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JEVTM follows guidelines and best practices published by professional organizations, including Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals by ICMJE, and Principles of Transparency and Best Practice in Scholarly Publishing (joint statement by COPE, DOAJ, WAME and OASPA).

Contents

Editorial

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JEVTM February 2019

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Hemodynamic instability in trauma and non-trauma patients remains a major clinical problem. Hemorrhages due to injury, gastrointestinal pathologies, spontaneous sources, post-partum complications or iatrogenic sources are encountered daily in major hospitals around the world. Patients with these hemorrhages are frequently fragile following hemodynamic instability and benefit from expedient and effective bleeding control. The concept of utilizing endovascular and hybrid (endo and open) tools to expedite bleeding control to this end, has undergone rapid development over the last 20 years [1–5]. The incorporation of endovascular adjuncts for this purpose has been termed Endovascular Resuscitation and Trauma Management (EVTM) [6]. EVTM has emerged as a true multidisciplinary effort, designed to collaboratively study and implement the optimal use of endovascular adjuncts – including balloons, embolization, endografts, and others – for the benefit of both expedient temporary and definitive hemorrhage control [7,8]. Many principles of EVTM are simply the re-purposing of adjuncts already proven as valuable interventions in other surgical disciplines, including vascular surgery and interventional radiology. Others are truly novel applications that continue to be developed, refined, and studied.

The EVTM concept is both inclusive and expansive, incorporating the use of endovascular adjuncts for both hemorrhage control and resuscitation of the critically injured and ill [8]. In this theme, EVTM efforts continue to integrate resuscitative adjuncts, such as extracorporeal membrane oxygenation (ECMO) and other concepts of cardio-pulmonary resuscitation, such as eCPR, into the conceptual construct of examination and study. In all situations, the underlying goal of EVTM is simple – deliver the correct tool to the right patient expediently, with the right team approach and expertise to optimize success and minimize the risk for mortality and morbidity.

This present edition is the fifth edition of the *Journal of Endovascular Resuscitation and Trauma Management*. As with each of the prior published editions, the enclosed contains peer-reviewed articles on hemodynamic instability and its treatment using EVTM adjuncts. These include the use of REBOA, embolization and other novel strategies using endovascular tools. The editorial board and editors strive to continue expanding the journal and its content to include the examination of an increasing array of EVTM concepts for applications in both trauma and non-trauma resuscitation. Our editorial board consists of a multidisciplinary, international collection of experts who specialize in EVTM related disciplines, including intervention radiologists, trauma and vascular surgeons, intensivists and emergency physicians. This collaborative team is dedicated to the construction of an increasing base of knowledge regarding EVTM methods and their use. In the coming year, we intend to expand and develop the journal even further, with emphasis on resuscitation, hemorrhage control, and technological developments. We remain a group dedicated to the exploration of EVTM applications in a variety of settings, including hospital, pre-hospital and combat casualty scenarios. As a peer-reviewed scientific journal with over 50 published articles that have been screened intensively for quality and content through a peer-review process, it is our shared goal to achieve PubMed index approval during 2019. In this fashion, we aspire to broaden the international academic recognition of this collaborative, evolutionary movement. We would like to thank the editorial board, our reviewers and – most importantly – the clinicians and researchers who consider JEVTM for the publication of their work.

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Original Article

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A Novel Automated Endovascular Variable Aortic Control Device to Expand Function of Standard REBOA Catheters

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Background: Endovascular methods for hemorrhage control, including resuscitative endovascular balloon occlusion of the aorta (REBOA), are evolving and are increasingly being applied clinically. Partial flow strategies to mitigate the consequences of complete aortic occlusion have been demonstrated in pre-clinical models to enhance REBOA and expand its application to various shock states. Initial studies demonstrated that controlled partial flow requires precision beyond the capabilities of manual balloon volume adjustment, therefore automation is required. Our group previously developed a proof-of-concept computer-controlled extracorporeal flow circuit capable of precision aortic flow regulation, but it was not clinically applicable. To bring this concept closer to clinical applicability, we have developed the first endovascular strategy to achieve precision aortic flow regulation, termed endovascular variable aortic control (EVAC).

Methods: Following instrumentation, five Yorkshire-cross swine were subjected to controlled 25% hemorrhage, followed by precision low volume aortic flow regulation using a commercially available compliant balloon catheter pre-positioned in the descending thoracic aorta, connected to a custom, wireless syringe pump. Closed-loop feedback algorithms based on streaming physiologic data were used to determine balloon volume changes.

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Author contributions: TKW, LPN, EMT, GLH, MAS, AJD, ESD, ERF, and MAJ contributed to the literature search and study design. TKW, LPN, EMT, GLH, MAS, AJD, ESD, ERF, and MAJ collected the data, performed the data analysis and interpretation. TKW, LPN, EMT, GLH, MAS, AJD, ESD, ERF, and MAJ wrote and critically revised the manuscript.

Conflicts of interest: Dr. Williams, Dr. Neff, and Dr. Johnson are named inventors on intellectual property indirectly related to this work, jointly owned by the University of California Davis and the United States Air Force, and are co-founders of Certus Critical Care, Inc, which has licensed this technology from UC Davis.

Funding: Funding for this study was provided by the Clinical Investigation Facility, David Grant Medical Center, Travis Air Force Base, CA.

Presentation: none.

Disclosure: The views expressed in this material are those of the authors and do not reflect the official policy or position of the U.S. Government, the Department of Defense, the Department of the Air Force, or the University of California Davis. The animals involved in this study were procured, maintained, and used in accordance with the Laboratory Animal Welfare Act of 1966, as amended, and the Guide for the Care and Use of Laboratory Animals, National Research Council. The work reported herein was performed under United States Air Force Surgeon General-approved Clinical Investigation No. FDG20170005A.

Results: The EVAC syringe pump was highly effective at maintaining precise aortic flow throughout the 45-minute intervention period during steady-state conditions as well as during rapid fluid administration. Aortic flow and distal mean arterial pressure remained stable during EVAC, despite changing proximal hemodynamics. Balloon volume was dynamic, averaging over 500 changes during intervention, with a mean volume change of 6.7 μL and a maximal change of 100 μL.

Conclusions: The EVAC syringe pump is capable of achieving aortic flow regulation with high precision, beyond what is achievable with manual control. This serves as a model for future device design, enabling as-of-yet unachievable clinical therapies for hemorrhage and shock states. Future technological development is required to fully translate this into clinical use.

Keywords: *EVAC; P-REBOA; REBOA; Automation; Hemorrhage*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a viable strategy to salvage trauma victims dying from non-compressible torso hemorrhage (NCTH) [1–4]. However, the distal ischemia that develops in tissues below the level of occlusion limits the duration of REBOA therapy to 30–45 minutes [5]. This limitation has prompted the development of new techniques to extend support beyond the finite period. Partial occlusion with REBOA catheters to allow distal flow past the point of occlusion has emerged as a promising means to mitigate the deleterious consequences of REBOA [6–10]. To date, the clinical efficacy of partial REBOA (P-REBOA) has been elusive because the control of balloon inflation and deflation with existing technology can only be accomplished by low-fidelity manual manipulation with a handheld syringe [9–11].

Manual regulation of P-REBOA represents a challenge for two principle reasons. First, the interplay of aortic physiology, cardiac performance, neuroendocrine responses, volume status and flow dynamics at high levels of aortic occlusion is highly complex and highly dynamic. Because of this, manual titration of partial flow requires very subtle changes in balloon volume to maintain stable flow, which is not possible with current REBOA balloon technology. Even small occlusion balloon volume shifts can result in rapid changes in aortic blood flow and pressure, creating significant challenges for medical providers trying to stabilize a critically ill patient [11,12]. Future balloon technology aimed at decreasing the wide swings in blood flow in response to changes in balloon volume may be able to improve manual control of P-REBOA.

Second and most important, achieving the type of consistent low-volume aortic flow needed for hemostasis requires rapid responsiveness to dynamic factors apart from simply the amount of volume in the balloon. Active intravascular volume resuscitation with and without ongoing blood loss, administration of vasopressors, distal tissue bed ischemia, and vasodilation all introduce additional layers of complexity that influence aortic flow past a static balloon. Therefore, compensatory changes in balloon volume must be just as dynamic as the changing physiology of an active trauma resuscitation to maintain stable flow past the balloon and ensure hemostasis. This need for a dynamic and "intelligent" balloon has major implications for the conduct of P-REBOA in the pre-hospital or resource-constrained environments, where rapid increases in blood flow from blood or IV fluid administration may destabilize clots and lead to continued life-threatening hemorrhage. Conversely, blood flow past the balloon may cease in response to decreased proximal perfusion pressure leading to a decreased aortic diameter and complete occlusion, resulting in additional downstream ischemia from complete REBOA. Even with manual balloon titration in the most skilled provider's hands, these physiologic considerations demand constant attention to balloon volume and real-time physiologic metrics including blood pressure above and below the balloon to maintain a consistent amount of distal perfusion. Early clinic experiences with P-REBOA during dynamic trauma resuscitations in level 1 trauma centers have indicated how labile the physiology can be with this process [8,11]. Thus, maintaining consistent patient physiology with P-REBOA is a resource and labor-intensive process that may prevent a key medical provider from focusing on more important aspects of patient care, such as definitive hemorrhage control. In many settings, particularly austere environments with limited medical providers, this may make P-REBOA impractical.

Our group's prior studies with robotic control systems have demonstrated that the precise regulation of ultra-low downstream aortic flow rates can balance the competing management priorities of hemostasis, blood pressure augmentation, and distal organ perfusion in the face of uncontrolled hemorrhagic shock [13–15]. This novel therapeutic concept, termed regionalized perfusion optimization (REPO), is predicated on a method that can precisely and dynamically control the flow of blood to the abdominal aorta, responding in real time to changing patient physiology. Given the difficulties surrounding manual control, REPO must be accomplished

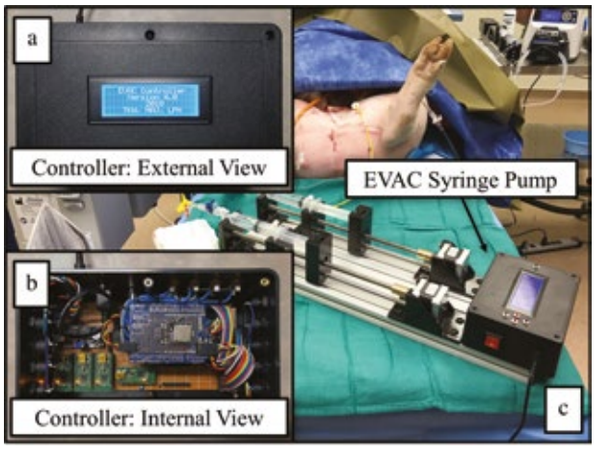

Figure 1 Endovascular variable aortic control (EVAC) hardware platform. (**a**) External view of the custom wireless EVAC controller. (**b**) Internal view. (**c**) Automated EVAC syringe pump in use during a representative experiment.

with endovascular devices that provide automated precision control by sensing the physiology of the patient and responding in real time with appropriate balloon volume changes. As an initial step toward the development of an endovascular variable aortic control (EVAC) device that can autonomously vary the degree of aortic occlusion, we developed a novel extracorporeal flow circuit to achieve precision regulation of aortic blood flow [14]. This and other experimental aortic flow regulation devices have achieved REPO successfully in multiple large animal models of controlled and uncontrolled hemorrhage, improving outcomes compared to REBOA for multiple physiologic endpoints including mortality, hemodynamics, and end-organ function [13,16]. Yet, these initial studies did not employ endovascular devices that could readily translate into a clinically viable technology. Nonetheless, the extracorporeal flow device and the subsequent automated aortic clamp served as a proof-of-concept for the physiologic implications of automated aortic flow regulation and regional perfusion optimization [15,16]. To advance these concepts closer to a clinically relevant therapy, we have developed an automated syringe pump and controller that can regulate the filling volume of a commercially available endovascular balloon catheter based on physiologic data inputs from the patient. The purpose of this communication is to describe the first-in-animal experience with a fully automated, endovascular method to achieve the precise regulation of aortic flow.

METHODS

Overview

The conduct of this experimental study involved *in vivo* animal testing of a custom-built hardware and software system to control aortic flow. The Institutional Animal Care and Use Committee at David Grant Medical Center, Travis Air Force Base, California approved this study. All animal care and use were in strict compliance with the Guide for the Care and Use of Laboratory Animals in a facility accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International. Healthy adult, castrated male and non-pregnant female Yorkshire-cross swine (*Sus scrofa*) were acclimated for a minimum of seven days. At the time of experimentation, animals weighed between 60 and 95 kg.

Hardware Architecture

The novel components of this platform include a precision automated syringe pump coupled with a custom microcontroller that integrates streaming physiologic data from the patient (Figure 1). Development and testing of the hardware and software platform were performed internally at the 60th Clinical Investigation Facility, Travis AFB, CA. The fundamental architecture of the master control system has been previously described, however, this experiment utilized a more compact design [14]. In brief, the hardware architecture utilizes a commercially available microcontroller (Arduino, Sommerville, MA) with wireless functionality and a multichannel 16-bit analog-to-digital converter for the acquisition of real-time physiologic data including aortic flow, proximal arterial pressure, and distal arterial pressure (Figure 1*a*,*b*). The custom syringe pump utilizes a NEMA 17 stepper motor that drives a standard lead screw, a commercially available stepper motor controller (BigEasyDriver, Sparkfun, Niwot, CO), custom 3D-printed components that hold the syringe and plunger, and a wireless microcontroller that performs bidirectional communication with the master controller unit (Figure 1*c*).

Custom software algorithms were developed to precisely regulate aortic flow using a closed loop feedback mechanism. A weight-based aortic flow rate of 4.3 mL/kg/min was established, which is approximately 10% of baseline distal aortic flow for a 70 kg animal.

In Vivo Testing

Animals were premedicated with 6.6 mg/kg intramuscular tiletamine/zolazepam (Telazol, Fort Dodge Animal Health, Fort Dodge, IA). Following isoflurane induction and endotracheal intubation, general anesthesia was maintained with 2% isoflurane in 100% oxygen. To offset the vasodilatory effects of general anesthesia, an intravenous infusion of norepinephrine (0.01 mg/kg/min) was instituted upon venous access and titrated prior to experimentation to achieve a target mean arterial pressure between 65 and 75 mmHg. Animals were mechanically ventilated to maintain end-tidal CO_2 at 40 ± 5 mmHg.

Plasmalyte (Baxter, Deerfield, IL) maintenance intravenous fluid was administered at a rate of 10 mL/kg/h until the abdomen was closed, at which point the rate was decreased to 5 mL/kg/h for the remainder of the study to overcome insensible losses. Intravenous heparin was administered to achieve an activated clotting time (ACT) of 100 seconds, similar to human baseline values. An underbody warmer was used to maintain core body temperature between 35 and 37°C.

Following laparotomy, a splenectomy was performed to minimize hemodynamic variation from autotransfusion. The supraceliac aorta was exposed by dividing the left diaphragm and dissected circumferentially for a length of 5–10 cm. A perivascular aortic flow probe (Transonic Systems Inc, Ithaca, NY) was placed with ligation of two adjacent intercostal arteries distally, thus preventing intervening flow between the flow probe and the endovascular occlusion balloon. The abdomen was closed with cable ties. External jugular veins were cannulated to facilitate medication and fluid administration. The right brachial artery was exposed and cannulated with a 7F sheath (SuperSheath, Boston Scientific, Marlborough, MA) for controlled hemorrhage. The left axillary artery was exposed and cannulated with a 9F sheath (SuperSheath, Boston Scientific) for proximal arterial pressure monitoring. The left femoral artery was exposed and cannulated with a 12F sheath (Cook Medical, Bloomington, IN), through which a 9F Coda LP balloon (Cook Medical, Bloomington, IN) was advanced under fluoroscopic guidance to the level of the supraceliac aorta (zone 1), just distal to the aortic flow probe. Distal pressure was also monitored via this sheath.

Data Collection and Analysis

Physiologic parameters and aortic flow measurements were collected in real time using a Biopac MP150 multichannel data acquisition system and the custom Arduino-based data acquisition system/controller (BioPac, Goleta, CA). Parameters measured included heart rate, blood pressure proximal and distal to the intra-aortic balloons, and aortic flow beyond the Zone I balloon.

Data analysis was performed and graphs constructed using Excel (Microsoft Corporation, (Redmond, WA) and STATA version 14.0 (Stata Corporation, Bryan, TX). Continuous variables are graphically presented as means and standard error of the means. Categorical variables are presented as means with standard deviation and standard error of the means.

Experimental Design

At the beginning of experimentation (T0), animals were subjected to a 25% total blood volume hemorrhage over 30 minutes. Following this 30-minute hemorrhage interval, the master controller initiated stepwise balloon inflation over approximately 3 minutes until the target weight-based flow rate was achieved. The EVAC syringe pump automatically adjusted the balloon volume to actively maintain aortic flow at this level for the duration of the 45-minute EVAC interval. To ascertain the performance of the EVAC syringe pump during active resuscitation, whole blood transfusion was initiated at T65. The EVAC syringe pump then initiated a 5-minute balloon deflation and weaning sequence, beginning at T75.

RESULTS

Five animals underwent instrumentation, hemorrhage and a subsequent 45 minutes of Zone 1 EVAC. All animals survived the experimental phase. Hemorrhage was associated with an anticipated decline in distal aortic flow and in mean arterial pressure as measured in both the proximal descending thoracic aorta and the distal abdominal aorta (Figure 2). Upon initiation of EVAC at T30, there was an abrupt increase in proximal mean arterial pressure and a concurrent decrease in distal mean arterial pressure. The EVAC syringe pump was able to maintain stable aortic flow throughout the 45-minute intervention period with minimal deviation from the aortic flow goal (Figure 2*c*). Distal aortic pressure also remained stable throughout EVAC, at approximately 16 mmHg.

Upon initiation of blood transfusion at T65, there was a steep rise in proximal mean arterial pressure (Figure 2*a*). The EVAC syringe pump responded with a compensatory increase in balloon volume to maintain the specified aortic flow rate. Both aortic flow and distal aortic pressure remained stable and unchanged during active volume resuscitation as a result of these compensatory balloon adjustments (Figure 2*b*,*c*).

The relationship between balloon volume and the various hemodynamic parameters is represented in Figure 3. The EVAC syringe pump made small, yet discernible changes in balloon volume throughout the EVAC interval, with the largest changes occurring during the 10-minute period of blood transfusion. Mean aortic flow throughout EVAC closely approximated the target aortic flow (4.5 vs 4.4 ml/kg/min) (Figure 3*d*). The EVAC syringe pump maintained aortic flow within a range of 4.2–4.6 ml/kg/min (12–13% of estimated baseline flow) for 62% of the intervention and 3.9–4.9 ml/kg/min (11–14% of estimated baseline flow) for 98% of the experiment (Figure 2*d*, Figure 3*a*).

Stepwise balloon deflation resulted in a rapid, steep increase in aortic flow around the balloon. Return to full baseline flow rates was observed following withdrawal of 2.5 mL from the balloon, with nearly twice the baseline flow observed upon full balloon deflation (34 ml/kg/min and 67 ml/kg/min, respectively, Figure 3*a*).

Throughout the 45-minute period of EVAC, the syringe pump made an average of 537 balloon adjustments, with a mean balloon volume change of 6.4 μL per adjustment. The largest average balloon volume

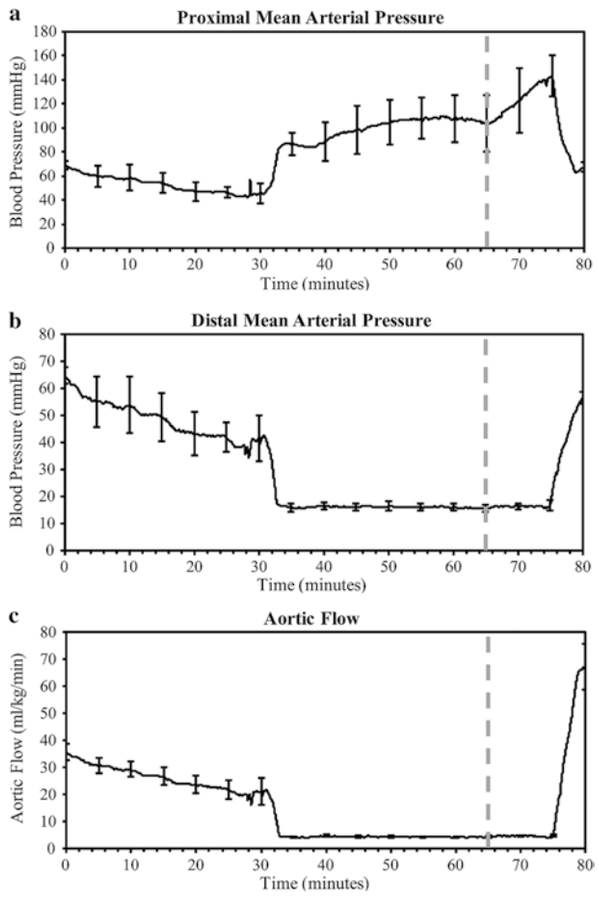

Figure 2 Endovascular variable aortic control (EVAC) hemodynamics during hemorrhage and intervention. The vertical dashed line represents the onset of whole blood resuscitation. (**a**) Proximal mean arterial pressure rises abruptly in response to EVAC, with a slow progressive rise during intervention. Note the steep inflection in blood pressure with transfusion. (**b**) Distal mean arterial pressure remains very stable during EVAC. (**c**) Aortic flow remains very stable during EVAC. Note the hyperemic response to balloon deflation beginning at T75.

change required in order to maintain flow within the specified range was approximately 100 µL (Table 1).

Figure 4 demonstrates the control of balloon volume by the EVAC syringe pump in response to aortic flow and proximal mean arterial pressure for a single representative experiment. Flow remains essentially unchanged over time due to small, dynamic adjustments in balloon volume (Figure 4*a*). Note that the profile of balloon volume closely mirrors the trend in proximal mean arterial pressure throughout the intervention (Figure 4*b*).

DISCUSSION

The present communication is the first-in-animal experience with EVAC using commercially available aortic occlusion catheters and an entirely automated flow regulating device. We have demonstrated that precision aortic flow regulation is feasible and imminently achievable with commercially available aortic occlusion catheters by adjusting occlusion balloon volumes with an algorithm-driven, autonomous syringe pump.

With the increase in REBOA use for hemorrhage control, innovations to address certain key limitations have swiftly ensued. REBOA, while effective at controlling hemorrhage at bleeding points below the level of occlusion, is limited by the adverse effects of proximal aortic hypertension and progressive ischemic burden to distal tissue beds [1,2,5,7,13]. Therefore the technique of partially inflating a balloon catheter was proposed to slow bleeding and improve blood flow to the heart, lungs, and brain, while mitigating the ischemic insult below the balloon. Yet, early clinical experiences have demonstrated that P-REBOA is extremely challenging and results in labile hemodynamics due to the lack of fidelity with manual balloon titration [8,11]. Additionally, large animal models of P-REBOA have demonstrated a tendency toward perpetuating ongoing hemorrhage [6]. Continued bleeding is a serious concern in every clinical environment, but especially in scenarios where blood products are in limited supply or when a significant delay to surgical hemostasis is anticipated.

In response, our group has explored the use of automation to improve upon the P-REBOA concept. Automation addresses several key limitations of the manual approach to aortic flow regulation. First, the EVAC syringe pump is capable of executing very small changes in balloon filling volume. The current hardware design of the syringe pump is capable of delivering or withdrawing aliquots of fluid less than 10 µL. These changes are too precise to be performed manually with any manner of fidelity or consistency, thereby necessitating robotic control. As we have demonstrated in prior experiments and again in the present experiment, very small adjustments in the degree of aortic occlusion translate into large variations in aortic flow rate [12,15]. Hyperemic aortic flow was again observed during the balloon deflation phase of this experiment and likely reflects the hyperdynamic cardiac state induced by aortic occlusion, combined with low systemic vascular resistance from vasodilated distal tissue beds. This hyperemic flow is fairly unpredictable in its onset and occurs at different balloon volumes depending on the individual animal [12]. Therefore, establishing clinical guidelines for manual balloon deflation based on a prescribed volume is not practical. Precise control of balloon filling volume based on real-time physiologic metrics is therefore necessary to prevent avoid rapid changes in aortic flow and distal perfusion pressure, which could lead to hemodynamic collapse or precipitate clot destabilization and hemorrhage. With balloon volume changes of less than 10 µL producing discernible differences in aortic flow rates, it is apparent why previous attempts at manual flow titration have resulted in erratic hemodynamics [6,11].

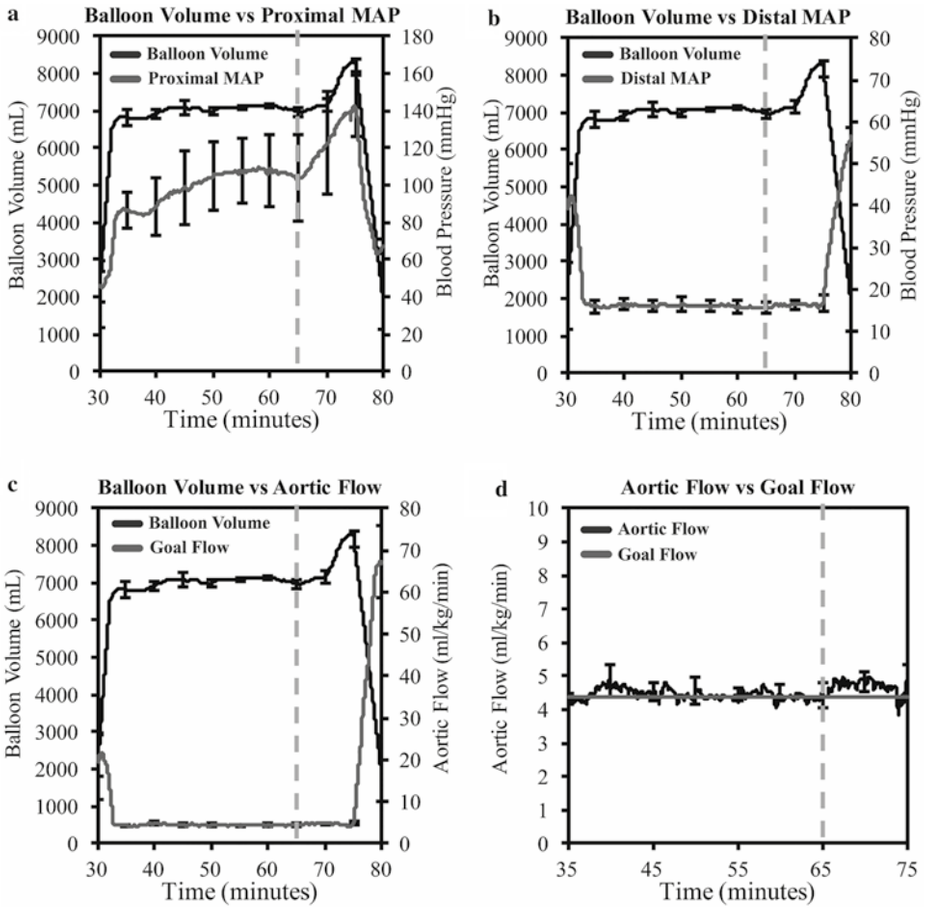

Figure 3 Endovascular variable aortic control (EVAC) hemodynamic and balloon volume during hemorrhage. The vertical dashed line represents the onset of whole blood resuscitation. (**a**) Balloon volume undergoes subtle changes during EVAC but inflates significantly in response to blood transfusion. (**b**) Distal mean arterial pressure (MAP) remains stable throughout EVAC. (**c**) Aortic flow remains stable throughout EVAC. Note the marked hyperemic response to early balloon deflation. (**d**) Aortic flow closely approximated the target distal flow for the EVAC controller and automated syringe pump.

Table 1 Balloon characteristics during a 45-minute EVAC intervention period

	Average	*Standard deviation*	*SEM*
Total volume moved (μL)	3,490.8	1,575.1	643.0
Total No. of movements	537	33	14
Largest volume change (μL)	98.7	101.5	41.4
Average volume change (μL)	6.4	2.5	1.0

Additionally, this syringe pump responds within milliseconds to changing patient physiology. In the present study, there was an average of nearly 600 balloon adjustments made over a 45-minute period to maintain the desired aortic flow rate. This frequency of adjustments would be difficult, if not impossible, to achieve with hand control of the balloon volume. Moreover, humans are highly inefficient at integrating multiple streams of continuous data and responding in a timely fashion with an appropriate, measured response. Yet, computers and robots excel at these focused computational tasks. Even if balloon technology evolves to where flow can be manually titrated with acceptable precision, this would still require near constant attention of the provider to manage balloon titration. Many environments lack the manpower capabilities needed to execute this type of focused task while simultaneously managing other acutely life-threatening issues, including achieving definitive surgical hemostasis. This potential misallocation of key medical expertise and manpower

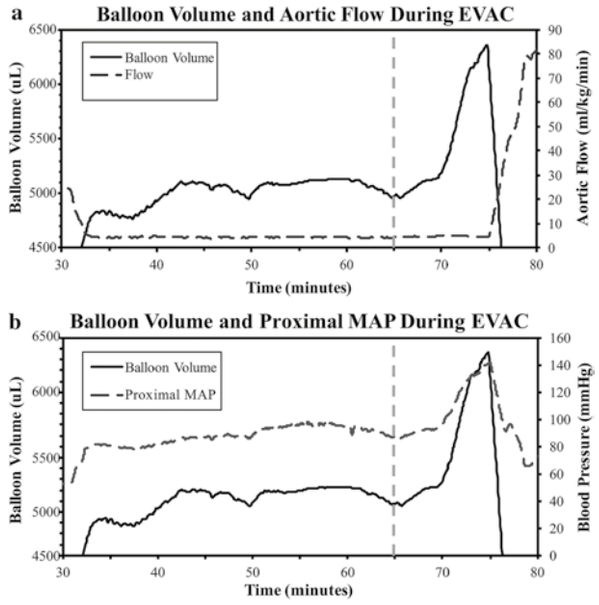

Figure 4 Endovascular variable aortic control (EVAC) hemodynamics in a single representative animal. The vertical dashed line represents the onset of whole blood resuscitation. (**a**) Note the stability of aortic flow during EVAC, whereas balloon volume remains dynamic throughout, particularly in response to resuscitation. (**b**) Note that balloon volume and proximal mean arterial pressure (MAP) closely mirror each other over time, underscoring the need for dynamic balloon regulation in response to changing proximal hemodynamics.

may prevent the adoption of partial aortic occlusion as a viable resuscitation adjunct in austere environments. If this rationale is extended to the care of multiple simultaneous casualties, then the notion of performing partial aortic flow regulation techniques with manual control alone becomes entirely impractical.

In comparison to our previous extracorporeal flow control circuit, the current EVAC syringe pump provides an equivalent, if not superior, degree of aortic flow control. With earlier approaches, we demonstrated that tight regulation of low volume distal aortic flow can effectively mitigate the ischemic burden of sustained aortic occlusion, while simultaneously minimizing hemorrhage. Unfortunately, utilizing aortic flow data as the target physiologic metric upon which balloon titration is based remains an experimental construct. In our experiments, this data is acquired from a surgically implanted perivascular flow probe, which is clinically impractical. Presently, there is no commercially available method of obtaining an accurate measure of aortic flow with a minimally invasive or endovascular means to enable careful titration of a balloon catheter. Despite this fact, this study does demonstrate that distal aortic pressure and aortic flow do correlate in this particular model of hemorrhage and ischemia. Therefore, it is conceivable that titrating the degree of occlusion to a specific distal aortic pressure would result in a stable downstream aortic flow. However, it is unclear whether other disease states or injury patterns would exhibit this same relationship.

Additionally, the present study did not directly compare the performance of the EVAC syringe pump to manual balloon control or other catheters designed specifically for P-REBOA. Future comparative studies with EVAC and manual P-REBOA may be justified. Yet, manual balloon titration will remain a less favorable option regardless due to its intense demands from a skilled provider. It also remains unclear whether this degree of precision flow regulation achieved by the EVAC syringe pump is required to achieve acceptable clinical outcomes. Further investigation to elucidate these points is essential prior to full clinical translation.

CONCLUSION

The development of a completely automated endovascular solution provides an important next step toward the clinical translation of EVAC as a novel resuscitation paradigm for non-compressible torso hemorrhage. The EVAC syringe pump is capable of continuous, dynamic control of a commercially available aortic occlusion catheter. Further work to refine balloon control algorithms based on readily available pressure-based metrics is warranted. Additionally, comparison of the EVAC syringe pump to manual P-REBOA is indicated to justify the in-human use of automated control in this context.

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Original Article

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Prompt Procedures to Hemodynamically Unstable Patients with Pelvic Fractures

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Background: Angioembolization is a widely accepted method for an effective and useful hemostasis procedure in pelvic fracture (PF) patients. We evaluated and introduced the time course of the initial management and angiography in hemodynamically unstable pelvic fracture patients.
Methods: We retrospectively reviewed 56 PF patients who underwent interventional radiology (IR) from May 2010 to Dec 2016. We defined arrival to angiography time (ATAT), and this was recorded in all enrolled patients in which the first angiography image represented the initiation of angiography. We also evaluated total embolization time (TET) and single artery embolization time (SAET; time for artery selection, injection, embolization, and confirmation).
Results: The median ATAT and TET were respectively 73 and 33 minutes. They were much faster than the previous reports.
Conclusions: Our trauma IR strategy with a specialized team might contribute to a shortening of the management time.

Keywords: *Pelvic Fracture; Interventional Radiology; Damage Control*

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BACKGROUND

Pelvic fractures mainly result from motor vehicle collisions or falls from a height [1] and can cause extensive retroperitoneal bleeding. The mortality rate in hemodynamically unstable (HU) pelvic fracture still remains high at 40–50% [2]. Angioembolization (AE) is widely accepted as an effective hemostasis in pelvic fracture patients [3,4]. However even in Level 1 trauma centers, time from hospital admission to pelvic AE can be prolonged, and the delay of AE may not only make it more difficult to control the hemorrhage but also increase mortality rate [5,6].

Our trauma center employs a proactive trauma interventional radiology (IR) team established on the "Prompt and Rapid Endovascular Strategies in Trauma Occasions" (PRESTO) concept [7]. The AE procedure is based on the damage control interventional radiology (DCIR) protocol [7]. In this paper, we hypothesize that proactive IR team involvement contributes to early angiography and rapid procedures. We demonstrate the time to angiography and procedure time during the initial management of HU pelvic fracture patients.

METHODS

PRESTO with DCIR

According to the PRESTO concept, the attending emergency physician/trauma surgeon activates the IR team when he/she assumed possible IR treatment as early as possible, even before the arrival of the patients. When hemodynamic instability or pelvic fracture were assumed, a femoral artery sheath is rapidly placed as part of the

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primary survey after the patient's arrival or recognition of shock. Bilateral femoral sheaths were obtained if needed for resuscitative endovascular balloon occlusion of the aorta (REBOA) or arterial pressure monitoring. The X-ray or CT images were evaluated by the IR physicians immediately. When the decision for IR was declared in the CT room, the patients were transferred to the angiography suite directly to minimize the time to angiography. All angiography was performed in the angiography suite 20 meters from the emergency room, which was next to the CT room. The IR team is ready to start angiography within 30 minutes from activation. All IR procedures are conducted by a trained radiology team which consists of IR physicians, fellows, radiology technicians, and nurses. The IR team comprises a conductor–operator–assistant. The conductor, a trained radiologist, diagnoses and processes the CT data to create virtual angiographic images in order to navigate the operator before or during the angiographic procedures (7).

Study Setting

We retrospectively enrolled HU pelvic fracture patients consecutively who required AE from March 2010 to May 2016 at a trauma center in a tertiary care hospital in Tokyo, Japan. The institutional review board approved the study prior to the registration of the patients' data. All patients were initially assessed and resuscitated by either emergency physicians or trauma surgeons. Pelvic injury was diagnosed by plain pelvic X-ray or CT. A pelvic binder was applied in open book type fractures in the emergency department. AE was chosen as the first-line hemostasis, then external fixation was added according to the fracture pattern as needed. Preperitoneal packing was not included in our institutional protocol. The indication of AE of pelvic fracture was hemodynamic instability, extravasation on the CT image, and hematoma neighboring to the fracture section. The decision of AE was preceded by hemodynamic response to the transfusion because a massive transfusion protocol with unmatched O-type blood was not established in the early study period. We aimed to perform AE in order to avoid or decrease the requirement of transfusion.

Data Collection and Definition

Patients' characteristics, injury severity score (ISS), and the revised trauma score (RTS) were collected and the probability of survival was calculated. HU was defined as shock index (SI) > 0.9 or systolic blood pressure (SBP) < 90 mmHg on arrival at the emergency department [8]. Hemodynamics data were recorded on arrival and after AE. Complications and transfusion requirement during the first 24 hours and survival outcomes were described.

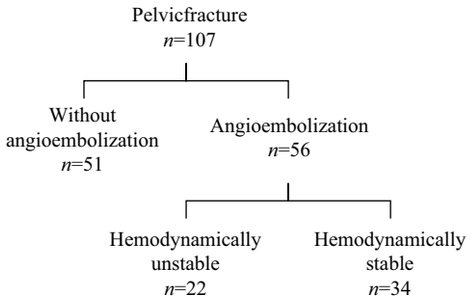

Figure 1 Flow chart of studied patients.

The time course was obtained from electronic medical records (EMR) or Digital Imaging and Communication in Medicine (DICOM) data. Arrival to angiography time (ATAT) was defined as the hospital arrival time on EMR to the first injection on DICOM data. Total embolization time (TET) was defined as the time from the first injection to the aortography after the embolization. In the cases requiring repeated AE, TET was calculated as the sum of each AE procedure. The number of embolized arteries were also recorded especially those observed in polytrauma patients. Single artery embolization time (SAET) was calculated by dividing TET by the number of embolized arteries. Embolic material such as gelatin sponge, metallic coil or N-butyl cyanoacrylate (NBCA) were also recorded.

Statistical Analysis

Data are presented as the median and interquartile range. Wilcoxon signed-rank test was used in the comparison of changes in SBP before and after AE. All levels of significance are reported at the level $\alpha = 0.05$ using a two-tailed test. Analyses were performed using GraphPad Prism for Mac OS X version 7.0c (GraphPad Software Inc, USA).

RESULTS

During the study period, we treated 107 pelvic injury patients. Of these, 56 patients underwent AE and 22 of these patients were HU on arrival (Figure 1). The median SBP and SI were 94 (83–110) and 1.19 (1.04–1.33), respectively. The SI significantly decreased from 1.19 to 0.86 after AE ($P < 0.001$). Median ISS was 25 (16–34). Median 24-hour survival rate was 90.9%. Transfusion requirement within the first 24 hours was 13 units of packed red blood cell, and 12 units of fresh frozen plasma (Table 1). The median ATAT and SAET were 73 (51–93) minutes and 7 (5–11) minutes, respectively (Table 2). As concomitant procedures among 22 HU patients, 14 underwent solid organ embolization, 8 required external fixation, 1 received REBOA, and 1 underwent craniotomy.

Table 1 Patients' characteristics and outcomes.

Characteristics and outcome	*n = 22*
Age (years)	50 (23–65)
Male, *n* (%)	13 (59)
Young–Burgess classification	
LC-I	5
LC-II	6
LC-III	1
APC-I	0
APC-II	2
APC-III	3
VS	5
Systolic blood pressure (mmHg)	94 (83–110)
Shock Index on arrival	1.19 (1.04–1.33)
Shock Index after angioembolization	0.86 (0.69–0.99)
Injury Severity Score	25 (16–34)
Revised Trauma Score	7.55 (6.81–7.84)
Transfusion during first 24 hours	
PRBC (mL)	13 (4.5–19), 1820 (630–2660)
FFP (mL)	12 (8.5–21.5), 1400 (1020–2580)
Platelet (mL)	0 (0–18), 0 (0–360)
Complication, *n* (%)	
Gluteal necrosis	1 (4.5)
Bladder necrosis	0
Morell–Lavalle	0
24-hour survival, *n* (%)	20 (90.9)
30-day survival, *n* (%)	18 (81.8)
Probability of survival, (%)	93 (79–97)

LC, lateral compression; APC, anterior posterior compression; VS, vertical shear; PRBC, packed red blood cell; FFP, fresh frozen plasma; Ps, probability of survival.

The data are presented as median and interquartile range for categorical data.

Transfusion units are presented in Japanese units. One Japanese unit of transfusion is made from 200 mL of donor blood.

DISCUSSION

A delay in angiography affects the mortality in pelvic fracture patients [6]. Currently, the ATAT is reported to be more than three hours even in a high volume level 1 trauma center in the United States [8,9]. The time course to angiography mainly depends on IR team activation, diagnosis of the image, and decision of angiography. Our results present 73 minutes of ATAT. This number is much shorter than in previous reports [8,9]. Our IR team is tolerant to overactivation based on the PRESTO concept. In addition, more lucid activation criteria may contribute to earlier initiation of angiography.

IR is considered in procedures for hemodynamically stable patients in abdominal trauma. In addition, IR is utilized as a definite hemostasis in pelvic trauma [5]. However, pelvic AE procedure time was reported between 60 and 130 minutes in past literature [10,11]. Our results revealed 33 minutes of TET. Our AE procedures were based on DCIR protocol, such as permissive wide range embolization or waiving diagnostic angiography, in HU patients. We reported approximately 7 minutes of SAET, including cannulation, injection, embolization, and re-injection. Rapid procedures could be explained by bilateral non-selective internal iliac artery embolization (observed in 77% of the analyzed patients) or NBCA injection (observed in 27% of the analyzed patients). In addition, the "Conductor" doctor plays a key role in our IR team, the navigation of the operator is based on CT volume data to provide precise anatomical information concerning access to target vessels [7], such as the level of the branch of the aorta, clock position in the cross-sectional plane of the aorta, and a visual angiographic image with a clear catheter route. After the procedure, SI improved from 1.19 to 0.86, which could be explained by whole resuscitation effort, including AE, transfusion, and correction of coagulopathy.

The present study has several limitations. Firstly, this is a retrospective, single center, observational study with a small number of cases. Secondly, we did not conclude

Table 2 Time course in initial management and endovascular procedure.

Characteristics	*HU group (n = 22)*
ATAT (min)	73 (51–93)
TET (min)	33 (11–72)
Number of embolized arteries	3 (2–5)
Embolized artery	Internal iliac artery Branches of internal iliac artery Lumbar artery Femoral artery branches Splenic artery Hepatic artery
SAET (min)	7.1 (5.1–11.5)
Bilateral non-selective IIA embolization, *n* (%)	17 (78)
Embolic material, *n* (%)	
Gelatin sponge	18 (82)
Coil	0 (0)
NBCA	6 (27)

ATAT, arrival to angiography time; HU, hemodynamically unstable; TET, total embolization time; SAET, single artery embolization time; IIA, internal iliac artery; NBCA, N-butyl cyanoacrylate.

The data are presented as median and interquartile range for categorical data.

ATST and STAT were recorded and analyzed in the CT first cases.

the benefit in survival or transfusion requirement in the studied trauma care system. Thirdly, this study included both isolated pelvic injury and polytrauma; the heterogeneity of the studied population could affect the results. Despite these limitations, a proactive IR team may contribute to a novel trauma care system.

CONCLUSIONS

Our proactive IR team established on the PRESTO concept started angiography 70 minutes after the patient's arrival. The AE procedure based on the DCIR protocol took 7 minutes per single vessel.

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Original Article

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Comparison of 7 and 11–12 French Access for REBOA: Results from the AAST Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry

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Background: The introduction of low-profile devices designed for resuscitative endovascular balloon occlusion of the aorta (REBOA) after trauma has the potential to change practice, outcomes, and complication profiles.
Methods: The AAST Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry was used to identify REBOA patients from 16 centers. Presentation, intervention, and outcome variables were compared via traditional 11–12 French access platforms and trauma-specific devices requiring only 7 French access.
Results: From November 2013 to December 2017, 242 patients with complete data were identified, constituting 124 7 French and 118 11–12 French uses. Demographics of presentation were not different between the two groups, except that patients using the 7 French had a higher mean Injury Severity Score (39.2 vs. 34.1, $p = 0.028$). The 7 French was associated with a lower cut-down requirement for access (22.6% vs. 37.3%, $p = 0.049$) and increased ultrasound guidance utilization (29.0% vs. 23.7%, $p = 0.049$). The 7 French afforded earlier aortic occlusion in the course of resuscitation (median 25.0 mins vs. 30 mins, $p = 0.010$) and a lower median requirement of packed red blood cells (10.0 vs. 15.5 units, $p = 0.006$) and fresh frozen plasma (7.5 vs. 14.0 units, $p = 0.005$). The 7 French patients were more likely to survive 24 h (58.1% vs. 42.4%, $p = 0.015$) and less likely to suffer in-hospital mortality (57.3% vs. 75.4%, $p = 0.003$). Finally, the 7 French device was associated with a four times lower rate of distal extremity embolism (20.0% vs. 5.6%, $p = 0.014$; OR 95% CI 4.25 [1.25–14.45]) compared to the 11–12 French.

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Conclusions: The introduction of trauma-specific 7 French REBOA devices appears to have influenced REBOA practices, with earlier use in severely injured hypotensive patients via less invasive means that are associated with lower transfusion requirements, fewer thrombotic complications, and improved survival. Additional study is required to determine optimal REBOA use.

Keywords: *REBOA; Trauma; Aortic Occlusion; Injury; Hemorrhage*

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INTRODUCTION

Endovascular technologies continue to evolve as modalities that can be effectively employed in the treatment of the severely injured. Resuscitative endovascular balloon occlusion of the aorta (REBOA), in particular, has emerged as a potentially important temporizing tool for select patients who exhibit significant hemorrhage from non-compressible sites and do not respond adequately to initial resuscitation [1–9]. Continued research remains vital to better understand the optimal utilization of this modality. There remains a need to better identify optimal training requirements and elucidate both ideal patient selection for use and define optimal practices related to patient management after associated aortic occlusion.

The American Association for the Surgery of Trauma (AAST) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry is one important effort devised to contribute to ongoing research in this area [2,4]. This prospective, multicenter registry is designed to capture details regarding patient demographics, physiology, and outcomes following aortic occlusion in the setting of trauma. In addition, the data collection from this source captures key data elements specific to aortic occlusion procedures that cannot be collected from traditional trauma registry sources.

As part of the data collection for the AORTA registry, specific data is captured on the types of access employed and devices utilized. Since the initiation of the registry in 2013, there have been several changes in the availability of devices that may be employed for the purpose of REBOA. In particular, the FDA approval of a wire-free, trauma-specific device in 2015 has resulted in a dynamic shift in practice patterns at most centers employing REBOA as a resuscitative tool. The introduction of 7 French wire-free devices, theoretically, represents a major improvement over the utilization of older devices – which involve additional steps for sheath and wire exchange and also require 11–12 French access at a minimum for use.

The purpose of our present study was to utilize the AORTA registry to compare results with REBOA use between older 11–12 French devices and newer 7 French access systems. It was our hypothesis that the newer, smaller diameter systems would improve time to aortic occlusion and potentially mitigate the risk for distal thromboembolic events of the lower extremities relative to their larger profile predecessors [10–13].

MATERIALS AND METHODS

The Prospective Observational Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) study was approved by the American Association for the Surgery of Trauma (AAST) Multicenter Trials Committee. All presently reported data were obtained from centers within North America that are either American College of Surgeons verified Level I/Level II Trauma centers or are active Canadian trauma centers. All collaborating centers have obtained individual local Institutional Board Review approval prior to participation. Data are collected prospectively and entered by registrars designated by individual centers into the online data collection portal resource developed by the AAST.

For the purposes of our present examination, the AORTA registry was queried to capture all adult (age >17) patients undergoing documented REBOA following trauma from November 2013 to December 2017. The final access size required for the conduct of REBOA was utilized to divide patients into either 7 French or 11–12 French categories. These groups were then compared relative to demographics, procedural elements of REBOA and outcomes – including complications.

Values are reported as means ± standard deviation (SD) for continuous variables with normal distributions as determined by the assessment of skewness calculation. For those continuous variables not possessing a normal distribution median values and interquartile range were utilized. Categorical variables are expressed as percentages. Groups were compared using chi-squared analysis and Student's t tests. Statistical significance was set at greater than $p < 0.05$. All analyses were performed using the Statistical Package for Social Sciences (SPSS Mac©), version 22.0 (SPSS Inc, Chicago, IL, USA).

RESULTS

From November 2013 to December 2017, 242 patients with complete data were identified, constituting 124 7 French and 118 11–12 French uses. The mean was 42.3 years and 75.2% were male. Blunt mechanisms of injury predominated, at 77.7% (Table 1). Demographics of presentation were not different between the two groups, except that the 7 French patients had a higher mean Injury Severity Score (ISS) (39.2 vs. 34.1, $p = 0.028$) and a higher mean GCS at arrival (6.9 vs. 5.6, $p = 0.039$).

Table 1 Comparison of 7 French and 11–12 French device utilization groups from the AORTA registry.

	Total	*7 French*	*11–12 French*	*p-Value*
	N = 242	*N = 124*	*N = 118*	
Age, mean (± SD)	42.3 (18.3)	41.9 (17.6)	42.6 (19.0)	0.798
Male, % (*n*)	75.2% (182)	75.8% (94)	74.6% (88)	0.825
Blunt mechanism, % (*n*)	77.7% (188)	76.6% (95)	78.8% (93)	0.706
MVC, % (*n*)	16.5% (40)	13.7% (17)	19.5% (23)	0.498
MCC, % (*n*)	29.3% (71)	30.6% (38)	28.0% (33)	0.498
Auto vs. Ped, % (*n/N*)	24.0% (58)	26.6% (33)	21.2% (25)	0.498
ISS, mean (± SD)	36.5 (16.0)	39.2 (17.2)	34.1 (14.5)	0.028
Head AIS, mean (± SD)	2.6 (2.1)	2.4 (2.1)	2.8 (2.0)	0.189
Chest AIS, mean (± SD)	2.6 (1.6)	2.6 (1.7)	2.6 (1.5)	0.818
Abdomen AIS, mean (± SD)	2.8 (1.7)	3.0 (1.8)	2.6 (1.7)	0.067
Pre-hospital CPR required, % (*n*)	28.9% (70)	28.2% (35)	29.7% (35)	0.806
Admission SBP, mean (± SD); *n*	77.1 (50.3); 239	79.6 (47.1); 123	74.4 (53.6); 116	0.423
Admission HR, mean (± SD); *n*	92.9 (51.9); 232	97.4 (46.9); 116	88.3 (56.3); 116	0.181
Admission GCS, mean (± SD); *n*	6.2 (4.9); 239	6.9 (5.1); 122	5.6 (4.7); 117	0.039
Admission Hgb (mg/dL), mean (± SD); *n*	10.9 (2.4); 192	11.2 (2.5); 104	10.5 (2.2); 88	0.031
Admission pH, mean (± SD); *n*	7.12 (0.18); 166	7.13 (0.18); 97	7.11 (0.19); 69	0.410
Admission lactate, mean (± SD); *n*	8.9 (5.0); 161	8.8 (5.5); 86	9.1 (4.4); 75	0.794
Location of REBOA				
Emergency Department, % (*n*)	81.0% (196)	84.7% (105)	77.1% (91)	0.161
Operating Room, % (*n*)	18.6% (45)	14.5% (18)	22.9% (27)	0.161
Access technique				
Cut-down, % (*n*)	29.8% (72)	22.6% (28)	37.3% (44)	0.049
Percutaneous landmarks, % (*n*)	40.9% (99)	46.8% (58)	34.7% (41)	0.049
Ultrasound guidance, % (*n*)	26.4% (64)	29.0% (36)	23.7% (28)	0.049
Imaging utilized to facilitate balloon positioning				
None/blind using external landmarks only, % (*n*)	33.5% (81)	34.7% (43)	32.2% (38)	0.096
Plain film, % (*n*)	58.3% (141)	58.9% (73)	57.6% (68)	0.096
Fluoroscopy, % (*n*)	3.3% (8)	0.8% (1)	5.9% (7)	0.096
Ultrasound, % (*n*)	3.3% (8)	2.4% (3)	4.2% (5)	0.096
Aortic zone of balloon deployment				
Zone 1, % (*n*)	66.1% (160)	64.5% (80)	67.8% (80)	0.113
Zone 2, % (*n*)	1.7% (4)	0.8% (1)	2.5% (3)	0.113
Zone 3, % (*n*)	30.2% (73)	30.6% (38)	29.7% (35)	0.113
Balloon migration observed, % (*n*)	5.4% (13)	5.6% (7)	5.1% (6)	0.068
Active CPR during REBOA placement, % (*n*)	34.3% (83)	32.3% (40)	36.4% (43)	0.788
AO initiation SBP [mm Hg], mean (± SD); *n*	54.9 (43.5); 217	60.3 (42.6); 114	48.8 (43.8); 103	0.052
Improvement in SBP observed, % (*n*)	75.6% (183)	73.4% (91)	78.0% (92)	0.317
Increase in SBP [mm Hg], Median (IQR); *n*	43.0 (62); 208	43.0 (61); 108	43.5 (75); 100	0.974
Hemodynamic stability achieved, % (*n*)	57.9% (140)	56.5% (70)	59.3% (70)	0.602
Duration of AO (min), median (IQR), *n*	32.0 (55); 185	32.0 (51); 107	37.5 (60); 78	0.153
Time admission to start of AO (min), median (IQR), *n*	17.0 (32); 201	16.0 (21); 117	19.0 (43); 84	0.018
Time admission to successful AO (mins), median (IQR), *n*	25.0 (38); 191	25.0 (23); 112	30 (56); 79	0.010
Time start of procedure to achievement of aortic occlusion (mins), median (IQR), *n*	7.0 (6); 182	7.0 (6); 109	7.0 (8); 73	0.421
Primary performer, Trauma Acute Care Surgeon, % (*n*)	88.4% (214)	93.5% (116)	83.1% (98)	0.011
Resuscitation requirements survivors at least 24 h				
Packed red cells (units), median (IQR), *n*	12.0 (15); 120	10.0 (10); 72	15.5 (24); 48	0.006
FFP (units), median (IQR), *n*	10.0 (14); 119	7.5 (12); 72	14.0 (18); 47	0.005
Associated procedures (patients surviving to reach OR)				
	N = 192	*N = 100*	*N = 92*	
Exploratory laparotomy, % (*n*)	72.9% (140)	73.0% (73)	72.8% (67)	0.978
Hepatic packing, % (*n*)	20.3% (39)	21.0% (21)	19.6% (18)	0.805
Pelvic packing, % (*n*)	20.8% (40)	26.0% (26)	15.2% (14)	0.066

(Continued)

Table 1 Continued.

	Total	*7 French*	*11–12 French*	*p-Value*
Hepatic resection, % (*n*)	5.7 (11)	5.0% (5)	6.5% (6)	0.650
Splenectomy, % (*n*)	17.2% (33)	17.0% (17)	17.4% (16)	0.943
Bowel resection, % (*n*)	19.8% (38)	190.0% (19)	20.7% (19)	0.774
Craniotomy/craniectomy, % (*n*)	3.6% (7)	5.0% (5)	2.2% (2)	0.447
External pelvic fixation, % (*n*)	13.0% (25)	12.0% (12)	14.1% (13)	0.661
Embolization of liver, % (*n*)	3.1% (6)	4.0% (4)	2.2% (2)	0.684
Embolization of pelvis, % (*n*)	9.9% (19)	10.0% (10)	9.8% (0)	0.960
Outcomes survivors at 24 hours				
ICU LOS (days); median (IQR), *n*	11.0 (12); 110	11.0 (13); 72	8.5 (12); 38	0.645
Hospital LOS (days); median (IQR), *n*	19.0 (29); 121	20.0 (25); 71	18.5 (35); 50	0.639
All patients				
Survivors to reach OR/IR, % (*n*)	79.7% (192)	81.3% (100)	78.0% (92)	0.520
Survivors at least 24 hours, % (*n*)	50.4% (122)	58.1% (72)	42.4% (50)	0.015
In-hospital mortality, % (*n*)	66.1% (160)	57.3% (71)	75.4% (89)	0.003
Mortality location				
ED, % (*n*)	20.2% (49)	18.5% (23)	22.0% (26)	0.032
OR, % (*n*)	17.4% (42)	12.9% (16)	22.0% (26)	0.032
ICU, % (*n*)	27.7% (67)	24.2% (30)	31.4% (37)	0.032

AORTA = Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery; SD = standard deviation; MVC = motor vehicle collision; MCC = motorcycle collision; Ped = pedestrian; AIS = abbreviated injury score; CPR = cardiopulmonary resuscitation; Hgb = hemoglobin; AO = aortic occlusion; SBP = systolic blood pressure; IQR = interquartile range; PRBC = packed red blood cells; FFP = fresh frozen plasma; LOS = length of stay; ED = emergency department; OR = operating room; ICU = intensive care unit.

Overall, there was no difference between the two groups with regards to admission physiology or admission laboratory values (Table 1).

The utilization of the 7 French device was associated with a lower rate of femoral cut-down requirement for access (22.6% vs. 37.3%, $p = 0.049$) and increased ultrasound guidance (29.0% vs. 23.7%, $p = 0.049$) for the purpose of arterial access. There were not, however, any significant differences between the two groups relative to the use of imaging to confirm placement, anatomic aortic zones of balloon deployment or hemodynamic response rates.

Time from admission to both the start of aortic occlusion procedure (median 16.0 vs. 19.0 min, $p = 0.018$) and subsequent successful occlusion (median 25.0 vs. 30 min, $p = 0.010$) were both shorter in the 7 French patient group, but there was no discernable difference between the two groups among those patients who had adequately recorded times from the start of procedure to the achievement of aortic occlusion (Table 1).

Among patients surviving at least 24 hours after admission, 7 French utilization was associated with a significant reduction in required units of packed red blood cells (PRBC) (10.0 vs. 15.5 units, $p = 0.006$) for resuscitation, and also lower fresh frozen plasma (FFP) requirements (7.5 vs. 14.0 units, $p = 0.005$) (Table 1). Utilization of the 7 French device was associated with higher rates of survival beyond 24 hours (58.1% vs. 42.4%, $p = 0.015$) and in-hospital mortality was less likely (57.3% vs. 75.4%, $p = 0.003$) compared to 11–12 French utilization.

Among patients surviving at least 24 hours, captured complications were compared. There was no significant difference in systemic complications among survivors. Among local, access specific complications, 7 French device use was associated with a four times lower rate of distal extremity embolism (20.0% vs. 5.6%, $p = 0.014$; OR 95% CI 4.25 [1.25–14.45]) compared to 11–12 French counterparts (Table 2).

DISCUSSION

Advancements in technologies successfully employed in vascular surgery, over the course of the last decade, have increasingly found potential roles in the realm of trauma surgery. REBOA has emerged as a manifestation of this borrowed experience, derived in part from the published success in the utilization of balloon occlusion during endovascular treatment of ruptured abdominal aortic aneurysms [14]. Initial experience, however, was limited by the absence of devices more specifically suited to trauma applications. As such, early experience with REBOA utilization for trauma was characterized by the need to rely upon larger diameter balloon systems which required over-the-wire placement, additional device exchange steps, and the use of larger profile 11 or 12 French femoral access sheaths.

These limitations represented potential major challenges for the use of REBOA in the scenarios most commonly considered as potentially beneficial after trauma. The recent introduction of a trauma-specific device for REBOA applications was designed to mitigate these

Table 2 Comparison of complications between 7 French and 11–12 French device utilization groups. Local complications among patients surviving at least 24 hours.

Complications	*Total (N = 122)*	*7 French (N = 72)*	*11–12 French (N = 50)*	*p-Value*
Hematoma at operative site, % (*n*)	3.3% (4)	2.8% (2)	4.0% (2)	1.000
Femoral pseudoaneursym, % (*n*)	0.8% (1)	0% (0)	2.0% (1)	0.410
Arteriovenous fistula, % (*n*)	1.6% (2)	2.8% (2)	0% (0)	0.512
Extremity ischemia, % (*n*)	4.9% (6)	6.9% (5)	2.0% (1)	0.399
Arterial stenosis, % (*n*)	0.8% (1)	0% (0)	2.0% (1)	0.410
Distal extremity embolism, % (*n*)	11.5% (14)	5.6% (4)	20.0% (10)	0.014
Need for patch angioplasty, % (*n*)	6.6% (8)	2.8% (2)	12.0% (6)	0.063
Need for amputation, % (*n*)	2.5% (3)	4.2% (3)	0% (0)	0.268

AKI = Acute kidney injury; ALI = Acute lung injury; ARDS = Acute respiratory distress syndrome; CVA = cerebrovascular accident.

challenges. The only trauma-specific device presently approved by the FDA for trauma indication is the Prytime ER-REBOA™ catheter. This device is a 7 French compatible balloon catheter with a nitinol reinforced spine and an atraumatic tip that obviates the need for over-the-wire placement. Among other potentially valuable characteristics, this device is also capable of emergent placement without imaging through a 7 French sheath and possesses a useful arterial monitoring port.

The lack of a need for over-the-wire placement represents a theoretical advantage over 11–12 French devices as it relates to the time for positioning and subsequent aortic occlusion in an emergently decompensating patient. Our present examination of early experience with these new devices demonstrates that an appreciable decrease in the time from start of the procedure to the achievement of aortic occlusion has not yet manifested. There was, however, a significant decrease in the time from admission to both the start of the occlusion procedure and subsequent successful occlusion. This finding may represent a decreased time to set-up the procedure with the simpler 7 French device, which requires less equipment to prepare compared to the multi-step exchanges required with 11–12 French access procedures. It may also, however, simply represent a lower threshold to move expediently to the use of 7 French systems due to their potential lower risk profile and perceived increased ease of utilization.

The 7 French group in our present study was also less likely to require open cut-down exposure for femoral artery access and more likely to undergo ultrasound-guided access compared to larger profile device counterparts. The increasing acceptance of ultrasound-guided access as a routine practice, when possible, in the setting of emergent femoral access likely contributes to this finding. In addition, the reticence to proceed to early cut-down with larger diameter devices may have been influenced by the consideration of subsequent closure approaches among survivors. While not well studied in the trauma realm, 7 French access is commonly considered safe for removal without formal suture closure – provided coagulopathy has resolved and an effective period of direct pressure can be applied to the arteriotomy site. In contrast, traditional thought has mandated that 11–12 French access requires open arteriotomy repair. That these larger diameter arteriotomies would require open repair anyway may have contributed to a lower threshold for initial open exposure during placement.

One interesting finding of our review was that patients using the 7 French required fewer PRBCs and FFP compared to larger diameter counterparts. They also appeared to have improved 24 h and in-hospital survival. This would seem to suggest that there may be a benefit in minimizing delays in aortic occlusion in specific trauma patients nearing extremis. Several groups have previously demonstrated similar findings [2,15]. In a recent review of the AORTA database, Brenner and colleagues demonstrated that the patients most likely to achieve survival after aortic occlusion for trauma were those partial or non-responders who had not yet decompensated to the degree that they required CPR after injury [2]. Although significant additional study is required to delineate optimal patient selection and timing for REBOA, existing data indicates that early identification and the expedient use of occlusion early in the course of worsening decompensation achieves the greatest benefit from REBOA.

One of the most striking differences between the 7 French and 11–12 French cohorts in our study was the rate of thrombo-embolic limb complications. Our exploration showed that the 7 French device use was associated with a four times lower rate of distal extremity embolism (20.0% vs. 5.6%, p = 0.014; OR 95% CI 4.25 [1.25–14.45]) compared to the 11–12 French use. The diameter of access may play an even more important role in trauma applications than among patients undergoing access for traditional vascular surgery. In the latter group, patients are almost universally systemically anti-coagulated in a controlled fashion in order to mitigate the risk for distal thromboembolic events in the distal arterial tree of the accessed extremity. While coagulopathy associated with trauma remains a reality among many

severely injured trauma patients, the degree to which this abnormality manifests is not predictable and cannot be relied upon to provide a reliable anticoagulation milieu to achieve a similar protective benefit to the limb. In addition, active resuscitation in these severely injured patients in the modern era almost universally includes balanced ratios of FFP and even platelets as well as tranexamic acid. Accordingly, and in direct contrast to the manipulation of the coagulation system in endovascular interventions for most other indications, trauma team efforts work to promote conditions that should be expected to increase the risk of thromboembolic events distally. This risk is further exacerbated by the small arterial diameter characteristic of many younger trauma victims. For all of these reasons, it is expected that smaller diameter access would be beneficial for use in severe trauma.

It must be recognized, however, that a myriad of additional influences may have also contributed to our findings. Perhaps the most significant is improved training in the employment of endovascular adjuncts by trauma and acute care surgeon providers. The Basic Endovascular Skills for Trauma (BEST) course of the American College of Surgeons was first formally described in the literature in 2014 [16]. This course is constantly updated to reflect evolving understanding and technologies related to the conduct of REBOA. It is now available at several formal sites throughout the United States, where over a thousand providers have been educated and trained in this procedure. A key element of this curriculum is to increase awareness of the risk for distal thromboembolic complications, including discussion of techniques to mitigate the risk of these adverse events. [12]. The degree to which this training has improved practices at individual centers, and subsequently influenced outcomes, is not directly discernable by our present effort.

In addition to the aforementioned considerations, our present study has other limitations that must be acknowledged. The AORTA registry is the largest prospective registry of aortic occlusion patients in existence and captures a granularity of data that is not discernable from other existing sources. Each of the participating centers, however, have varying degrees of experience with this modality. This experience is almost certainly changing over time as well, influenced not only by provider experience but advances in technology and practices that go beyond the introduction of the first FDA approved lower profile device. This fact must be carefully considered in the interpretation of our present report.

There are other distinct elements of care that might contribute to specific complications but are not readily available in the AORTA registry. Most importantly among these may be the lack of granularity regarding sheath use duration, which has significant potential to impact thromboembolism of the limb. Specifically, the registry does not afford the ability to determine how long after REBOA the utilized sheath remained in the common femoral artery. Finally, there is also no uniform protocol for REBOA use across centers. Our findings must be considered in the context of all of these issues.

CONCLUSION

As REBOA continues to evolve as a trauma tool, the introduction of new low-profile devices appears to be associated with earlier use in the course of decompensation and potential benefits with regards to both transfusion requirements and survival. The introduction of lower profile devices appears to mitigate the risk of distal thromboembolic events relative to older, larger diameter-based platforms. Continued research is required, however, to optimize patient selection and the use of REBOA for trauma applications.

CONTRIBUTORS

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Original Article

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Unstable Without a Source: The Non-Diagnostic Triad in Hypotensive Blunt Trauma Victims

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Background: Current algorithms for resuscitation of blunt trauma patients rely on chest x-ray (CXR), pelvic x-ray (PXR), and focused assessment with sonography for trauma (FAST), to quickly elicit a source of major bleeding in the trauma bay. The non-diagnostic triad (NDT), defined as negative initial CXR, PXR, and FAST, complicates the management of the hypotensive blunt trauma victim. Currently, there are no evidence-based recommendations for management of hemodynamically unstable patients with NDT.
Methods: Hypotensive blunt abdominal trauma without a source was defined as a systolic blood pressure below 100 mmHg with NDT. Retrospective chart review was performed to characterize patient demographics, injuries, and outcomes. Subgroup analysis was performed to compare NDT patients with and without severe injury.
Results: We reviewed 649 hypotensive blunt trauma victims. A total of 47 patients (33 males, 14 females) with a mean age of 40.0 years (standard error of the mean 2.5) had NDT upon initial assessment. Of the NDT group, 19/47 (40.4%) were found to have a major injury contributing to hypotension, while 28/47 (59.6%) were not diagnosed with a severe injury that could contribute to hypotension.
Conclusions: Hypotensive blunt trauma patients with NDT are a unique and difficult population to diagnose and resuscitate. The majority of NDT patients lack significant injury. Among the severely injured NDT patients, acute blood loss was common and the potential utility for resuscitative endovascular balloon occlusion of the aorta in these patients warrants future study.

Keywords: *REBOA; Blunt Trauma; ATLS; Algorithms*

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INTRODUCTION

Critically ill trauma patients require advanced trauma life support (ATLS) and institution-based protocols to guide resuscitation. When an unstable patient arrives at the trauma bay, the primary and secondary survey, adjunctive imaging (chest x-ray (CXR), pelvic x-ray (PXR), and focused assessment with sonography for trauma (FAST)), and resuscitative measures (advanced cardiac life support, massive transfusion protocol, thoracotomy, and resuscitative endovascular balloon occlusion of the aorta (REBOA)) are initiated. These protocols are implemented to diagnose and treat life-threatening injury, as well as determine patient disposition (operating room, computed tomography, intensive care unit, interventional radiology suite).

In this retrospective review, we examine a specific patient population that lacks evidence-based recommendation for treatment—hypotensive blunt trauma patients with a "non-diagnostic triad (NDT)", which we define as a negative CXR, PXR, and FAST. REBOA placement is becoming increasingly common for hypotensive, blunt trauma patients. Current published algorithms for REBOA use these three point-of-care imaging modalities to determine treatment, but the guidelines

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are unclear when all three are negative [1]. This subset of blunt trauma victims should be evaluated to determine injury patterns, extent of resuscitation required, interventions performed, and potential utility of REBOA. We identify hypotensive blunt trauma victims admitted to a busy inner-city Level 1 Trauma Center with a negative CXR, PXR, and FAST. We determine the types of injuries present, attempt to elicit the cause of hypotension, and discuss the implications of these injuries in the context of REBOA.

METHODS

Blunt abdominal trauma victims presenting to an inner-city Level 1 Trauma Center between 2016 and 2018 were identified using appropriate ICD 9/10 codes. Patients were initially stratified by their systolic blood pressure (SBP) upon presentation. Hypotensive blunt abdominal trauma without a source was defined as a SBP below 100 mmHg with a NDT (negative CXR, PXR, and FAST). A SBP of less than 100 mmHg in the prehospital setting or in the trauma bay was included. Retrospective chart review was performed by two independent reviewers. Patients with a positive CXR, displaced pelvic fracture on PXR, or a positive FAST were excluded from the NDT group. We did not exclude patients with non-displaced rib fractures without concurrent hemothorax, pneumothorax, or flail chest. Patients with non-displaced pelvic fractures were also not excluded. Preliminary data collection included patient demographics, length of stay, disposition at discharge, injury severity score, and mortality. NDT patients were identified and analyzed to identify the injury patterns and etiology of hypotension. Subgroup analysis of the NDT group was performed to compare seriously injured patients and patient without serious injuries. Patients with minor orthopedic injuries or patients discharged without a diagnosis of severe traumatic injury were allocated to the "not severely injured" group. Data were compared using a Fisher's exact test for categorical variables and an unpaired tow-tailed *t*-test for continuous variables. $P < 0.05$ was considered significant. Data analysis was performed using GraphPad, Version 5 (GraphPad Software, San Diego, CA). This study was approved by our institutional review board (IRB) and followed all appropriate protocols.

RESULTS

We reviewed 649 patients with blunt abdominal trauma and hypotension between January 2016 and July 2018. As summarized in Table 1, a total of 47 patients (33 males, 14 females) with a mean age of 40.0 years (standard error of the mean (SEM) 2.5) had negative initial imaging and were allocated to the NDT group. In comparison, 602 patients (415 males, 187 females) had at least one positive initial imaging modality. The average Injury Severity Score (ISS) for the NDT group was 12.1 (SEM 1.9) compared to an average ISS of 13.9 (SEM 0.5) for the control group ($P = 0.34$). Injuries among the NDT group were as follows: 24/47 (51%) had peripheral orthopedic injuries; 15/47 (31.9%) had traumatic brain injury, and 8/47 (17%) had spinal fractures. Intoxication was present in 31/47 (61%) NDT patients. The NDT and control group had an average length of stay (LOS) of 6.6 (SEM 1.0) days and 7.7 (SEM 0.7) days, respectively ($P = 0.66$). There was a trend toward significantly lower blood pressure in the control group ($P = 0.06$). Among the NDT group, 2/47 (4.2%) patients died versus 110/602 (18.3%) patients in the control group ($P = 0.01$). Causes of death in the NDT group included: one hypoxic arrest due to lack of a secure airway; one retroperitoneal bleed.

The majority of the NDT group, 28/47 (59%), were thought to be hypotensive from causes other than direct trauma, including medical causes, dehydration, or intoxication. These patients ultimately were discharged without a diagnosis of severe traumatic injury contributing to their hypotension. Subgroup analysis of the NDT group was performed to compare seriously injured patients and patients without serious injuries (Table 2). There were 19/47 (40.4%) seriously injured patients and 28/47 (59.6%) not seriously injured patients. The seriously injured group had an ISS of 20.5 (SEM 3.6) compared to an ISS of 6.4 (SEM 1.4) in the not seriously injured group ($P = 0.0002$). Additionally, the seriously injured group had significantly lower SBP than the not seriously injured group, 80 mmHg (SEM 7) versus 97 mmHg (SEM 2), respectively ($P = 0.014$). Lactic acid was 4.2 (SEM 0.5) and 2.4 (SEM 0.3) in the seriously injured and not seriously injured group, respectively ($P = 0.002$). The seriously injured group was also more likely to have a significantly lower serum bicarbonate ($P = 0.048$). The seriously injured group had a significantly prolonged length of hospital stay ($P < 0.0001$).

Figure 1 illustrates the suspected source of hypotension in NDT patients. The etiology of hypotension was as follows: 1/47 (2.1%) patients were hypotensive from a blunt cardiac injury causing arrhythmia, 1/47 (2.1%) patients had hypoxic arrest, 15/47 (31.9%) patients had acute blood loss. Of the 15 patients with acute blood loss, 6/15 (40%) had intraabdominal bleeding (3 liver lacerations, 2 splenic lacerations, 1 mesenteric vascular injury), 5/15 (33.3%) had retroperitoneal bleeding (2 renal lacerations, 1 psoas muscle rupture, 2 unknown source), 4/15 (26.7%) had severe lower extremity orthopedic injuries. We identified 2/47 (4.2%) patients with thoracic aortic injury (TAI) despite an initially negative CXR. One TAI was a grade 3 injury that required a covered endovascular stent and the other TAI was a grade 1a intimal injury that required no intervention. Neither of these injuries had extravasation of contrast, and thus were not thought to directly contribute to the patients' hypotension at presentation.

Table 1 Demographics, admission information, and clinical outcomes of the NDT group and control group.

	NDT n = 47	*Control n = 602*	*P value*
Demographics and admission information			
Average age, years (SEM)	40.0 (2.5)	41.8 (0.8)	0.54
Male gender, *n* (%)	33 (70.2)	415 (68.9)	1.00
Caucasian, *n* (%)	23 (48.9)	323 (53.7)	0.55
African American, *n* (%)	21 (44.7)	217 (36.0)	0.27
Other race, *n* (%)	3 (6.4)	62 (10.3)	0.61
Injury Severity Score, avg (SEM)	12.1 (1.9)	13.9 (0.5)	0.34
Lowest systolic blood pressure, average (SEM)	96 (3)	87 (1)	0.06
Clinical outcomes			
Length of stay, average (days)	6.6 (1.0)	7.7 (0.7)	0.66
In-hospital mortality, *n* (%)	2 (4.3)	110 (18.3)	**0.01**

NDT, non-diagnostic triad; SEM, standard error of the mean; n, number. Numbers in bold represent statistically significant values with P < 0.05.

Table 2 Sub-group analysis of the NDT group

	Not seriously injured n = 28	*Seriously injured n = 19*	*P value*
Demographics			
Average age, years (SEM)	40.1 (3.6)	39.8 (3.4)	0.95
Male gender, *n* (%)	18 (64.3)	15 (78.9)	0.34
Caucasian, *n* (%)	12 (42.9)	11 (57.9)	0.38
African American, *n* (%)	13 (46.4)	8 (42.1)	1.00
Other race, *n* (%)	2 (7.1)	0	0.51
Injury Severity Score, average (SEM)	6.4 (1.4)	20.5 (3.6)	**0.00020**
Intoxicated, *n* (%)	18 (64.2)	13 (68.4)	1.00
Vital signs and labs on presentation			
Lowest systolic blood pressure, average (SEM)	97 (2)	80 (7)	**0.014**
Lactic acid, average (SEM)	2.4 (0.3)	4.2 (0.5)	**0.0020**
Bicarbonate, average (SEM)	23.1 (0.5)	21.4 (0.7)	**0.048**
Clinical work up			
CT scan, *n* (%)	25 (89.3)	19 (100.0)	0.26
Outcomes			
Length of stay, average (days)	2.7 (0.4)	12.2 (1.9)	**<0.0001**
In-hospital mortality, *n* (%)	0	2 (10.5)	0.16

NDT, non-diagnostic triad; SEM, standard error of the mean; n, number; CT, computed tomography. Numbers in bold represent statistically significant values with P < 0.05.

DISCUSSION

Hypotensive blunt trauma patients with NDT are a uniquely difficult population to diagnose and resuscitate. This analysis of 47 patients with NDT shows a much lower mortality compared to the control group. This is likely due to the high percentage of this group who were not diagnosed with a significant traumatic injury that could explain hypotension. We suspect dehydration, intoxication, and other medical causes were the reason for initial hypotension in these patients, as they improved after initial resuscitation and required no further intervention. Future studies could seek to eliminate this group by having a larger sample population and selecting out sicker patients, although it is of some value to note that most of our NDT patients may have better outcomes than patients with positive imaging in the trauma bay. A significant number of NDT patient were found to have major injuries, and we decided to sub-stratify the NDT group into those with and without significant traumatic

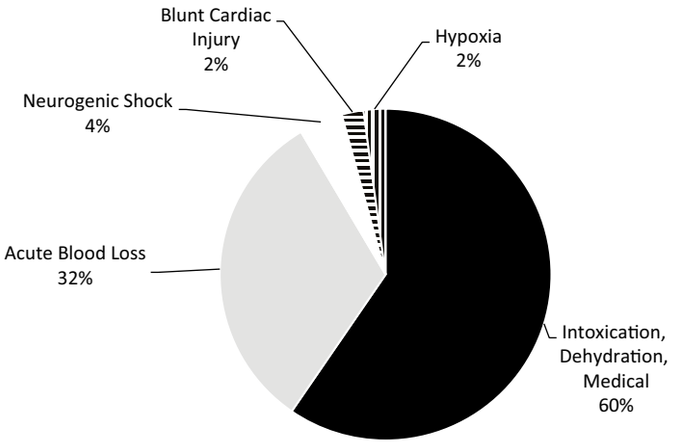

Figure 1 Etiology of hypotension among 47 NDT patients.

injury. A significant number of the seriously injured subgroup had acute blood loss (78.9%), while non-hemorrhagic shock was less common. Intra-abdominal, retroperitoneal, and severe lower extremity orthopedic injuries were found. This implies that these patients may benefit from aggressive resuscitative measures targeting hemorrhagic shock, including Massive Transfusion Protocol and consideration of REBOA placement.

The NDT population is inherently difficult to manage due to a lack of diagnosis or clear direction on where to proceed from the trauma bay. Existing algorithms fail to provide adequate disposition for these patients [1], and in the age of REBOA and hybrid Operating Rooms the decisions can become more complicated. It is perhaps more tempting to travel to the computed tomography (CT) scanner with the NDT population, even in the setting of hemodynamic instability. Surprisingly, only two of the NDT patients did not receive CT scans. This was not due to instability, but a low clinical suspicion for severe traumatic injury, and these patients were in the "not severely injured" sub-group. The obvious cost of delaying definitive treatment to obtain imaging is a concern known to most trauma surgeons. The conundrum that faces the physicians treating the NDT patient could be improved with modernized facilities, such as hybrid operating rooms with imaging, catheter-based, and surgical capabilities in one place. Some pioneering institutions have gone so far as to combine resuscitation, imaging, catheter, and operative capabilities in the trauma bay [2]. We believe the NDT population in particular may benefit from these advances.

The role of REBOA in the NDT population is unclear, and we began this study wanting to evaluate the NDT population with respect to the safety of REBOA. There were two patients who had thoracic aortic injuries without extravasation or free rupture, and hypotension was not thought to be due to these aortic injuries. Major thoracic hemorrhage is known to be the primary absolute contraindication for REBOA placement and most algorithms mandate thoracotomy [3] in these patients. It is unclear whether low-grade aortic injuries represent a contraindication to REBOA. The potential that distal occlusion could cause aortic injuries to progress, or result in direct damage from the device is an understandable concern. However, low-grade injuries will likely present with a negative CXR, requiring CT or angiography to diagnose. Therefore, most of these injuries will be found after the decision to place REBOA has been made. It is likely that the judicious use of REBOA to restore central blood pressure in the presence of a low-grade aortic injury may be worth the risk of the aortic injury progressing.

Two of the NDT group were hypotensive from neurogenic shock, and one patient was hypotensive from a suspected blunt cardiac injury. While most of the evidence regarding the safety and efficacy of REBOA is in hemorrhagic models, some studies suggest a benefit from increased coronary and cerebral perfusion in non-traumatic models [4]. This suggests that both neurogenic and blunt cardiogenic shock could potentially benefit from REBOA, and there is a lack of evidence to suggest REBOA would be unsafe in these patients. Furthermore, with the lower profile REBOA devices and decreasing vascular complication rates [5], it is likely that the risk-to-benefit ratio will continue to improve for all types of shock.

This study provides a limited but worthwhile view of a difficult patient population. We have attempted to characterize the injury patterns of the NDT population. However, further research is needed before creating formal recommendations and guidelines for resuscitating the NDT population.

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Narrative Review Article

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Endovascular Resuscitation and Trauma Management in the Hybrid Emergency Room System: Ideal Solution for Surgical, Endovascular and Radiological Trinity

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The concept of endovascular resuscitation and trauma management (EVTM) refers to endovascular techniques for resuscitation, hemorrhage control, and definitive trauma management. The use of EVTM or computed tomography (CT) imaging is still limited in hemodynamically unstable patients. The hybrid emergency room system (HERS) is a suitable context to facilitate EVTM. The HERS consists of an operating table with a C-arm and a sliding CT scanner system in the resuscitation area, allowing emergency diagnostic and therapeutic interventions without relocating the patient. The primary purpose of this study was to present the feasibility and assess the potential for the successful implementation of HERS. The second aim was to reduce concerns on the validity of this context and the third was to lay a foundation for planned intervention studies in EVTM and HERS. In the HERS environment, endovascular treatment will be performed in the resuscitation room, which expands the indications of endovascular treatment to include hemodynamically unstable patients. HERS can also reduce the logistic burden and thus provide time to identify injuries with CT. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a viable adjunct treatment for refractory hemorrhagic shock but its procedure-related complications must be considered. In the HERS environment, REBOA can be performed more safely, rapidly, and accurately with fluoroscopy, followed by immediate definitive hemostasis without relocation. In addition, HERS may safely extend

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the application of REBOA-CT to identify accurate injury sites. HERS may be an ideal EVTM solution for the trinity of surgery, endovascular treatment, and imaging in trauma care. We will continue to explore the most radical and safest EVTM in the HERS environment.

Keywords: *Computed Tomography; Interventional Radiology; Surgery; Resuscitative Endovascular Occlusion of the Aorta; REBOA; Hybrid ER*

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BACKGROUND

Hemorrhage is a leading cause of potentially preventable trauma death. Historically, open surgery was the only option to isolate and alleviate non-compressible torso hemorrhage [1]. However, endovascular treatment is now widely accepted as another essential hemostasis tool in cases of blunt trauma [2]. The concept of endovascular resuscitation and trauma management (EVTM) refers to the use of endovascular techniques for resuscitation, hemorrhage control, and definitive trauma management [3]. In this regard, the availability and quality of computed tomography (CT) have progressed rapidly thanks to emerging technologies. Furthermore, endovascular treatment has changed standard practices in the treatment of patients with blunt trauma. The popularity of resuscitative endovascular balloon occlusion of the aorta (REBOA) has grown globally. Nonetheless, the use of CT imaging and/or endovascular treatment in patients who are hemodynamically unstable is not standard in the current Advanced Trauma Life Support (ATLS) guidelines [1], and the indication is still limited.

In addition, "circulation" is prioritized over "disability" in the so-called "ABCDE approach," even in the most recent ATLS guidelines [1]. The scanning and transferring of patients significantly delays hemostasis, resulting in critical circulation collapse. In the resuscitation area, to identify the hemorrhagic source, a focused assessment with sonography in trauma (FAST) examination is carried out, as is plain X-ray of the chest and pelvis. It is usually after this that CT scans of any traumatic brain injury (TBI) are obtained. However, this delay of neurological diagnosis in polytrauma patients with TBI could lead to critical morbidity or death [4].

To overcome the current limitations of endovascular procedures or CT imaging, the hybrid emergency room system (HERS) was introduced in 2011 [5]. It allows all emergency therapeutic interventions without relocating the patient. HERS is a modern trinity, bridging surgery, endovascular treatment, and CT imaging. The current paper proposes solutions to the current limitations of EVTM by using HERS.

Implementation of the HERS and Launch of the Japanese Association for HERS

The accurate CT-based identification of bleeding sites has expanded the indications for endovascular treatment. Therefore, rapid access to a CT scanner, endovascular procedures, and an operating table are key innovations in trauma care. For this reason, Osaka General Medical Center (Osaka, Japan) installed an operating table with a C-arm and a sliding CT scanner system in the resuscitation area [5]. HERS is located in the resuscitation area of the emergency department, not in the radiology department or operating room (OR). Most open surgery, except for cardiovascular surgery or thoracic endovascular aortic repair, can be performed in the HERS. In addition, the HERS Institute installed a high-quality air flow the same as in the OR. Emergency procedures are prioritized 24/7, thus each procedure time should be limited, usually within 60 mins.

In the dual room HERS system, the sliding gantry CT scanner emerges from the neighboring room to the patient in the angio-resuscitation room (Figure 1a, Supplement 1). After scanning, the CT scan may work independently for other patients during the surgery or angiography (Figure 1b, Supplement 1). An elective or non-emergent CT scan or fluoroscopic procedures may be planned in the dual room HERS system to increase the occupancy rate in a moderate volume center. HERS absolutely has the risk of overlap with new emergent trauma cases, especially in a high volume center. Trauma leaders need to coordinate and deny full treatment in HERS, and to force the trauma team to move to the OR or angiography suite when receiving multiple patients.

Within our "HERS" terminology, the term "hybrid" refers to the combination of examinations and treatments in the same space. This differs from other uses of the term, such as in "Hybrid OR," which is the combination of "surgery" and "angiography." Because HERS is widely used in Japan, we launched the Japanese Association for HERS (JA-HERS) on June 21, 2018, in Kyoto, Japan. JA-HERS has been exploring the ideal utilization of HERS.

Innovative Use of Time-Rigorous Interventional Radiology in Trauma

Endovascular embolization, the most frequently employed endovascular treatment procedure in patients with trauma, is widely used to control hemorrhage in torso trauma, such as pelvic or solid organ injuries. In all patients with severe trauma, time to hemostasis is a critical factor. This is known as the "golden hour." Meanwhile, the time from a patient's arrival until their angiography

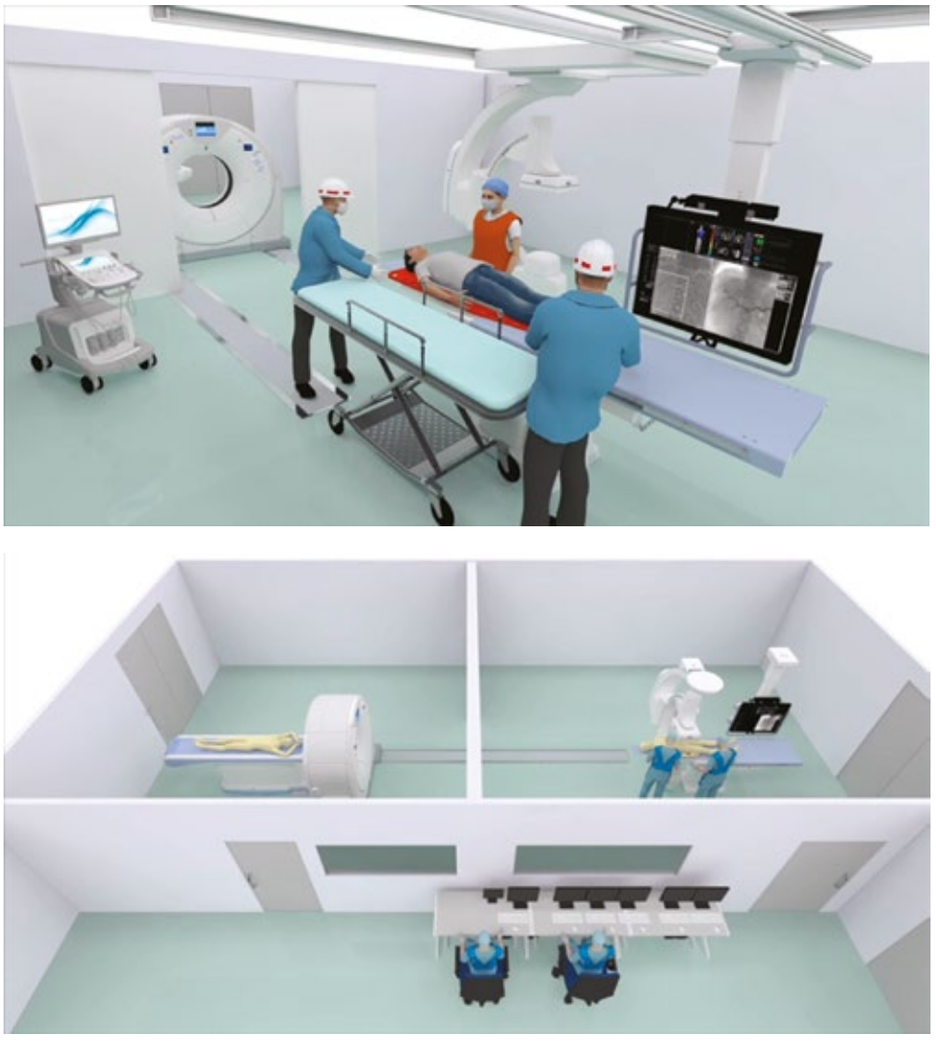

Figure 1 The dual room type hybrid emergency room system. (**a**) The patient is transferred to the angio-resuscitation room. The sliding gantry CT scanner comes from neighboring room to achieve immediate and safe scan even in a hemodynamically unstable patient. Surgery or embolization can be performed without moving elsewhere. (**b**) CT scan works independently in the neighboring room for other patients during the surgery or angiography.

examination can be several hours, even in Level 1 trauma centers in the United States [6]. One of the reasons why embolization might not be the current treatment of choice in unstable patients is because it, in general, is time-consuming and in most centers results in a patient transfer. Since endovascular embolization delays are related to an increased risk of in-hospital mortality [7], to employ rapid embolization will benefit hemodynamically unstable patients in a forthcoming trauma care system [8,9].

To maximize the potential benefits of endovascular treatment, the concept of "Prompt and Rapid Endovascular strategies in Trauma Occasions" (PRESTO) has been proposed [9]. PRESTO is characterized by a time-rigorous workflow that can deliver prompt and effective diagnosis and treatment to patients with severe exsanguinating injuries. This concept has recently received much attention in EVTM. In the PRESTO protocol, the endovascular team should be activated before the patient's arrival. The early activation of the endovascular team, quick focused evaluation of the CT images, and immediate rapid surgery or endovascular treatment reduce the time to hemostasis, potentially saving the patient's life. With PRESTO, endovascular treatment can be used in hemodynamically unstable trauma patients, even in conventional trauma settings. However, such proactive endovascular treatment use in unstable patients does risk sudden collapse during the procedure. It also carries an inherent uncertainty due to variations in vessel anatomy and atherosclerosis, especially in elderly patients. Thus, it is not recommended in the current guidelines [1].

In the HERS environment, hemodynamically unstable patients can be scanned safely in the resuscitation area. Whole-body CT promptly provides precise information regarding the patient's injury, playing a pivotal role in decisions regarding endovascular-based treatment for trauma. Moreover, patients can undergo endovascular treatment without the need for transfer from the resuscitation area. Thus, PRESTO advances the use of endovascular treatment in patients with severe trauma, and the combination of HERS and PRESTO may expand the indications of endovascular treatment to include patients with hemodynamically unstable trauma.

Maximizing the Potential Benefits of Computed Tomography

Although CT findings confer accurate anatomical information, the technique was ridiculed as the "tunnel of death" in early days. However, a survival benefit of whole-body CT scan has been reported in several recent reports [10], although the results have been inconsistent [11], perhaps because the duration of the examination and quality of image reading can vary.

Japan has the longest life expectancy in the world (84.2 years; 2016), although life expectancy has increased in many other developed countries as well. For this reason, elderly patients who have suffered blunt injury and who are often taking antithrombotic agents present unexpected bleeding due to coagulopathy. In patients who have suffered polytrauma, physicians need to isolate and prioritize the main source of the bleeding. FAST examination and X-ray of the chest and pelvis evaluate only cavitary hemorrhages and pelvic fractures. However, retroperitoneal hemorrhage, which cannot be detected using FAST or X-ray, can lead to hemorrhagic death [12]. To control cavitary hemorrhage, open surgery is preferable, while endovascular treatment is preferred in the treatment of non-cavitary hemorrhage, including extra-pelvic retroperitoneal hemorrhage, paravertebral hematoma, and lumbar artery injury, which present a "triple negative" (FAST, chest, and pelvis X-ray) situation in the resuscitation room. Whole-body CT can identify whether patients should undergo endovascular treatment rather than open surgery [13]. Although the ATLS guidelines do not recommend scanning hemodynamically unstable patients, trained teams and regular drilling could shorten the duration of whole-body CT to approximately 7 minutes [14]. Although scanning patients may delay the start of surgery, it may also expedite the completion of the surgery by revealing the location of injuries and allowing surgeons to choose the appropriate hemostasis modality [15].

Because HERS can reduce scanning time, it increases the likelihood that unstable patients will be scanned safely and that unexpected injuries will be identified. According to the ABCDE approach in the ATLS, TBI evaluation, which prevents secondary brain injury, is to be carried out after hemostasis. However, earlier brain CT may provide a red flag for possible neurological deterioration, leading to prompt neurosurgical intervention that can be performed simultaneously with hemorrhage control in HERS [16,17].

Rapid and Safe Resuscitative Endovascular Balloon Occlusion of the Aorta

REBOA is a viable adjunct treatment for refractory hemorrhagic shock [18]. It works as a bridge toward definitive hemostasis and can be used as a proximal control for subdiaphragmatic hemorrhage. Although REBOA constitutes minimally invasive aortic occlusion, particularly when compared to resuscitative thoracotomy, it is not a magic tool. Japanese observational study implied that REBOA delays definitive hemostasis [19]. Thus, subsequent immediate hemostasis using surgery and/or endovascular treatment must follow temporary stabilization with REBOA. The HERS confers safe and rapid hemostasis without the need for patient relocation.

Even though REBOA is minimally invasive, its procedure-related complications must be considered [20]. REBOA can be carried out under ultrasound guidance or portable X-rays outside the angiography suite. However, fluoroscopy also helps ensure that REBOA is performed more safely, rapidly, and accurately. Fluoroscopy accurately visualizes the occlusion zone of the aorta without any external measurement. It also immediately notifies the operator when they have misinserted the guidewire or catheter into the vena cava. Thus, it is of great help, especially in the elderly patients with a tortuous aorta, as are often seen in developed countries with aging societies. In summary, HERS is an ideal environment to employ REBOA in life-threatening situations.

Current Limitations and Future Directions of HERS

HERS may change trauma care drastically. However, it has several limitations. Firstly, no standard workflow has yet been established, unlike current ATLS initial assessment and resuscitation. FAST and X-ray can be omitted during HERS, but obstructive shock evaluation, intubation timing, CT scan duration, and scan protocol during HERS have not been well examined. Secondly, HERS requires a trained trauma team consisting of multidisciplinary professions—previous reports have shown that estimated mortality rose temporarily during the first year of HERS implementation and then decreased to lower than baseline [16]. Despite these limitations, HERS may be an ideal EVTM solution for the trinity of surgery, endovascular treatment, and imaging in civilian trauma care. We at the JA-HERS will continue to explore the most radical and safest EVTM in the HERS environment.

SUPPLEMENTARY DIGITAL CONTENT

Supplementary material related to this article can be found, in the online version.

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Images of interest

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Emergency Embolization of a Ruptured Renal Artery Aneurysm

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Keywords: *Emergency; Renal Artery Aneurysm; Endovascular*

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Renal artery aneurysm (RAA) is a rare clinical entity with an incidence rate of 0.1% [1]. Clinically most patients are asymptomatic [2], but mortality from acute rupture is 10% [3]. Conventional management includes open surgery which may, unfortunately, require a nephrectomy [4]. However, the success of endovascular interventions has led to a paradigm shift in treatment [4].

A 77-year-old medically frail woman presented to the physicians with symptomatic anemia of hemoglobin 4.6 g/L. At this time, she was hemodynamically stable. Past medical history included hypertension and hypothyroidism. Clinical examination demonstrated a soft abdomen with a palpable mass in the left flank and upper quadrant. She was transfused with 3 units of blood and a CT angiogram was performed. This demonstrated a 7 × 6 cm ruptured left RAA associated with a retroperitoneal hematoma (Fig. 1).

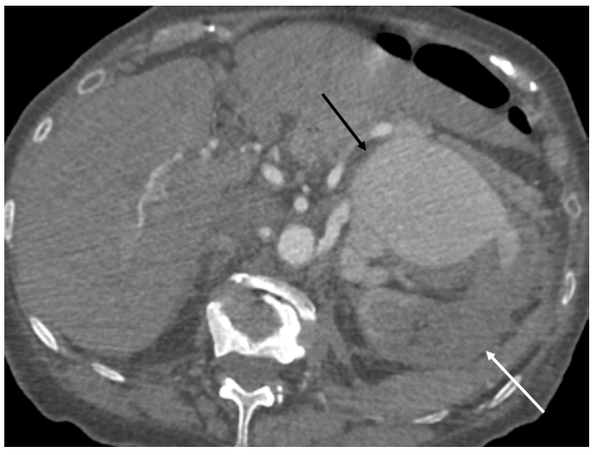

Figure 1 Computed tomography angiogram demonstrating a 7 x 6 cm ruptured left renal artery aneurysm (black arrow) associated with retroperitoneal hematoma (white arrow).

After the CT scan, the patient became hemodynamically unstable with a Glasgow Coma Scale of 6. A decision was made to attempt endovascular control of the hemorrhage as she was unfit for a laparotomy or nephrectomy.

At digital subtraction angiography, the renal artery was selectively catheterized using a 5 Fr angiographic catheter (Sim 1, Cordis, USA) and a microcatheter (Progreat, Terumo, Japan) advanced within the sac of the aneurysm. The sac was embolized using 10 large-diameter

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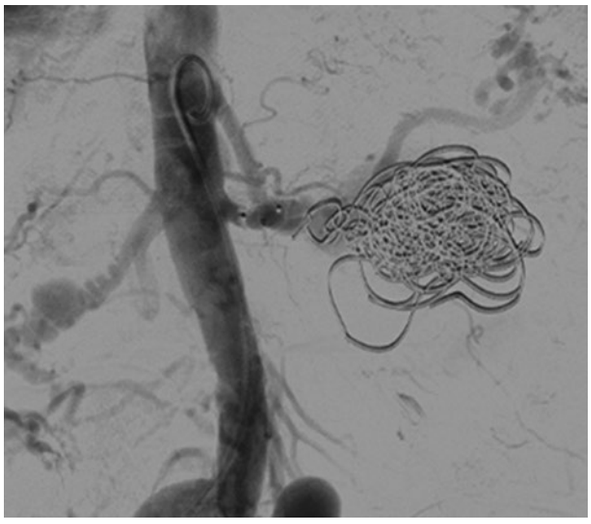

Figure 2 Digital subtraction angiography demonstrating concerto coils filling the aneurysm sac. Due to concerns over the length of the neck, an AMPLATZER plug was deployed.

detachable coils (Concerto, Medtronic, USA) and a 12 mm vascular plug (Amplatzer, Abbott, USA) deployed at the neck (Fig. 2). Post-operative duplex confirmed thrombosis of the left RAA and the patient recovered without sequelae.

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Case Report

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Endovascular Repair of the Blunt Injury to Persistent Sciatic Artery in a Case of Pelvic Fracture

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Background: Endovascular embolization has become a preferred treatment in the management of retroperitoneal bleeding due to pelvic injuries. These techniques have spread across most trauma centers as minimally invasive management of one of the most dreadful conditions in trauma.
Methods: We present a patient with persistent sciatic artery who arrived at our facility with blunt pelvic trauma suffering from retroperitoneal bleeding. Timely recognition of this anomaly led to the preservation of the vital artery and prevention of ischemic complication.
Conclusions: Although embolization of the bleeding has become a routine procedure in most busy trauma centers, precise imaging, recognition of significant anatomic variants and careful intervention planning are essential in preventing substantial complications.

Keywords: *Trauma; Pelvic Blunt Trauma; Vascular Injury; Vascular Anomalies; Persistent Sciatic Artery; Endovascular Treatment*

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INTRODUCTION

Pelvic fractures represent approximately 3% of all skeletal injuries [1] and are associated with mortality rates as high as 50% [2]. The considerable associated vascular injury presents in up to 3.5% [3]. Lately, endovascular embolization has become a paradigm of this often life-threatening injury [4]. This minimally invasive procedure supplies a rapid and safe solution and is available in most tertiary trauma centers. Nevertheless, although perceived to be routine, a thorough understanding of the anatomy and planning is crucial in this vascular intervention. We present a case of "open book" pelvic fracture with retroperitoneal bleeding due to injured persistent sciatic artery (PSA). A short discussion of this rear anatomic variant follows.

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Conflicts of interest: None.

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Case Report

A 23-year-old male presented to our facility after a road accident. He was fully conscious. His arterial systolic blood pressure was around 100 mm, and he was tachycardic with pulses around 100. The primary survey disclosed an unstable pelvis with thigh deformity. After completion of the primary evaluation and wrapping of the pelvis, the patient underwent total body CT scan.

The CT scan revealed fractures of the pelvic ring and femur with a considerable hematoma in the right retroperitoneal area. The iliac artery on the same side did not show extravasation but the cut off of what seemed to be the internal iliac artery (Figure 1). As the patient had already received several blood transfusions and showed signs of continuous bleeding, the embolization was assigned, and the patient was transferred to the angiography suite with intent to embolize the right internal iliac artery.

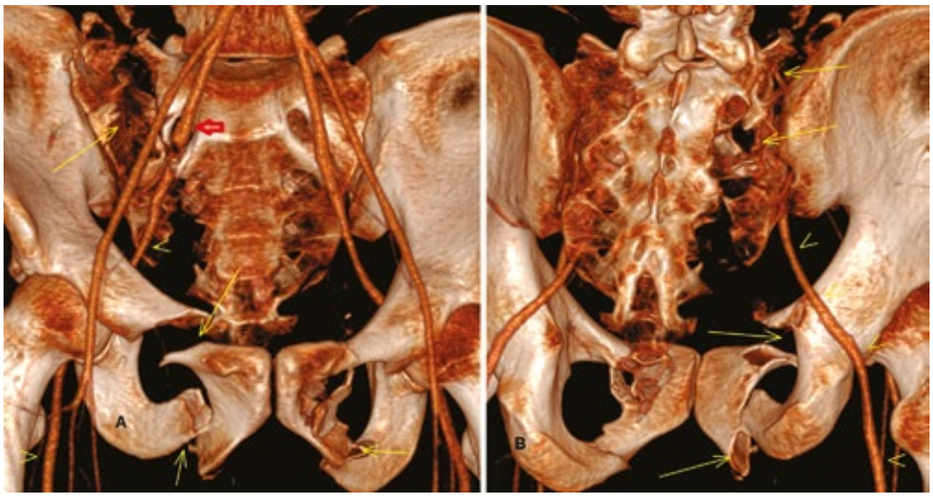

Figure 1 A three-dimensional reconstruction of the preoperative CT angiography. (**a**) Anterior and (**b**) posterior view. Yellow arrows point at multiple fractures with the disjunction of the pelvic ring. The yellow arrowheads point at the persistent sciatic artery (PSA). The red arrow points at traumatic occlusion of the PSA.

After left femoral access, a cross-over guidewire with a sheath was introduced and diagnostic angiography performed (Figure 2). The anatomy was confusing, so a trauma team invited a vascular specialist, who diagnosed the PSA on both sides, with a hypoplastic superficial femoral artery.

After successful passage of the guidewire through the occluded segment of the PSA, the balloon mounted 6×49 mm^2 covered stent (BeGraft, Bentley Innomed, Hechingen, Germany) was delivered and deployed, with preservation of the artery and restoration of the blood flow to the limb. Two days later the orthopedic team performed a successful reconstruction of the pelvis (Figure 3). The rest of the hospitalization was uneventful, and the patient was referred to a rehabilitation program.

DISCUSSION

A PSA is a rare vascular anomaly with an estimated incidence of 0.03–0.06% [5]. The sciatic artery is a major branch of the internal iliac artery and is the principal blood supply to the lower extremity in the human embryo before the development of the femoral artery. It leaves the pelvis next to the sciatic nerve and is continuous with the popliteal artery. With the development of the femoral artery, the sciatic artery disappears. If it persists, two types are recognized by its relationship to the femoral artery: complete and incomplete [6]. The complete type denotes complete preservation of the sciatic circulation with hypoplastic femoral elements.

The reported patient had a complete type with a dominant, persistent sciatic vessel from the pelvis straight to the popliteal artery as the main trunk and hypoplastic superficial femoral artery (SFA). The significance of the timely recognition of this variant is crucial. In circumstances of the sometimes chaotic environment of trauma management, hasty advised embolization of the internal iliac artery can be disastrous with severe ischemic complications and inadvertent amputation or even mortality. Correct, timely recognition of this anomaly by the vascular surgeon in our patient led to the preservation of the artery by covered stent with optimal outcome. This case underscores the importance of familiarity with vascular anatomy and awareness of vascular anomalies.

In general, the vascular specialist is not part of a trauma team routinely, and the decisions are almost exclusively taken by cooperation with the invasive radiologist. In this context, we strongly recommend immediate consultation with a vascular specialist in any case of unusual or uncertain anatomy. A diagnostic angiography of the limb is an additional important point. Complete imaging of the circulation of the area of interest is essential in even the sometimes pressing and chaotic conditions of trauma management. That is the only way to demonstrate vascular anatomy and anomalies and accordingly reveal them and take therapeutic decisions.

The precision of the embolization is another interesting point. Embolization of the main stem of the artery is unnecessary in most cases and may be counteractive, with multiple distal feeders inaccessible after embolization. Selective embolization is more precise and retains the main trunk for additional interventions if required later.

The patient we described was relatively stable. It would be interesting to speculate what should be the management of the same, but hemodynamically unstable patient. Generally, it would depend on the facilities, protocols, and skills available at the institution. Historically, the severely unstable patient would go straight to the

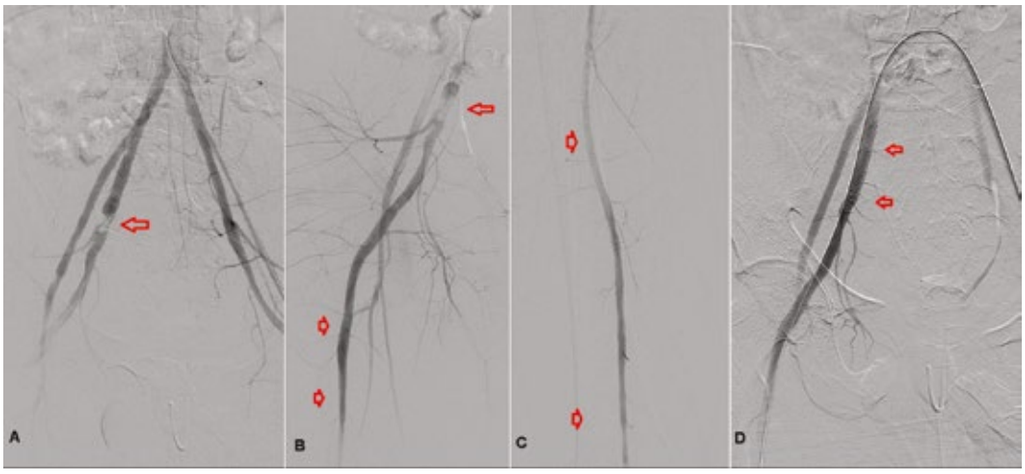

Figure 2 Angiographic images of the persistent sciatic artery (PSA). (**a**) The arrow points at the traumatic occlusion. (**b**) Short arrows point at the pelvic portion of the PSA. (**c**) A femoropopliteal portion of the PSA. (d) Patient artery after repair. Arrows point at the covered stent.

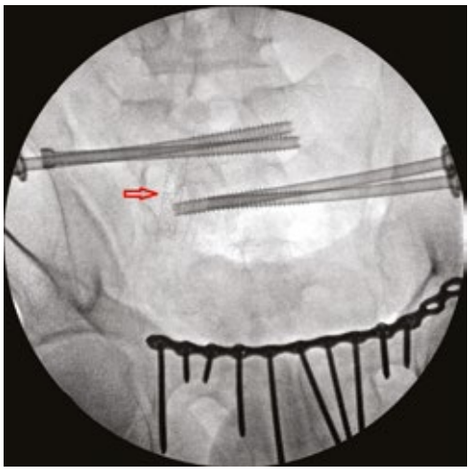

Figure 3 Repaired pelvic ring. The arrow points to the covered stent in the persistent sciatic artery.

operating room; however, we want to note that the open access to bleeding PSA is an extremely challenging undertaking and if successful, reconstruction would most probably include ligation of PSA and performance of the femoropopliteal bypass. Considerable bleeding and collateral damage (pelvic veins, ureter for example) are generally feared complications.

Lately, the paradigm of unstable patient management has begun to change. In our opinion, such a scenario would be a classic indication for REBOA in zone 3 with hypotensive resuscitation on the way to the angio suite or hybrid room. The management there would depend on the information available at the initiation of angio. If the area and side of bleeding are unknown, the diagnostic angiography can be performed through the opposite side to the REBOA by positioning the REBOA a few centimeters above the aortic bifurcation. If the side of bleeding is opposite the REBOA, it can be switched to the cross-over PTA balloon in common iliac artery for bleeding control and provide a platform for precise imaging and crossing of the lesion. Deployment of the covered stent follows at the last stage. If the bleeding is ipsilateral to the REBOA the cross-over sheath with a PTA balloon can be introduced through the opposite side and the procedure accomplished by the same strategy. The main principle is to keep endovascular hemostatic proximal to the injury occlusion up to the last stage of the covered stent deployment. We used this strategy with success in non-compressible high groin vascular injury. The technique is user-friendly to those who have expertise in endovascular management. Multidisciplinary cooperation and thorough intervention planning are critical and would improve the results of trauma patient management.

CONCLUSION

Rare vascular anomalies can present as an emergency in trauma and require interventions. Early vascular specialist involvement in patient management, multidisciplinary cooperation with thorough imaging, and intervention planning are essential in preventing ischemic complications with resulting limb loss.

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Case Report

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The Non-Diagnostic Triad in a Hypotensive Blunt Trauma Victim: What is the Role of REBOA?

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Background: With the growing use of REBOA as an alternative to Emergency Department thoracotomy in select patients, the algorithms are still evolving, and current guidelines for resuscitative endovascular balloon occlusion of the aorta (REBOA) use appear to have gaps as evidenced by this case. Most algorithms include chest x-ray, focused assessment with sonography for trauma (FAST), and pelvic x-ray to guide where to place the device, either in zone 1 or zone 3. There is a lack of guidance for patients in whom all three of these studies are negative, which we define as a non-diagnostic triad (NDT). Furthermore, there is a lack of guidance after placement of the device in patients who fail to respond or only minimally respond.
Methods: We describe a difficult case where a blunt trauma patient with unstable hemodynamics had marginal response to placement of zone 1 REBOA, while physical exam and imaging in the trauma bay did not reveal a source for his hypotension.
Results: The patient was sent to the CT scanner whereupon multiple injuries were identified and detailed in the case. The patient unfortunately expired soon after.
Conclusions: Further clinical studies with better classification are needed in order to better understand the significance of REBOA responders and non-responders in patients with an unknown source of hypotension. The NDT of negative chest x-ray, FAST, and pelvic x-ray represent a significantly challenging patient population that should be studied further.

Keywords: *REBOA; Non-Diagnostic Triad; Blunt Trauma*

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BACKGROUND

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is becoming a standardized adjunct in the management of critically ill patients with non-compressible torso bleeding. Trauma centers using REBOA are instituting algorithms that help guide the location and indications for REBOA use. Most of these algorithms use three basic point of care imaging studies, the chest X-ray (CXR), focused assessment with sonography for trauma (FAST), and pelvic X-ray (PXR). Unfortunately, there is still a lack of evidence or recommendations when all of these studies remain negative in an unstable patient, which we call the "non-diagnostic triad" (NDT). In the age of the Emergency Department (ED) thoracotomy, the patient would immediately go to the operating room (OR). Today, with the advent of REBOA, hybrid ORs, and better diagnostic imaging, decisions have become more complicated. Should Zone 1 REBOA mandate immediate transport to the OR, or can you send the patient to the CT scanner for further imaging? We present a hypotensive blunt trauma victim with NDT who transiently responded to Zone 1 REBOA, and

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Conflicts of interest: None.

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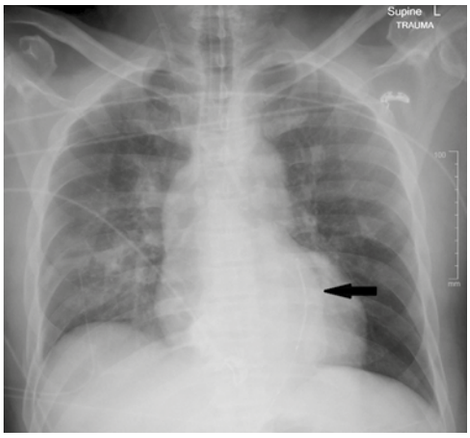

Figure 1 Portable CXR from Trauma Bay after placement of REBOA in (low) Zone 1 (black arrow).

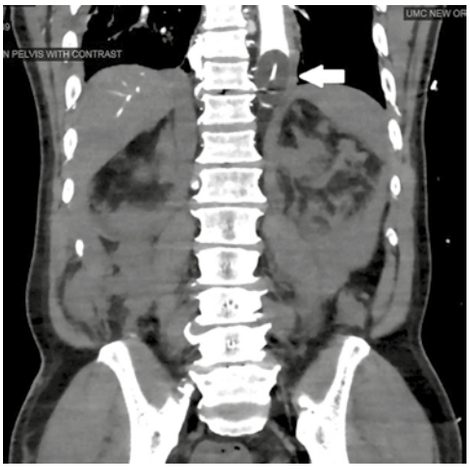

Figure 2 Coronal Iimaging of REBOA in Zone 1 with IV contrast proximal but minimal progression distally.

is thought to have expired from retroperitoneal hemorrhage in the setting of a blunt cardiac injury.

Case Details and Results

A 58-year-old male presented to our Level I trauma center after a high-speed head-on motor vehicle collision. Prior to arrival, the patient underwent pre-hospital advanced cardiac life support (ACLS) with the successful return of spontaneous circulation (ROSC). Upon arrival at our facility, he had weakly palpable pulses with a systolic blood pressure of 80 mmHg. Physical examination was unrevealing for the source of his cardiac arrest and shock, although he had a head laceration and posturing. Blood transfusions were started and the massive transfusion protocol (MTP) was activated. Adjunct imaging included a CXR, FAST, exam, and pelvic X-ray, all of which were grossly negative. The patient lost pulses approximately 7 minutes after arrival, and ACLS was begun again. Given that he had a normal CXR, and FAST was negative for pericardial tamponade, the decision was made to place a REBOA catheter instead of proceeding with an ED thoracotomy.

REBOA was performed percutaneously in the right femoral artery under ultrasound guidance, with ER-REBOA through a 7 Fr sheath. The REBOA balloon was inflated in Zone 1 with 10 mL of saline. The patient had a delta REBOA response from a mean arterial pressure (MAP) of 30 mmHg to a MAP of 70 mmHg, after which ACLS was terminated. ED arrival to full aortic balloon occlusion time was 17 minutes. CXR showed well-positioned Zone I REBOA placement. Adequate inflation was confirmed by a lack of the contralateral femoral pulse. The patient was brought to the CT scanner whereupon a large amount of bilateral retroperitoneal blood was identified, however, due to the balloon occlusion, definitive extravasation was not found.

On final CT imaging reports, the patient was found to have diffuse cerebral and cerebellar contusions without mass effect or shift on the head CT. His chest CT revealed an anterior mediastinal hematoma with contrast extravasation and multiple bilateral rib fractures. The abdominal CT showed a large amount of retroperitoneal hematoma bilaterally with possible contrast extravasation near the infrarenal aorta (balloon occlusion likely limited this finding) and bilateral renal lacerations.

Unfortunately, the patient lost vital signs again soon after leaving the CT scanner and was returned back to the trauma bay. Despite aggressive MTP and receiving 16 units of balanced blood products and ACLS, the patient expired. Post mortem autopsy demonstrated cortical and cerebellar contusions, a mediastinal hematoma with sternal and rib fractures, cardiac contusions with severe coronary atherosclerosis, and retroperitoneal hematoma with bilateral renal lacerations.

DISCUSSION

In 1954, the first reported use of REBOA for the treatment of traumatic hemorrhagic shock was documented in 3 critically ill US soldiers [1]. Since then, many cases and trials have presented favorable outcomes following the use of REBOA for the treatment of hemorrhagic shock, and suggest it as potentially superior (or at least equivalent) to ED Thoracotomy [2]. Aortic balloon occlusion has also been used successfully in many situations such as ruptured aortic aneurysm control, aortoenteric fistula aortic hemorrhage control, postpartum or abdominal/pelvic surgery hemorrhage, hemoperitoneum due to splenic artery aneurysm, gastrointestinal hemorrhage, and for control of other vascular injuries [3].

The areas for REBOA balloon inflation are divided into aortic zones: Zone I extends from the left subclavian artery branch off to the celiac trunk, Zone 2 (no

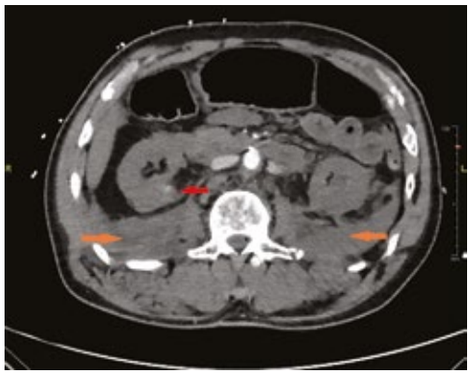

Figure 3 Potential right renal blush (red arrow) with bilateral retroperitoneal blood (orange arrows).

occlusion zone) extends from celiac trunk to the lowest renal artery, and Zone 3 from lowest renal artery to the aortic bifurcation. If there is evidence of abdominal or truncal bleeding, a balloon is inflated in Zone I. With pelvic hemorrhage, the REBOA balloon is inflated in Zone 3. In our particular case, the guidelines as outlined by these algorithms were followed. In the presence of NDT in this patient with persistent class IV shock a REBOA was positioned in Zone 1 and inflated with a transient increase in blood pressure.

Given an NDT, the role of obtaining definitive imaging is unclear if the patient is unstable. Admittedly, CT is the gold standard for thoracic, abdominal, and pelvic trauma imaging. However, the CXR, FAST, and PXR all have a significant advantage in unstable patients due to point of care applicability. CXR was shown to have low sensitivity for thoracic injuries when compared to CT for trauma [4]. However, it is thought most of the missed injuries are clinically less significant in a hypotensive patient, such as non-displaced rib fractures or occult pneumothorax. Our patient was found to have cardiac contusions with a sternal fracture on autopsy, both were not seen on CXR or CT. There were a mediastinal hematoma and rib fractures present on CT, without a sternal fracture. Thus, it is unclear how much of the patient's blunt cardiac findings on autopsy were due to ACLS versus the initial injury.

The FAST exam has been accepted as having an adequate sensitivity for diagnosing intra-peritoneal free fluid as well as pericardial effusion, with an overall sensitivity of 73–99% which is thought to increase in hypotensive patients [5]. PXR in the trauma bay helps to identify life-threatening types of pelvic fracture. While sensitivity remains low (50-68%) for pelvic fractures, it is adequately able to diagnose the major life-threatening pelvic ring injuries, including open book and vertical shear fractures [6].

This case brings into question the controversial decision to delay operative intervention to pursue cross-sectional imaging in the hemodynamically unstable patient. In hindsight, we believe that the patient in the case presented expired due to large retroperitoneal blood loss, with blunt cardiac injury likely contributing. It is hard to determine the extent to which each injury contributed, especially in the setting of prolonged ACLS. The patient's transient initial response to Zone 1 REBOA placement in the setting of NDT raises the question on the need for further diagnostics versus faster surgical intervention with earlier aggressive MTP activation. While MTP was initiated soon after arrival to the trauma bay, the resuscitation was likely sub-optimal while the patient was in the CT suite. Our institution does not currently have a protocol in place for running MTP while obtaining CT imaging. Even slight delays in MTP have been shown to be associated with increased time to hemorrhage control and mortality in the multiply injured patient [7]. REBOA was shown in an animal model to restore central perfusion faster than MTP alone [8], and its use as an adjunct to both resuscitation and hemorrhage control could be synergistic. At the time of this case, our institution stored blood outside the ED and had an average time to release of trauma blood products of 7.5 minutes. This was likely a factor in the patient only receiving 4 units of blood prior to traveling to the CT suite. The amount of time to release MTP at our institution has since been decreased by storing blood products within the ED.

Given the patient's initial report from the field of a head laceration with posturing, we initially had suspicion of a devastating brain injury. There is limited evidence for the safety and efficacy of REBOA in a patient with traumatic brain injury (TBI), however, some important studies do exist. REBOA with MTP versus MTP alone in an animal TBI model was actually shown to increase MAP and carotid blood flow, while at the same time decreasing peak intracranial pressure [9]. Serial imaging in the REBOA groups did not show worsened progression of bleeding compared to controls.

Similar to the TBI population, there is questionable safety and efficacy for REBOA in blunt cardiac injury. REBOA has been compared to intra-aortic balloon pump devices routinely used for cardiogenic shock. Both devices can increase coronary and cerebral perfusion pressures, decrease the required amount of cardiac output, and thus decrease cardiac oxygen demand [10]. Increased coronary pressures and flow were also found to be significant predictors of ROSC, and survival to discharge in patients undergoing ACLS for non-traumatic arrest [11].

Prior to REBOA, when ED thoracotomy was the single resuscitative procedure in non-responder patients with persistent hypotension and trauma codes, obtaining CT with an aortic cross-clamp would be unheard of. With the advent of hybrid ORs, endovascular therapy, MTPs, better imaging capabilities, and ED-REBOA, the algorithms have become more complicated. We believe that a patient with NDT could potentially benefit from

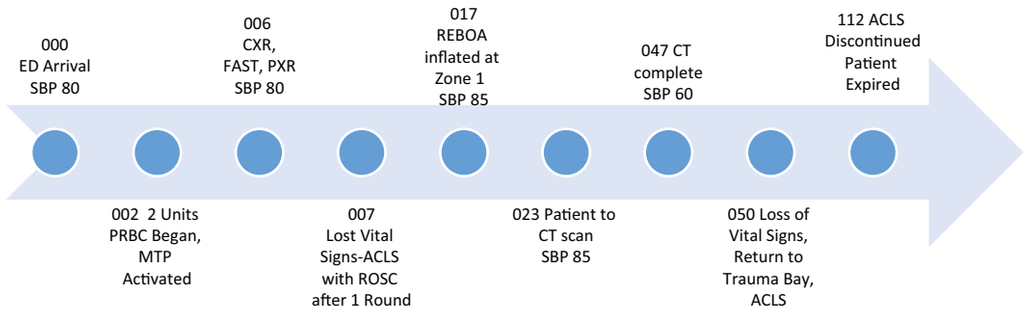

Figure 4 Timeline of events.

a hybrid OR. It is possible that other unstable NDT patients are hiding significant retroperitoneal injuries. Modern hybrid suites have the advantage of diagnosing and treating these conditions without compromising or delaying resuscitation. Currently, at our institution, the role of the hybrid OR for trauma has not been well defined. Time to mobilize catheter-based teams is much longer than for the conventional OR, which currently limits the application in trauma scenarios. It is likely that many institutions across the U.S. face similar challenges, and it is unclear where the hybrid OR will fit into institutional algorithms. Select centers across the world are pioneering the resuscitation of the patient with multiple injuries by combining the trauma bay, OR, angiography suite, and CT scanner in one physical location [12]. The NDT patient raises an important clinical scenario where there is a gap in current algorithms. The case presented was a difficult scenario with a high likelihood of mortality, but the decision to send the patient to the CT suite came with a significant cost in terms of time lost resuscitating and intervening on his injuries. Perhaps with modernized facilities that combine resuscitation, imaging, and intervention, the costs of patient transport will decrease and the algorithms may simplify.

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Case Report

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REBOA Enables Operative Management of the Peripartum Trauma Patient in Hemorrhagic Shock

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Trauma-related injury is the leading cause of non-obstetric maternal death. The gravid uterus is at risk for injury, particularly during motor vehicle accidents. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a means of controlling pelvic hemorrhage in the setting of trauma. We report the use of REBOA in a hemodynamically unstable, multiply-injured young woman with viable intrauterine pregnancy.

Keywords: *REBOA; Trauma; Pregnancy; Peripartum*

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INTRODUCTION

Trauma-related injury is the leading cause of non-obstetric maternal death [1]. Motor vehicle accidents comprise half of all traumas in pregnancy and are responsible for the majority of trauma-associated fetal deaths [2]. The intra-abdominal position of the intrauterine pregnancy in the second and third trimesters as well as the significant risk of improper lap belt use during pregnancy are major pre-disposing factors for this fetal mortality [3].

The multiply-injured pregnant trauma patient is a unique subset of the trauma population. The physiologic changes of pregnancy are well adapted to the potential for obstetric bleeding, with a disproportionate increase in maternal plasma volume relative to red cell volume resulting in the minimized loss of red blood cells while ample plasma proteins allow for hemostasis [4].

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A growing body of literature increasingly supports the use of REBOA in trauma patients. A recent report from the Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry demonstrated comparable outcomes between open and endovascular resuscitative aortic occlusion [5]. Further, REBOA has utility in augmenting the systolic blood pressure in patients with pelvic trauma [6]. Interestingly, within the Obstetrics literature, there are multiple reports on the utility of endovascular occlusive techniques of the iliac arteries for the management of peripartum hemorrhage [7–9]. In this paper, we report the use of REBOA in a young woman with blunt exsanguinating hemorrhage of the placenta.

CASE REPORT

A 20-year-old woman arrived at the trauma bay after a motor vehicle collision with ejection. Admission vitals were Glasgow Coma Scale 14, blood pressure 90/60s, heart rate 60s. She was intubated for extensive facial trauma and combativeness. In concert with intubation, early arterial access was secured with ultrasound-guided placement of an 18-gauge arterial line in the right common femoral artery, and a central venous cordis catheter placed in the subclavian vein. Chest x-ray showed the endotracheal tube to be in an adequate position, and a left chest tube thoracostomy was subsequently performed for the finding of hemothorax. With intubation and chest decompression, systolic blood pressure improved to the 150s. The primary survey was otherwise intact, and the secondary survey was notable for deep

lacerations to the face, an unstable mandible, and road rash to the chest and abdomen. Focused assessment with sonography in trauma (FAST) exam was negative for free fluid but did reveal an intrauterine pregnancy.

Pan computed tomography (CT) imaging revealed extensive facial fractures, blunt cerebral vascular injury, rib fractures, and uterine wall bleeding with indeterminate finding of uterine wall rupture (see Figure 1). In consultation with Obstetrics, the decision was made to pursue non-operative management given an estimated fetal gestational age of 24 weeks, at the borderline of viability. However, just prior to transfer to the Shock Trauma Intensive Care Unit (ICU), the patient became hypotensive requiring 2 units of packed red blood cells and 2 units of fresh frozen plasma with transient response. The massive transfusion protocol was initiated and she was transferred emergently to the operating room.

On arrival at the operating room, systolic blood pressure was in the 60s with massive transfusion ongoing. The right femoral arterial access was upsized to 7 French sheath, and an ER-REBOA device deployed via anatomic landmarks to zone 3 at 16:46 local time. Blood pressure improved and was maintained at 90s systolic. A laparotomy was performed and a quick survey of the abdomen revealed no gross hemoperitoneum. The gravid uterus was elevated into the field and found to have no free wall rupture but the uterus was grossly enlarged and blood filled. A cesarean section was performed, and the newborn in extremis handed off to Neonatal staff for resuscitation at 16:55. The bleeding placenta was subsequently delivered. The uterus was closed in layers and found to have appropriate tone. After delivery of the infant and survey of the lower abdomen revealing no zone 3 retroperitoneal hematoma, the REBOA balloon was sequentially deflated in coordination with Anesthesia with final down time at 17:04. The REBOA catheter was removed at 17:15 with the sheath left in place. A second look at the abdomen revealed a Morel–Lavallee defect to the left lower quadrant with transected rectus abdominus. The avulsed edges of the inferior epigastric artery were not actively bleeding but were ligated. The abdomen was closed and the patient transported back to the ICU. The ER-REBOA device was inflated at zone 3 for a total of 18 minutes. Intra-operative blood product requirement was 11:11:12 of packed red blood cells: fresh frozen plasma:platelets. The REBOA sheath was removed in the ICU within 24 hours of placement in the Emergency Room.

With regard to REBOA deployment in the setting of pregnancy, the decision was made due to the mother's cardiovascular status and impending hemodynamic collapse. It was believed that any fetal decompensation related to occlusion of uterine blood flow was a superior option compared to loss of vitals in the mother. Placement of REBOA and sterile preparation of the abdomen occurred concurrently. Trauma laparotomy and subsequent delivery of the infant occurred expediently after aortic vascular occlusion.

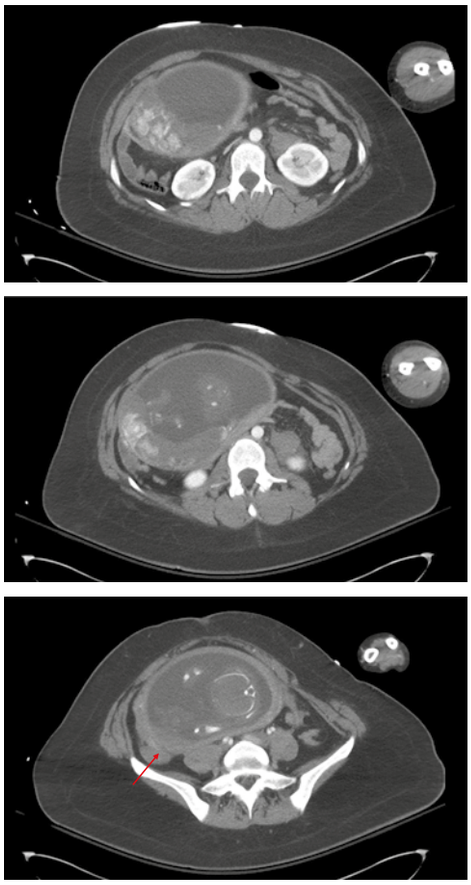

Figure 1 CT abdomen/pelvis axial images, venous phase, demonstrating active hemorrhage of the placenta and uterine wall, and concern for uterine wall rupture in the lowermost image.

PATIENT OUTCOME

The patient had a prolonged hospital stay with multiple operations for fixation of complex facial and orthopedic fractures. After intensive in-hospital rehabilitation, she was discharged home to the care of her family on hospital day 38. The patient's son, born at an estimated gestational age of 24 weeks, unfortunately passed away due to complications of extreme prematurity 3 weeks into the hospital admission.

DISCUSSION

We report the use of REBOA in a multiply-injured pregnant trauma patient. In this instance, placental bleeding manifested delayed onset of hemorrhagic shock. Deployment of the ER-REBOA device allowed augmentation of the hemodynamic status in the setting of impending vascular collapse. A total deployment time of 18 minutes

facilitated rapid laparotomy, delivery of the fetus, and definitive management of the bleeding uterus. REBOA has utility in the exsanguinating trauma patient and has potential applications in the management of both trauma and non-trauma-related obstetric bleeding.

TEACHING POINTS

- REBOA is deployed via percutaneous access of the common femoral artery. Access of the superficial femoral artery risks vascular occlusion or dissection of the artery. Access of the distal external iliac artery risks retroperitoneal hemorrhage which is not compressible.
- Access of the common femoral artery is ideally performed with ultrasound guidance. Access utilizing landmarks, fluoroscopy, cut-down or blind is also possible and dictated by available materials and the urgency of the patient's condition.
- In the trauma setting, zone 1 of the aorta is from the origin of the left subclavian artery to the celiac artery. Zone 2 is from the celiac artery to the most distal renal artery. Zone 3 is from the most distal renal artery to the aortic bifurcation.
- The decision to utilize REBOA in the setting of the trauma injured pregnant patient must be made with the understanding that vascular occlusion of the aorta, while potentially augmenting the hemodynamic status of the mother, will likely result in decompensation of the fetus due to ischemic injury. REBOA is a temporizing maneuver until definitive control of hemorrhage can be obtained.
- REBOA is an emerging technology. Its indications in resuscitation are institution dependent and likely to evolve with emerging data.

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Case Report

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Use of REBOA as a Bridge to Endovascular Aortic Repair in Blunt Abdominal Aortic Injury

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Blunt abdominal aortic injury (BAAI) is a rare but challenging traumatic lesion. Since BAAI is difficult to suspect and diagnose, frequently lethal, and associated to multiorgan injuries, its management is objective of research and discussion. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an accepted practice in ruptured abdominal aortic aneurysm. Conversely, blunt aortic injuries are the currently most cited contraindications for the use of REBOA in trauma, together with thoracic lesions. We report a case of BAAI safely managed in our Trauma Center at Maggiore Hospital in Bologna (Italy) utilizing REBOA as a bridge to endovascular repair, since there were no imminent indications for laparotomy. Despite general contraindication to blindly placing REBOA in aortic rupture, we hypothesize that a multidisciplinary approach, involving endovascular specialists able to exclude the lesion with the balloon, could be feasible and relatively safe when introduced in a resuscitative damage control protocol.

Keywords: *REBOA; Blunt abdominal injury; EVAR; Endovascular aortic repair; Aortic rupture; Damage control approach*

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INTRODUCTION

Blunt abdominal aortic injury (BAAI) is defined as an injury of the abdominal aorta from the diaphragmatic hiatus to the aortic bifurcation. Aortic injuries are classified into four categories based on severity [1]: (1) grade 1, intimal tear; (2) grade 2, intramural hematoma; (3) grade 3, aortic pseudoaneurysm; and (4) grade 4, free rupture. To date, BAAI is reported in less than 1% of all blunt trauma [2,3] and the leading cause is motor vehicle collisions [4]. BAAI is one of the most challenging injuries because of the associated lesions and because of the hemodynamic instability of those who survive to reach the hospital [4]. In Italy victims of severe trauma (Injury Severity Score (ISS) > 15) are estimated at 400/500 per million population per year, mainly from traffic injuries [5].

BAAI is rarely found as an isolated lesion [6]. Therefore, the diagnosis of BAAI is challenging: the presence of concomitant multiorgan injuries may by themselves explain hemodynamic instability and extended focused

assessment with sonography in trauma (E-FAST) could be either positive for the bleeding of other intra-abdominal organs or negative because of retroperitoneal rupture. This makes it difficult to suspect BAAI without performing advanced diagnostic imaging such as a computed tomography (CT) scan or angiography.

A Western Trauma Association multicenter retrospective study about patients presenting with BAAI [4] reported that the majority of those with aortic rupture presented with hypotension and about 30% of them experienced a cardiac arrest either before arriving at the radiology service or at the operating room (OR). In a half of the cases, resuscitative thoracotomy with aortic cross clamping was performed, despite poor outcomes of this procedure in blunt trauma [7].

We report a case of BAAI safely managed in our Trauma Center at Maggiore Hospital in Bologna (Italy) utilizing resuscitative endovascular balloon occlusion of the aorta (REBOA) as a bridge to endovascular repair, since there were no imminent indications for laparotomy.

CASE PRESENTATION

We report the case of a healthy 47-year-old woman, the victim of a high impact collision with a bus when, due to an engine breakdown, she was stationed with her car in the highway emergency lane.

The patient was initially found unconscious. The Helicopter Emergency Medical Service (HEMS) was activated, while venous access was set and initial fluid bolus started. On scene, after a prolonged and complex extrication, the primary survey showed a Glasgow Coma Scale of 11 (E3V2M6), a respiratory rate (RR) of > 30/min, a heart rate (HR) of 130 beat/min and systolic blood pressure (SBP) of 60 mmHg. Due to a pelvic instability and a negative E-FAST, a pelvic binder was applied and an infusion of 1000 ml of crystalloids started in refracted bolus, with poor hemodynamic response. She was rapidly transferred to the Emergency Department (ED) of Maggiore Hospital, the Level 1 Trauma Center in Bologna (Italy), while activating the trauma team. She was intubated under general anesthesia and a pleural drainage was inserted because of a hemo-pneumothorax. Since the patient remained unresponsive also to massive transfusion, the Intensive Care Physician cannulated the left common femoral artery under ultrasound guidance, and an 8 F introducer sheath was placed through the Seldinger technique (Fig. 1). A REBOA was promptly positioned in zone 3 (Fig. 2), ascribing the life-threatening hemorrhagic shock to pelvic trauma [8,9]. Abdominal US = ultrasound also confirmed zone 3 balloon position.

We used a NUMED PTS® sizing balloon catheter (Fig. 3) designed for pediatric cardiovascular defect measurement as a REBOA.

This device does not require placement over a guide wire and allows pressure measurement through an arterial port distal to the balloon. We utilized a partial-REBOA technique [10–12] achieving a target SBP of 90 mmHg, with a residual distal flow (confirmed by arterial pressure measurement through the femoral sheath).

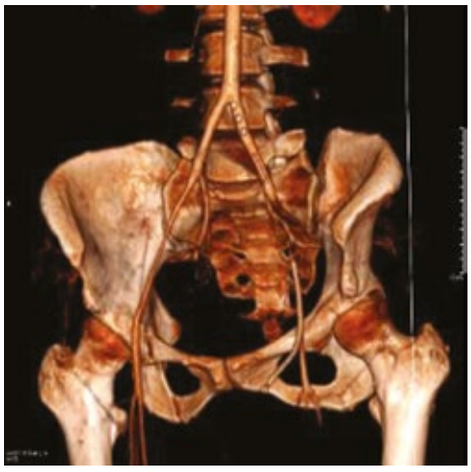

Figure 1 Introducer sheath positioned in the left common femoral artery (note that the image was taken for the best resolution and visualization of the introducer, but REBOA is retracted during the phase of replacement from Zone 3 to Zone 2).

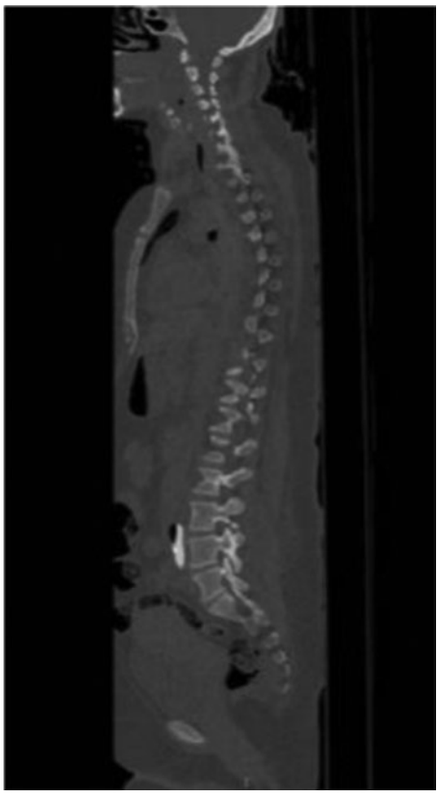

Figure 2 CT-scan showing REBOA in zone 3, between renal arteries and aortic bifurcation.

Figure 3 Balloon catheter used as REBOA.

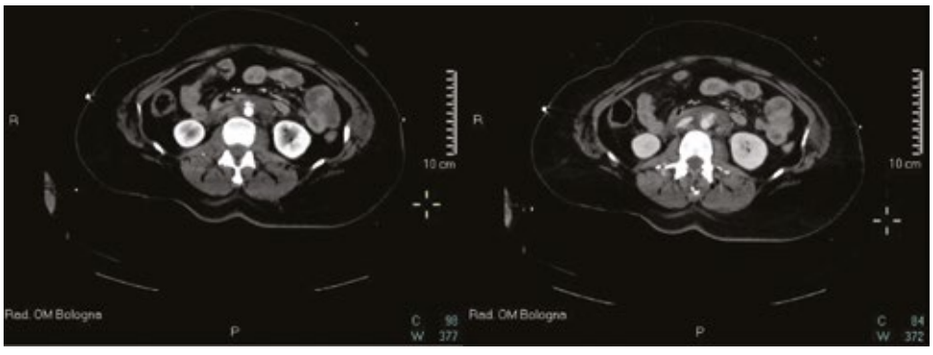

Figure 4 Aortic leak in the arterial and portal phases.

After obtaining an acceptable hemodynamic response, it was possible to transfer the patient to the radiology service and to perform a CT scan, which showed two important bleeding sources: a grade 4 BAAI just below the renal arteries (Fig. 4) and a pelvic injury with active arterial blush (Fig. 5).

Since our trauma team has multidisciplinary components, after collegial discussion, the REBOA was repositioned with CT guidance in zone 2, between the celiac tripod and the superior mesenteric artery, despite contraindication [9], to exclude the aortic injury and stop the bleeding. Considering the elevated grade of the aortic injury and the ready availability of both vascular

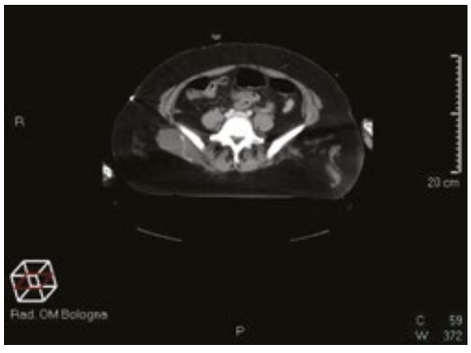

Figure 5 Gluteal arterial blush with hematoma (portal phase).

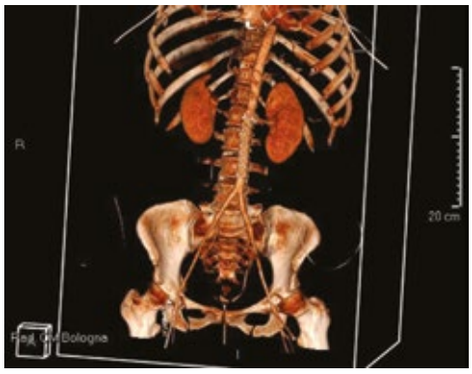

Figure 6 Endovascular prothesis.

surgeon and interventional radiologist we decided to perform endovascular aortic repair (EVAR) first.

In about 1.5 hours from the arrival at the ED, we transferred the patient to the OR with REBOA inflated in zone 2 above the IV grade BAAI. The team leader performed the anesthetic management. The vascular surgeon isolated and cannulated the right common femoral artery. When everything was ready to perform the angiographic study, we deflated and removed the REBOA. A covered endoprosthesis Endurant™ II (Medtronic, ETLW1616C93EE) was placed just below the renal arteries, with a proximal landing zone of 1 mm, and above the iliac bifurcation (Fig. 6). At the end of the procedure, the arteriotomy was sutured with Prolene 6/0 and a drainage left in place. It was a relatively simple procedure, requiring 1 hour. Renal artery flow was documented at the end of the procedure. After collegial discussion we decided not to infuse heparin, because of the ongoing bleeding. The pelvic blush was stopped subsequently by the interventional radiologist through the same sheath in the left femoral artery, with hemostatic sponge in several branches of the right hypogastric artery.

Total inflation time of the REBOA was 30 minutes in zone 3 and 45 minutes in zone 2. The catheter was left in place for 2 hours. The sheath was left in place for 19 hours, in case of emergent reintervention. It was then removed by our interventional radiologist utilizing the Angio-Seal™ vascular closure device. A distal flux was present during the angiography, demonstrating that the size of the introducer fits the vessel avoiding limb ischemia, until the removal left limb was clinically evaluated as normothermic and well perfused. Access site surveillance was carried out by our Intensive Care Unit nurses.

The patient survived the procedure and is still alive with a positive outcome, despite having an ISS of 75. Other main injuries included: subarachnoid hemorrhage, traumatic right carotid artery dissection, thyroid hematoma, multiple rib fractures, bilateral lung contusions, hepatic laceration, spleen devascularization, closed pelvic fracture, gluteal hematoma and multiple vertebral fractures. Early continuous renal replacement therapy was started to prevent crush syndrome consequences. The patient suffered from transient intestinal impairment and acute limb compartment syndrome as major complications of REBOA positioning, possibly related to ischemia-reperfusion injury.

Four days after trauma, after clinical suspicion , we diagnosed the compartmental syndrome of the left limb by measuring the circumference (right thigh 55 cm vs. left thigh 60 cm; right calf 32 cm vs. left calf 38 cm) and compartmental pressure (left calf internal compartment 70 mmHg; external compartment 86 mmHg). Fasciotomy was therefore performed as an emergency within 1 hour of diagnosis. Despite negative pressure therapy, necrosis of the fasciotomy occurred, making left leg amputation mandatory.

She also experienced post-traumatic stress disorder, extreme brady-arrhythmias requiring implantation of a pacemaker and an abscess of the gluteal hematoma requiring repeated surgical debridement.

After a total hospitalization time of three months she was discharged to a rehabilitation facility with an excellent neurological outcome, being autonomous in daily activities and without chronic organ failure.

DISCUSSION

REBOA is a resuscitative technique which involves percutaneous or surgical cut-down arterial access—usually via the femoral artery—to place a catheter balloon inside the aorta. The purpose of this procedure is partial or total occlusion of the aorta at different zones, in order to stop a distal hemorrhage. This procedure has been recently gaining popularity in the management of non-responsive hemorrhagic shock in different contexts, such as post-partum and gastrointestinal bleeding, abdominopelvic trauma and ruptured abdominal aortic aneurysm (rAAA) [13–16]. The first use of an aortic tampon for emergency control of a ruptured abdominal aneurysm dates back to 1964 [17]. A recent systematic review found 50 studies in which REBOA was used to control hemorrhagic shock in rAAA [18] and it is now considered a standard of care in this setting.

Indications and contraindications of REBOA in trauma are objects of discussion and revision [18–20]. Despite the experience in rAAA, the currently most cited contraindications are aortic injury together with thoracic lesions, especially of the large pulmonary vessels [19], since its distal placing would have the sole effect of increasing the bleeding [9]; nonetheless an anecdotal case of good outcome has been described [21]. For these reasons, reported use of REBOA in traumatic abdominal aortic injury remains sporadic [16].

In the past, laparotomy was used to manage BAAI and EVAR was not deemed suitable because the time needed to set up the procedure was considered too long given the impending risk of death. Patients suitable for EVAR were reported to be younger, hemodynamically stable and less critically ill (lower ISS) [4]. Recently, successful endovascular treatment of BAAI has been described, revolutionizing the approach for this scenario [1,22], although there is a lack of comparative data between the pros and cons of the two techniques. A Cochrane Review comparing EVAR versus open repair in rAAA reported no difference in the 30-day mortality outcomes [23], even though none of the trials have randomized patients with hemorrhagic shock.

When available, anatomically feasible and safe EVAR is preferred over open repair [24], so it is reasonable to consider REBOA as a bridge to allow definitive endovascular treatment in more severe traumatic aortic injuries, as in rAAA.

In our case, the reasons for hemodynamic instability were multiple and the elevated grade of aortic rupture made patient survival very unlikely. One hypothesis was that severe hypotension (caused by thoracic, aortic and pelvic bleeding) in the pre-hospital phase prevents exsanguination from the aortic rupture. We also supposed that due to some precautions the aortic rupture was not iatrogenic: we placed the REBOA without a guidewire, we confirmed the correct balloon placement with ultrasound and we never overinflated the balloon, but used a partial inflation technique. In addition, an aortic injury below the renal arteries was compatible with the dynamic of the trauma, the vertebral fractures of D10 and L1–4, and the clinical presentation.

The use of REBOA in this case followed two different strategies: the first was the indication of a patient in extremis (the zone 3 step); the second, compared with rAAA, was the use under CT or fluoroscopic guidance to exclude the traumatic aortic lesion (the zone 2 step).

REBOA for trauma is generally blindly placed in extremis and the precise nature of a patient's injuries are unknown. In all patients who are victims of high impact collisions and in found in extremis condition, it is possible to suspect an aortic lesion. Nevertheless, some of these patients fit the criteria for positioning of zone 3 REBOA—as did the patient in our case—which can be a lifesaving procedure, even if excluding the possibility of an aortic lesion remains impossible because CT scan or angiographic study cannot be performed at that time. We therefore believe that aortic rupture cannot be "a priori" a contraindication in itself and that REBOA must be positioned in zone 3 when the patient requires it. Some strategies are mandatory to minimize both the possibility of causing new vascular injuries or increasing pre-existing ones. Above all, the most important point is partial occlusion: it reduces aortic wall stress (which can determine a vascular injury itself) and allows a decrease in distal flow and bleeding without increasing aortic bleeding or rupture. It also allows a target SBP to be reached—measured at the tip of the catheter: in our case we tried to achieve a SBP of 90 mmHg, which can be considered adequate both in blunt trauma (with negative FAST and without traumatic brain injury (TBI)) and in rAAA. In fact, recent guidelines on the care of patients with an AAA by the Society for Vascular Surgery suggest that a permissive hypotension (defined as a SBP between 70 and 90 mmHg) "appears sufficient to maintain critical end-organ perfusion" and "limits excessive haemorrhage" [24]. In our view this strategy allowed the transfer to the CT scan room with partial hemodynamic stabilization despite the undiagnosed IV grade BAAI.

At that moment, taking inspiration from rAAA management, we repositioned the REBOA above the rupture—even if it was in Zone 2—postponing angioembolization of the pelvis and performing EVAR. We utilized REBOA as a bridge to definitive endovascular management, and no longer as a lifesaving blind procedure.

CONCLUSIONS

Complex management was made possible by the contemporary presence in the trauma bay of different specialists in a multidisciplinary approach. Together with intensive care physicians and trauma surgeons, endovascular specialists complete our trauma team. All advanced trauma centers should improve their endovascular competence, including vascular surgeons and an interventional radiologists, who can cooperate in a hybrid suite. This strategy guarantees a modern approach to trauma patients, with conservative management in several injuries or prompt damage control resuscitation.

The indication for the use of REBOA in BAAI is still lacking, due to the potential risk of extension of the aortic lesion and the paucity of reported cases. We think that, with some precautions, placing REBOA in zone 3 in patients with correct indications is also almost safe in undiagnosed BAAI and the possibility of this finding must not be an exclusion criterion "a priori". Partial occlusion is nowadays mandatory to minimize complications: it allows a tailored SBP target to be reached, to protect the aorta wall and to reduce both distal bleeding and unpredictable proximal bleeding. These considerations, together with progressive experience and equipage training, led our Trauma Center to include the REBOA in HEMS equipment.

If BAAI is then diagnosed, the REBOA must be replaced proximal to the lesion with fluoroscopic or CT-scan guidance. This technique could represent a bridge to definitive treatment in life-threatening situations. Given the agreement on REBOA use in rAAA and the increasing experience in traumatic settings, it seems desirable to upgrade this approach in BAAI, from a

"last-ditch" attempt into part of a damage control resuscitation protocol. We think this is an important issue, that is also achievable in centers without our multidisciplinary team and which necessitate transfer of the patient for definitive vascular management.

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Residents Corner

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Endovascular Management following Unintentional Subclavian Artery Injury during Central Venous Catheter Placement

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Background: Traumatic injury to the subclavian artery during central venous catheter (CVC) placement is rare but can be catastrophic. Standard open surgical treatment is challenging and associated with significant complications. Presented is a case of endovascular treatment of these injuries and associated complications.
Methods and Results: This is a description of the endovascular repair of a subclavian artery injury during CVC placement at Örebro University Hospital.
Conclusions: This case report suggests that endovascular repair of subclavian artery injuries a less invasive and may decrease the morbidity and mortality associated with open surgical repair.

Keywords: *Subclavian Artery; Endovascular; Stent; Hemorrhage; Central Venous Catheter*

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INTRODUCTION

Central venous catheter (CVCs) are commonly placed in critically ill patients [1]. The procedure is performed bedside using anatomical landmarks or by ultrasound guidance [2]. Severe mechanical complications involving hemorrhage are rare but can be life threatening [3]. Traditional open surgical repair is challenging because of the difficult exposure and the close relationship to vital structures [4]. This case report describes the late detection, endovascular treatment and complication of a right subclavian artery injury after central venous catheter insertion.

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PATIENTS AND METHODS

This is a description of a clinical case where hemorrhage from the right subclavian artery was treated using endovascular repair at Örebro University Hospital, Sweden, by the on-call vascular surgeon in the hybrid operating room.

RESULTS

A previously healthy 38-year-old male was monitored and managed on the intensive care unit for bilateral pneumonia of unknown etiology. When the patients condition worsened, he was put under general anesthesia, intubated and, on day 6 a triple lumen CVC was inserted by an experienced intensive care physician into the right internal jugular vein using an ultrasound-guided supraclavicular approach. Subsequently, because of suspected pulmonary embolism, a computer tomography (CT) was performed which showed a 5 cm supraclavicular hematoma with ongoing extravasation from the right subclavian artery. The patient was hemodynamically stable and was taken to the hybrid operating room where the on-call vascular surgeon placed a 4 Fr introducer retrograde in the right brachial artery. The angiography showed continued extravasation (Figure 1). The introducer was upgraded to a 6 Fr and a 6 × 50 mm^2 Viabahn

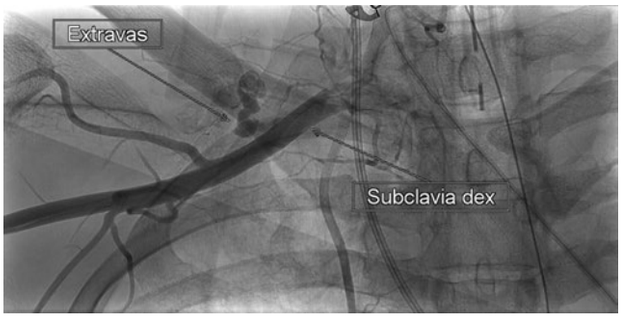

Figure 1 Angiography showing extravasation from the right subclavian artery after CVC placement.

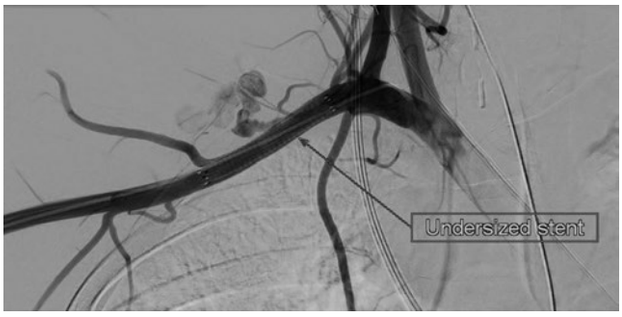

Figure 2 Undersized stent graft with continued extravasation from the right subclavian artery.

Figure 3 Angiography via right femoral access showing distal migration of undersized stent graft in the right subclavian artery.

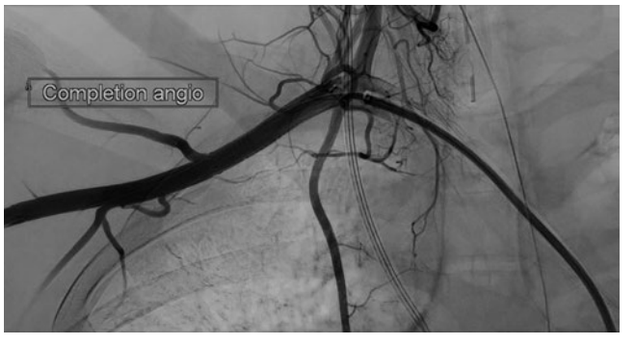

Figure 4 Completion angiography after placement of a correctly sized stent graft in the right subclavian artery showing no extravasation.

stent graft (W.L. Gore & Associates, Flagstaff, Arizona) was placed in the right subclavian artery, distally to the right vertebral artery, covering the vessel injury. The stent graft was, however, undersized resulting in continued extravasation (Figure 2). Additionally, the undersized stent graft migrated distally in the subclavian artery and after unsuccessful attempts were made to reposition the migrated stent graft the decision was made to puncture the right common femoral artery and a 6 Fr introducer was placed retrograde (Figure 3). An 8 × 50 mm^2 Viabahn stent graft was successfully positioned in the right subclavian artery, distally to the right vertebral artery, covering the vessel injury and discontinuing the extravasation (Figure 4). After the procedure, both radial and ulnar pulsations could be heard using doppler.

DISCUSSION

Misplacement or injury to the subclavian artery during CVC placement is reported in the literature and is almost always right-sided, thought to be because of the specific anatomy [5]. Most are detected immediately because of the bright red, pulsatile backflow from the puncture needle or cannula [6]. If not, it may be hard to identify as a hematoma since extravasation from the subclavian artery is generally only visible at a late stage and the outcome may then be catastrophic. A CT scan can be very useful for confirmation of the suspected diagnosis as well as determining its relation to other vessels. Once detected, surgical treatment is often required since alternative treatment is generally inadequate. Manual compression of the subclavian artery is often not possible because of subcutaneous tissue, bony structures, and as lack of structural support around the artery. Open surgical management of subclavian artery injuries is extensive requiring sternotomy or clavicular transection, associated with high morbidity and mortality in these often already critical patients [4]. Using an endovascular approach with stent grafts avoids the increased risk of open surgery but is, however, not risk free. The proximity of the subclavian artery to the origin of the vertebral artery risks thromboembolic events or covering the vertebral artery completely, and migration of the stent graft risks distal extremity ischemia [7]. The correct choice of stent graft is therefore paramount. Balloon-expandable stent grafts allow for higher precision when deployed, but self-expandable stent grafts have better long-term patency.

CONCLUSIONS

Endovascular management following traumatic subclavian artery injury during CVC placement is possible, effective and avoids the need for extensive open surgery. However, this carries its own risk of complications, which are important to be aware of.

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- JEVTM – the Journal of Endoascular Resuscitation and Trauma Management, an open access peer-reviewed journal.
- The EVTM round table symposium, a platform for continuous debate and data exchange.
- Educational opportunities in the form of manuals (Top Stent), courses, workshops, and web seminars.
- Promoting open dialogue and cooperation between societies, organizations and the industry.
- Promoting new guidelines and recommendations for EVTM-related issues and protocols.
- Promoting research in EVTM-related areas, both human and animal.
- Promoting PR for EVTM issues, grants, and collaboration with industry.
- Encouraging residents and young colleagues to carry out research on EVTM issues.
- Promoting cooperation and data exchange with other medical instances.

Structure:
The EVTM council, led by the society chair will change membership periodically (i.e., after two years). The council aims to have one or two representatives from each participating country and discipline.

The EVTM society is supported at this stage by Örebro University Hospital in all financial respects (as part of EVTM research group support). This support has been granted for the forthcoming two years.

The main task of the council is to pave the way for the EVTM venture, and promote the JEVTM/EVTM symposium, EVTM-related courses, cooperation, and free exchange of information.

Members will obtain free access to all JEVTM information and discussions as well as regular updates on EVTM-related activities, education, and developments. Members will also be offered a reduced fee for the EVTM round table symposium.

EVTM Society is registered in Sweden, and is managed in collaboration with the EVTM program at Örebro University Hospital, the JEVTM journal and web platform, and other institutes.

Since the society is registered in Sweden, it will follow the rules and guidelines of the Swedish government and the EU. Expansion to other countries is welcome, but should follow our ethical guidelines and the EVTM society should be named in all documents appropriately.

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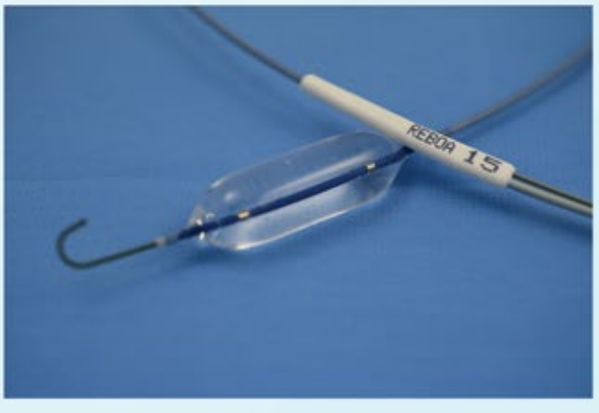

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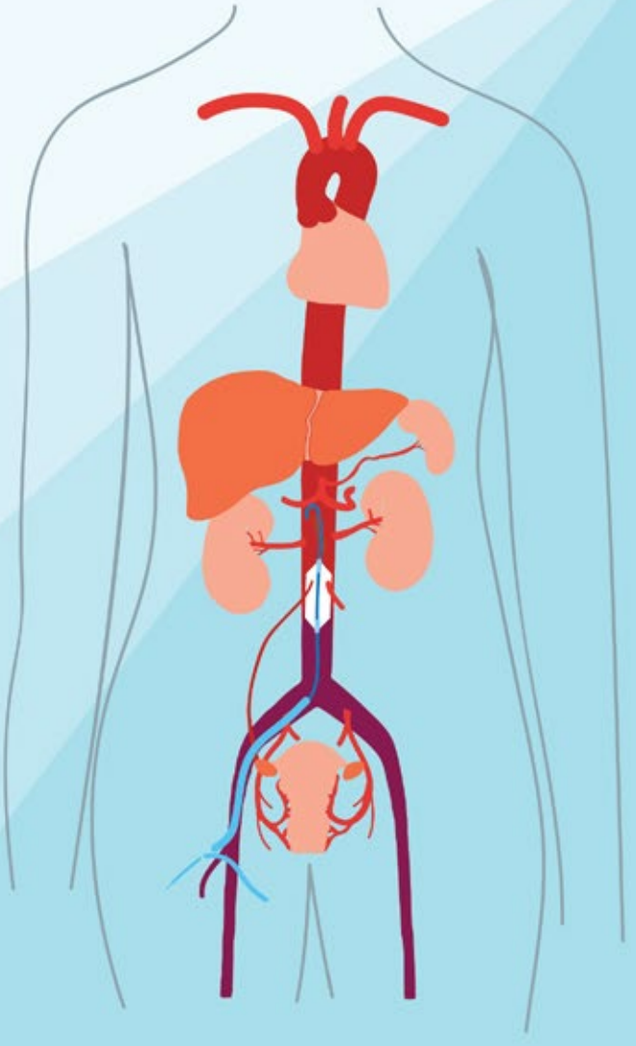

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