



# JEVTM

## Journal of Endovascular Resuscitation and Trauma Management

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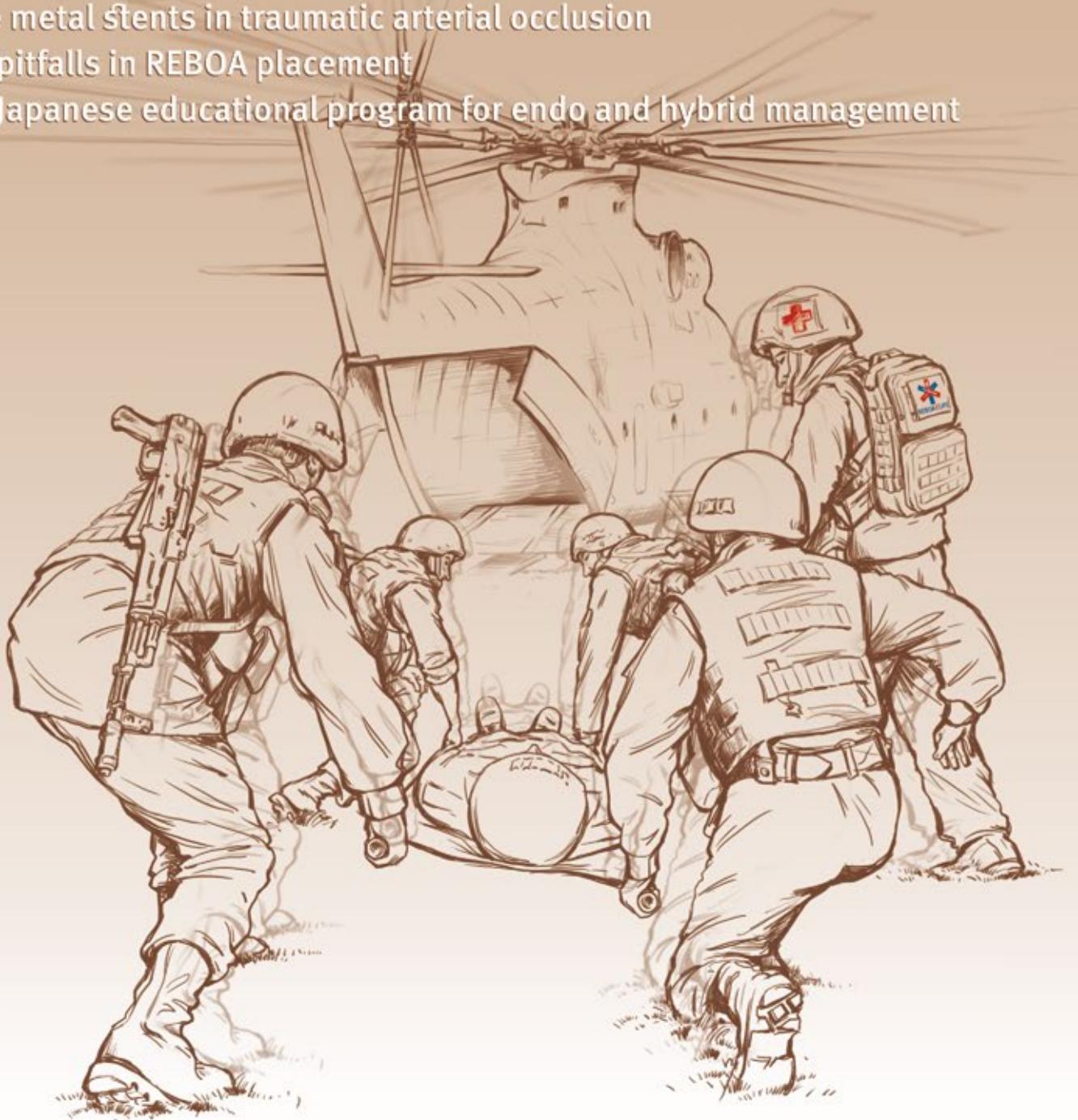
### Issue Highlights

Effect of severe traumatic hemorrhage on large arterial diameter

Bare metal stents in traumatic arterial occlusion

The pitfalls in REBOA placement

The Japanese educational program for endo and hybrid management



# J E V T M

## Journal of Endovascular Resuscitation and Trauma Management

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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](http://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.

The Journal will publish quarterly and will be truly Open Access. There will be no article processing charges or publishing fees. All articles will be published online and indexed using a digital object identifier. The Journal aims to be PubMed cited by 2019.

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# EVTM Society

## Join the Endovascular Resuscitation Platform

**The EVTM society is a non profit organization that aims to share information on advanced methods for bleeding control and endovascular resuscitation, exchange of data, and cooperation and education. It is also designed to serve as a professional platform for the multidisciplinary approach.**

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

### **Vision and Mission:**

Our mission is to promote optimal treatment and new methods for bleeding control in trauma and non-trauma patients, and state-of-the-art endovascular resuscitation. This will be achieved by a joint international body that will support the following:

- A web-based free platform for EVTM issues (jevtm.com).
- JEVTM – the Journal of EndoVascular and hybrid Trauma and bleeding Management, which promotes high quality research. It is an open access peer-reviewed journal.
- The EVTM round table symposium, which offers 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 and organizations, and with 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 information, and access to all JEVTM material. Members will also be offered a reduced fee for the EVTM round table symposium. A further benefit of society membership is receipt of regular updates on EVTM-related activities, education, and developments.

Members will be able to contribute in different ways, and create a professional discussion forum for this new movement. Information will be directed at members via JEVTM.com and different social media platforms.

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.

**Call for collaboration:** We call out to physicians with an interest in endovascular resuscitation, trauma and bleeding management. We need the contributions of the medical professionals who want to be a part of our venture.

**To join, please visit [www.jevtm.com](http://www.jevtm.com) and click on "Join the EVTM Society".** Membership is free at this stage.



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# Introduction to the Second Edition of JEVTM

**Megan L Brenner MD MS**

*RA Cowley Shock Trauma Center, Baltimore, Maryland, USA*

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Dear Readers,

Welcome to the second edition of the JEVTM! Our goal is to present quality, peer-reviewed articles to keep you up to date on all aspects of endovascular and hybrid therapies for resuscitation and trauma. This particular area is a rapidly growing field with a wide variety of specialties spearheading efforts all around the globe.

In this edition you will find articles relating to embolization and stent-grafting of injuries, potential pitfalls with REBOA placement from military and civilian experience, changes in arterial diameter with severe hemorrhage, a novel endovascular training paradigm from Japan, and the first reported use of REBOA for inter-hospital transfer of trauma patients in the US.

The cover illustration of this edition is a tribute to our military colleagues and friends. We thank you for your service, and for your relentless efforts in pushing REBOA and endovascular techniques forward safely and effectively. Our civilian–military partnerships are instrumental in helping to refine and improve the care of the injured patient.

We hope to see you all at the EVTM meeting in June!

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University Hospital and Örebro University, Sweden

# Bare Metal Stents Can Maintain Arterial Patency in Traumatic Occlusion

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**Background:** The standard approach to an occlusive vascular injury is open arterial reconstruction, although endovascular stenting is becoming more common, despite limited evidence. The aim of this study is to examine whether bare-metal stents can be effective in an ovine model of occlusive arterial trauma.

**Methods:** Through a groin incision, a 2-cm segment of the left superficial femoral artery (SFA) was bluntly injured using a hemostat and injection of air to achieve thrombosis. Animals then underwent a stent deployment (stent group,  $n = 5$ ) or no-treatment (control group,  $n = 5$ ). In the stent group, recanalization of the thrombotic lesion, thromboaspiration, and bare-metal stent deployment were performed. Enoxaparin 1.5 mg/kg was given to all animals. The stent group animals were fed clopidogrel 75 mg and aspirin 125 mg daily. Angiography and Doppler ultrasound were used to evaluate arterial patency during the 7-day observation period.

**Results:** A thrombosis was obtained in all cases. After a fall in the systolic velocity (SV, cm/sec) in both the control (43 (36–56) to 6 (0–16);  $P < 0.001$ ) and stent groups (45 (32–53) to 8 (0–12);  $P < 0.001$ ), stent implantation resulted in a significant permanent increase of the SV. Day 7 angiography confirmed SFA patency in all (5/5) stented animals, with persisting occlusions in the control group ( $P = 0.008$ ). There was no evidence of distal emboli in the run-off arteries.

**Conclusions:** Bare-metal stent implantation restores arterial patency of a traumatic occlusive lesion in a standardized ovine model with a short follow-up period.

**Keywords:** Arterial Trauma; Trauma Surgery; Endovascular Trauma Management; Bare-Metal Stent; Vascular Surgery

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design and acquisition of funding. IMS: Study design. Critical revision and work supervision.

**Conflicts of interest:** None.

**Funding:** This study was funded by a grant from the President of Russia #MK-7508.2016.7.

**Presentation:** Aspects of this work were presented orally at the 16<sup>th</sup> Congress of the European Society for Trauma and Emergency Surgery, May 10–12, 2015, in Amsterdam, the Netherlands.

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## INTRODUCTION

Vascular injury represents a significant source of mortality and morbidity in trauma patients [1]. Arterial injury can present as hemorrhage, pseudoaneurysm formation, dissection or occlusion. Hemorrhagic lesions can often be very dramatic, with exsanguination constituting a major cause of potentially preventable death [2]. Occlusive lesions, while less dramatic, affect one-in-five patients with arterial injury and can lead to significant morbidity without prompt reperfusion [3,4].

The mainstay of contemporary management is with operative repair using an interposition or bypass graft in threatened limbs [5]. Endovascular intervention offers another method with which to assess and treat arterial injury. The advantage of such an approach is less invasiveness and relatively easy access to anatomical regions that are challenging to approach via open surgery [6]. This has resulted in a substantial increase in the use of endovascular intervention in arterial trauma; however, this has mainly been done on an impromptu basis and does not have a strong evidence base [3,4,7].

The current experience of traumatic arterial occlusion leans toward the use of covered nitinol stent-grafts to restore patency [8]. The alternative is the use of bare-metal balloon-expandable stents, which has not been evaluated in this context previously. The aim of this pilot study is to examine whether bare-metal stents can be effective in an ovine model of occlusive arterial trauma.

## MATERIALS AND METHODS

### Overview

Experiments were carried out in an accredited specialized animal research laboratory under the supervision of veterinary staff. Approval for the study was obtained from the local institutional ethics committee of the Kirov Military Medical Academy (protocol no. 163, approved June 30, 2015). All work was carried out in accordance with the National Institutes of Health guide for the care and use of laboratory animals.

The study utilized female, non-pregnant North Caucasus sheep, weighing between 35 and 45 kg. Sheep were housed in quarantine at the animal facility for 7 days to ensure good health and permit acclimatization. Prior to enrollment in the study protocol, animals were fasted for 36 hours, with free access to water. The study comprised a four-stage protocol consisting of preparation, injury, intervention (stent or control) and follow-up phases (Figure 1).

### Animal Preparation

General anesthesia was induced using an intramuscular injection of tiletamine and zolazepam (Zoletil®; Virbac,

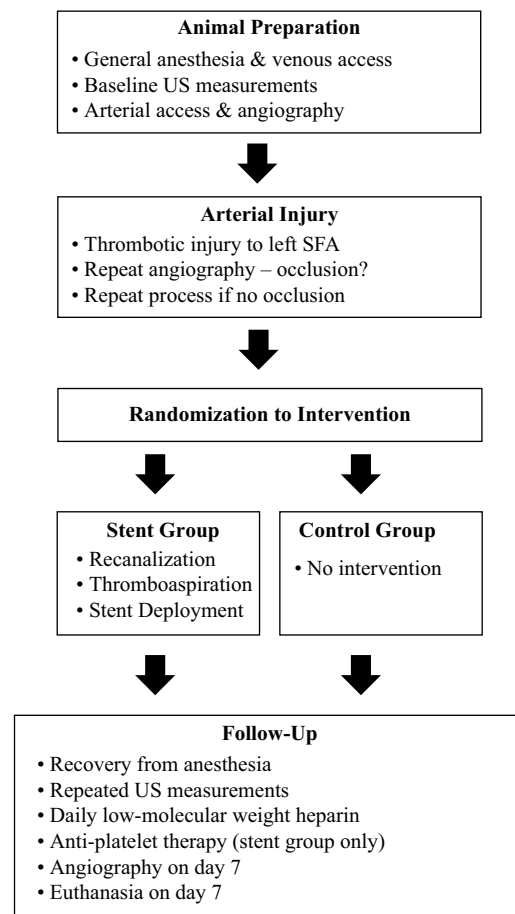


Figure 1 Overview of the experimental protocol.

Carros, France) at a dose of 10 mg/kg. A 1.5 mg intravenous (IV) injection of atropine was also administered to reduce salivation and help facilitate orotracheal intubation. Anesthesia was maintained using inhaled isoflurane at 1–2% concentration. Animals were placed on a radiolucent operating room table in dorsal recumbency. An orogastric tube was inserted for the administration of medication. A 6 French (Fr) sheath was placed into an external jugular vein for drug and fluid delivery. Maintenance fluid (Sterofundin, B. Braun, Germany) was administered at a rate of 3–4 mL per minute during surgical procedures using an infusion pump.

Both groins were prepared with an alcohol solution and draped. Ultrasonography (US) was used to collect baseline measurements of the left and right superficial femoral arteries (SFA). Measurements were made using the linear transducer (10–5 MHz) of a Micro-Maxx® Ultrasound System (Sonosite Inc., Bothell, WA, USA). US was then used to guide the retrograde cannulation of the right SFA between its middle and distal third. A 6 Fr sheath was then inserted over a wire into the vessel, which was used for endovascular access, continuous blood pressure monitoring, and blood sampling.



**Figure 2** Computed tomography (CT) angiography of the injured left superficial femoral artery demonstrating a sharp cut-off (arrow).

Following baseline blood sampling, catheter angiography of the left-sided extremity was accomplished through the right arterial sheath. A 0.035" wire and a 5 Fr multipurpose small (MPS) catheter (Cordis Endovascular, USA) were used to cross over the aortic bifurcation and to cannulate the orifice of the left iliac artery. An iodine contrast agent Iopamidol 300 mg I/mL (Scanlux, Sanchemia Pharmazeutika AG, Austria) was used in an equal mixture with 0.9% saline for angiography. Images were captured using a mobile fluoroscopy unit or "C-Arm" (SM-20HF, Listem Corporation, Republic of Korea).

### Arterial Injury

This injury model has been previously described in detail [9]. Briefly, a 2-cm segment of the left SFA is exposed through a 5–7 cm incision in the groin crease. Proximal and distal control is established and the arterial segment traumatized by repeated clamping and un-clamping of a hemostat. Air (0.5 cc) was injected into the lumen and then aspirated after one hour. Finally, the clamps were removed to restore inline blood flow.

Repeat angiography was then performed via the right groin to assess the lesion. If this demonstrated a complete occlusion, the groin incision was closed with interrupted sutures and post-injury US measurements taken. If flow was observed across the lesion, the lesion was controlled for a further 30 minutes and another cycle of clamp trauma performed. Figure 2 presents a CT angiogram of a characteristic occluding lesion produced by this method.

Following the demonstration of an occluding lesion, animals were ventilated for 60 minutes, simulating the time from injury to treatment. Animals were then randomly allocated to one of two groups: animals undergoing revascularization with a bare-metal stent (stent group,  $n = 5$ ) or a control group undergoing no-treatment (control group,  $n = 5$ ).

### Intervention – Stent Group

Animals in the stent group underwent a complex endovascular procedure consisting of three parts: recanalization of the thrombotic lesion, thromboaspiration, and stent deployment. One surgeon trained in vascular and endovascular surgery performed all of the operations (VAR).

A 6-Fr guiding contralateral II catheter (Cordis Endovascular, USA) was advanced into the orifice of the left SFA. After per os administration of a loading dose of 150 mg clopidogrel, 125 mg aspirin and 50 units/kg of IV heparin, recanalization of the occlusive thrombotic lesion was performed using a 0.014" hydrophilic intermediate stiffness guide wire (Angioline, Novosibirsk, Russia) (Figure 3a). When passed through the occlusion zone, the tip of the guidewire was placed in the popliteal artery.

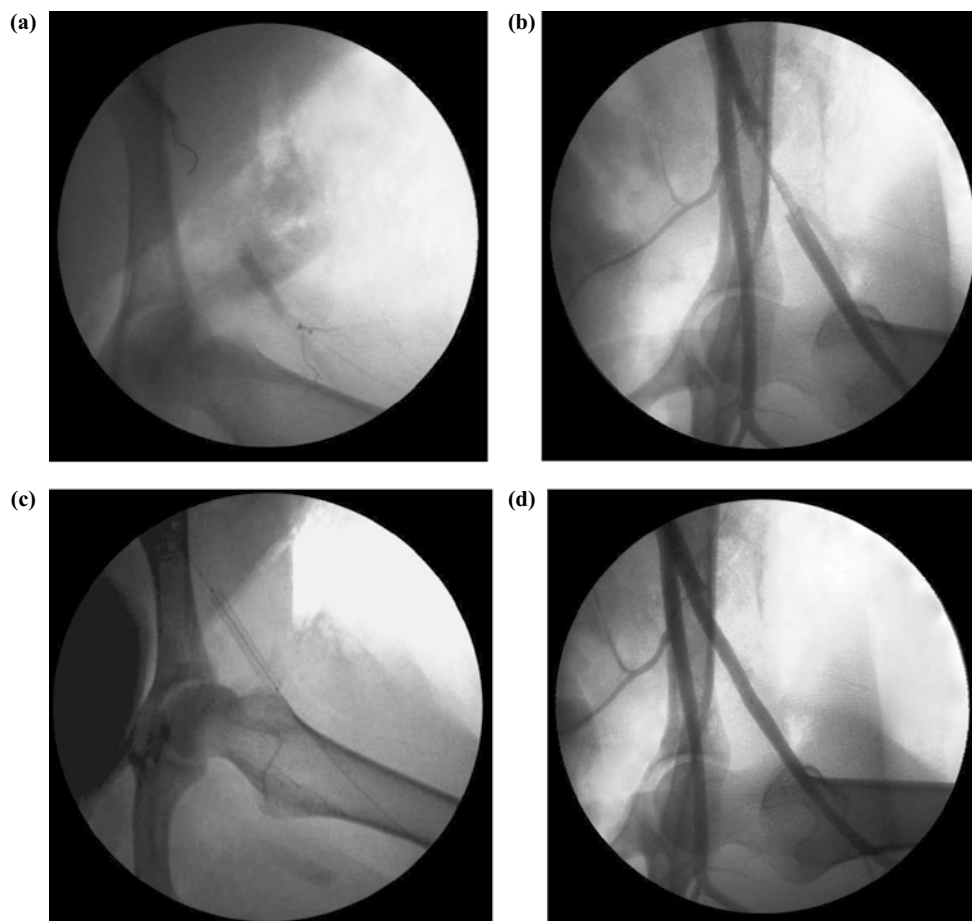
To evaluate an extension of the occlusive lesion and to prevent distal emboli during stent positioning and deployment, a thromboaspiration procedure was performed. A 6 Fr Eliminate™ aspiration catheter (Terumo, Tokyo, Japan), was passed across the lesion between one and three times, sufficient to permit flow on repeat angiography (Figure 3b). A Sinus™ balloon-expandable bare-metal stent (Angioline, Novosibirsk, Russia) was then inserted over the wire and positioned across the lesion. US and angiographic images were used to determine appropriate stent size. The stent was deployed under a nominal pressure of 9 atm (Figure 3c). If the diameter of the SFA was slightly larger than previously measured on the US, then a balloon was overinflated to 12–15 atm (rated burst pressure is 18 atm). Following deflation and balloon removal, completion angiography was carried out (Figure 3d). At the conclusion of the procedure, catheters, wires, and sheath were removed and manual hemostasis performed for 5–7 minutes.

### Intervention – Control Group

For the animals in the control group, no operation was performed or primary anticoagulation administered. Arterial and venous access sheaths were removed 60 minutes after the SFA thrombosis was obtained.

### Follow-Up

Following completion of the intervention phase, a post-operative blood sample was drawn and US measurements were taken. The sheep then were extubated and placed into vivarium with free access to food and water.



**Figure 3** Endovascular sequence for revascularization for the stent group: (a) recanalization, (b) thromboaspiration, (c) stent deployment. (d) Completion angiography demonstrates arterial patency.

Postoperatively and daily thereafter, all animals received 1.5 mg/kg of enoxaparin SC and 1.0 g of cefazoline IM. Animals in the stent group also received 75 mg of clopidogrel and 125 mg of daily aspirin. The wound dressing was changed every other day.

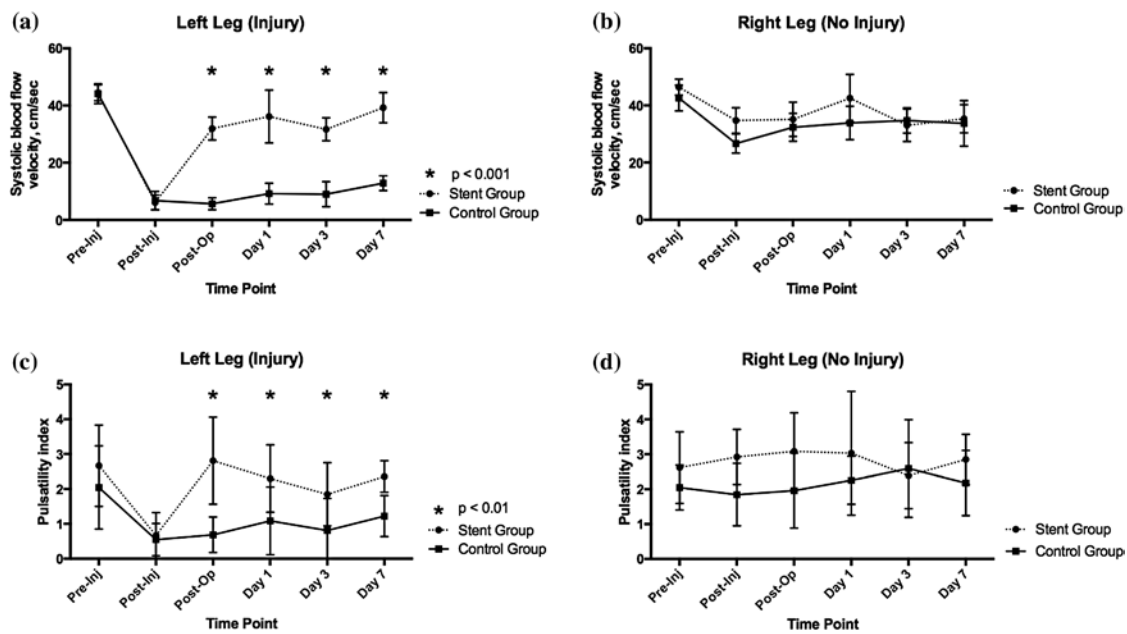
Each animal's hind limb function was assessed daily by means of the modified Tarlov hind limb function scale. This is a 5-point ordinal scale from 0 to 4, where 0 is the worst score (unable to sit, paralyzed limb) and 4 the best score (fully ambulatory). US measurements were performed on post-injury day 1, 3 and 7.

On post-injury day 7, the animals in both groups were transported to the operating room and underwent general anesthesia as described earlier. The left carotid artery was instrumented using a 6 Fr sheath. The orifice of each external iliac artery was then selectively cannulated with an MPS catheter, permitting angiography of each extremity. This allowed for an estimation of the patency of the femoral and popliteal arteries. Once the angiography was complete and a final blood sample from the jugular vein was taken, the animal was euthanized by exsanguination under anesthetic.

### **Study End-Points and Statistical Analysis**

The primary end-point of this study was stent patency, which was assessed using a combination of US measurements and angiography. US was used to assess blood systolic velocity (SV), measured in cm/sec and pulsatility index (PI), comparing the left (injured) and right (control) sides at the following time points: pre- and post-injury, and post-operative at day 1, 3 and 7. Each US parameter was valued three times to minimize error. Angiography was performed on day 7 to assess stent patency and the run-off to look for evidence of occluding distal emboli in the branches of the SFA, deep femoral and popliteal artery with its two main branches.

Secondary end-points consisted of laboratory indices of hypocoagulation, reperfusion injury, contrast-induced acute kidney injury (AKI), complications relating to arterial access, functional gait outcomes, and the need for euthanasia due to limb-related problems. Laboratory tests included activated partial thromboplastin time (APTT), international normalized ratio (INR), prothrombin time (PT), creatinine, urea, and lactate.



**Figure 4** Ultrasonographic measurements of blood flow. Graphs demonstrate a significant increase of (a) systolic blood flow velocity (SV) and (c) pulsatility index (PI) in the left (injured) leg and no changes in (b) SV and (d) PI in the right (control) leg in post-operative period and during the 7-day observation period.

Data were analyzed using GraphPad Prism v6.0 (Graphpad Software Inc., La Jolla, CA, USA). Variables were evaluated for normal distribution, and nonparametric data were reported as medians with interquartile ranges (IQRs). Between-group and within-group comparisons were performed using a two-tailed Mann-Whitney *U* test. Data for two groups with repeated measures were assessed with two-way analysis of variance (ANOVA). A *post hoc* Bonferroni correction was applied for multiple comparisons. Chi-square test was used to compare ordinal data. Fisher's exact test was used to compare SFA patency rate between groups. Results were considered significant when  $P \leq 0.01$ .

## RESULTS

### Baseline Characteristics, Arterial Injury, and Intervention

A total of ten sheep underwent induction of a traumatic SFA thrombosis and were then randomized into either the stent ( $n = 5$ ) or control ( $n = 5$ ) groups. There were no significant differences observed between the groups when comparing baseline characteristics, laboratory tests or hemodynamic parameters (Tables 1 and 2).

An occluding thrombosis was successfully created in all animals, as observed on angiography, taking on average 60 mins to achieve (Table 1). This was confirmed by US flow indices, which fell when comparing the pre- to post-injury values in the left limb (Figure 4). The fall in

SV was similar for both the control (43 (36–56) to 6 (0–16);  $P < 0.001$ ) and stent groups (45 (32–53) to 8 (0–12);  $P < 0.001$ ). There was no significant change in US indices measured in the uninjured limb for either group.

Recanalization of the occlusive thrombi was the most time-consuming part of the whole procedure taking 80 minutes on average (Table 1). It was likely due to significant intima-media injury resulting from an excessive force applied to a vessel wall during the creation of the injury. After passing the occlusion, all animals allocated to the stent group underwent successful deployment of a balloon-expandable bare-metal stent, across the zone of arterial injury. No distal emboli were observed on angiography at the time of stent deployment.

### Primary Outcome: Stent Patency

Stent deployment saw the restoration of inline flow through the SFA on angiography. This was accompanied by a significant rise in SI and PI measurements when comparing the stent group against the control group (Figure 4). These changes were sustained through to day 7, when angiography confirmed SFA patency in all (5/5) stented animals, with persisting occlusions in the controls (Table 1;  $P = 0.008$ ). There was no evidence of distal emboli in the run-off arteries on angiography at day 7. There were no significant differences in US measurements recorded between the stent and control groups in the uninjured limb.

**Table 1** A comparison of baseline, operative and follow-up characteristics between groups.

Parameter	Stent Group	Control Group	P
<i>n</i>	5	5	
Female	5 (100%)	5 (100%)	
Weight, kg	39.0 (36.5–41.0)	38.0 (36.5–41.0)	0.976
<i>Physiology</i>			
Heart rate, beats/min	71 (60–82)	88 (62–105)	0.341
Systemic SBP, mmHg	110 (105–121)	107 (103–128)	0.857
<i>Thrombosis</i>			
Time to creation of injury, min	60 (60–105)	60 (60–150)	0.841
<i>Operative</i>			
Anesthesia time, min	300 (225–330)	210 (180–270)	0.143
Operative time, min	80 (63–120)	–	–
Intraoperative fluids, mL	950 (740–1,125)	800 (650–960)	0.548
Intraoperative heparin, U	4,000 (3,500–4,500)	500 (400–550)	0.008
Volume of contrast medium, mL	100 (100–113)	40 (40–55)	0.008
<i>Tarlov gait score</i>			
Day 1	2 (2–2)	2 (2–3)	0.970
Day 3	3 (3–4)	3 (3–4)	0.990
Day 7	4 (4–4)	4 (4–4)	1.000
<i>Arterial data</i>			
Diameter of SFA, mm	4.0 (3.8–4.0)	3.5 (3.5–4.2)	0.524
EOS Patency (%)	5/5 (100)	0/5 (0)	0.008

Values are median (IQR). Mann–Whitney U Test is used to compare continuous data, chi-square test and the Fisher's exact test is used to compare Tarlov gait score and the patency of the targeted SFA, respectively. EOS, end-of-study; SBP, systolic blood pressure; SFA, superficial femoral artery.

**Table 2** A comparison of end-of-study characteristics between groups.

Parameter	Stent Group		Control Group		BL vs. EOS P*	BL vs. EOS P*	BL	EOS
	BL	EOS	BL	EOS				
					SG vs. CG		P*	P*
Hb, g/dL	10.3 (9.0–11.1)	9.3 (9.3–9.8)	0.206	10.1 (8.8–11.0)	9.9 (8.1–10.7)	0.460	0.794	0.881
RBC, $\times 10^{12}/L$	9.9 (3.3–11.3)	9.1 (3.4–9.6)	0.548	9.4 (8.4–12.3)	9.2 (7.4–12.0)	0.841	0.691	0.421
WBC, $\times 10^9/L$	44.1 (22.6–56.4)	35.0 (9.2–44.7)	0.310	42.8 (12.4–52.5)	47.2 (27.8–49.5)	0.841	0.841	0.095
Platelets, $\times 10^9/L$	180 (115–310)	470 (457–490)	0.100	236 (211–506)	364 (261–629)	0.746	0.250	0.250
APTT, s	47.3 (39.0–64.8)	36.1 (33.4–49.8)	0.421	45.4 (30.4–48.6)	35.2 (26.3–40.1)	0.222	0.421	0.310
PT, s	37.3 (34.9–39.0)	36.0 (24.0–42.0)	0.886	34.3 (31.0–40.0)	41.0 (31.3–53.4)	0.310	0.413	0.286
INR	2.4 (2.2–2.5)	2.3 (1.4–2.8)	0.886	2.2 (1.9–2.6)	2.7 (2.0–3.7)	0.310	0.413	0.286
Lactate, mmol/L	2.2 (1.5–2.9)	3.9 (2.2–7.2)	0.151	2.1 (1.4–3.6)	2.1 (1.7–2.9)	0.999	0.999	0.151
Urea, mmol/L	6.4 (5.7–7.2)	9.9 (7.9–12.7)	0.016	11.1 (7.4–13.0)	11.8 (6.4–12.9)	0.905	0.032	0.999
Crea, $\mu\text{mol}/L$	34.3 (25.5–38.1)	35.2 (6.2–67.5)	0.999	51.1 (35.2–82.2)	64.6 (36.9–83.5)	0.999	0.143	0.310

Values are median (IQR). \*Mann–Whitney U Test.

APTT, activated partial thromboplastin time; BL, baseline; CG, control group; Crea, creatinine; EOS, end-of-study; Hb, hemoglobin; INR, international normalized ratio; PT, prothrombin time; RBC, red blood cells; SG, Stent group; WBC, white blood cells.

### Secondary Outcomes: Laboratory Indices, Limb Function, and Morbidity

Table 2 reports the laboratory indices recorded at baseline (BL) and end-of-study (EOS). The only parameter to trend toward a significant difference was the urea value in the stent group demonstrating a tendency to AKI due to much more contrast agent administered to animals of this group (Table 1). This saw a rise from

6.4 (5.7–7.2) at BL to 9.9 (7.9–12.7) at EOS, although this did not achieve statistical significance ( $P = 0.016$ ).

The experimental protocol did not result in a significant reduction in limb function. The lowest Tarlov gait score took place on post-injury day 1, while all animals demonstrated an improvement in their scores over time (Table 1). By day 4, the majority of animals has achieved a Tarlov score of 4, with all animals fully ambulatory by day 7. There was no significant difference in Tarlov gait

score between the groups at any time point including EOS (Table 1).

All animals were followed up to day 7, with none requiring euthanasia. No cases of death or limb necrosis were observed in either group. One animal in the stent group had sustained a puncture site hematoma (pseudoaneurysm excluded by US) which had completely resolved by post-operative day 3.

## DISCUSSION

The current study is the first to report the performance of bare-metal stents in an ovine model of traumatic arterial occlusion. An endovascular procedure consisting of recanalization, thromboaspiration, and stenting was demonstrated to be effective in restoring and maintaining arterial patency for the 7-day duration of the study. End-of-study angiography did not identify any evidence of distal emboli and no animal requiring euthanasia for a limb-related complication.

This work builds on our group's research into the management of traumatic arterial occlusion. We have previously described the injury model employed in this study, which demonstrates the ease with which a reproducible occlusive lesion can be produced, with minimal animal morbidity [9]. Within that study, we also successfully demonstrated the compatibility of human endovascular maneuvers within the ovine arterial tree. The current study expands upon this work, by formally assessing the performance of a bare-metal stent compared to a control group, using this injury model.

Few investigators have sought to examine the role of stents and stent-grafts in large animal models of arterial injury. Most models have been developed to investigate mechanisms of vascular trauma [10,11], methods of diagnosis [12] and the efficacy of open surgical treatment [13–15]. The majority of the published literature in regard to stents and stent-grafts relate to long-term biocompatibility testing of new devices in normal arteries [16–18].

In a recent paper, Tang and co-workers proposed the deployment of a covered stent through an open incision in order to permit revascularization [19]. The authors created a 2-cm defect of the ovine SFA and then deployed a covered stent inside through a distal arteriotomy. Aspirin 325 mg was administered and US revealed 5/8 stents patent at 2 months postoperatively. Overall, their view was that this technique held promise for surgeons unfamiliar with vascular anastomoses, but required further study.

This is in contrast to the clinical evidence published in regard to endovascular intervention in trauma. Several large retrospective registry studies have seen a year-on-year increase in the reporting of endovascular technique in trauma [3,5,7]. However, the introduction of these techniques has been very informal and relate to the *ad hoc* extension of techniques employed in vascular disease to trauma.

The most detailed clinical data published to date is from the prospective PROOVIT registry [4]. Occlusive arterial injuries occurred in 17.7% of patients sustaining a vascular injury, although only 7.4% were managed by endovascular means. The most common arteries treated by endovascular means were the aortic and iliac segments.

The current study builds on this evolving evidence base by using a standardized model to test a bare-metal stent, in “ideal” trauma circumstances, ie: where anticoagulation was permitted. The choice of stent in this study is unusual, in that most clinicians would elect to use a fabric-covered stent-graft, usually incorporating a self-expanding alloy such as nitinol. While a stent-graft may appear an intuitive choice, for a purely occlusive lesion, there is no strong evidence supporting either type of conduit.

A balloon-expandable bare-metal stent has the advantage of precise deployment control, coupled with the option to increase the diameter in the event of undersizing while being relatively inexpensive compared to self-expanding stent-grafts. In theory, thrombus can protrude through the metal to initiate an in-stent thrombosis or distal embolism. No instances of either were observed in the current study. A drawback of bare-metal stents is their rigidity, thus a relatively akinetic segment of artery was selected, as deployment across joints and mobile regions is contra-indicated. It is especially important for the young and healthy trauma population, where long-term patency has not been well investigated and open vascular repair likely remains the gold standard.

There are several limitations to discuss. The current study is small, only consisting of two groups of five animals and thus should only be characterized as a pilot study. The “control” group consisted of no intervention which does not necessarily reflect current practice, where an interposition graft or similar could have been fashioned.

Animals of the stent group were administered dual antiplatelet therapy according to a current protocol for peripheral arterial interventions [20,21]. Relatively high daily dosages of both clopidogrel and aspirin were given as recommended in some ovine models [19,22–24]. Connel et al. found that the sheep, weighing even less than our animals, 17–35 kg, had a modest antiplatelet response (platelets inhibition by 25–36%) to 75 mg of daily clopidogrel [22]. The dose of aspirin that the sheep receive varies between studies, but doses of 81 or 325 mg of daily aspirin prevail [19,23–25]. As long as aspirin has shown to be ineffective in the inhibition of platelet aggregation in sheep [26], we chose a mid-dose taking into account that no clear recommendation and evidence exists.

Furthermore, a follow-up period of 7 days can only really assess early in-stent thrombosis and gives no indication of the risk in later occlusion. The long-term aim is to extend this model to a much longer follow-up (e.g., months) in future study protocols.

Finally, and most importantly, trauma rarely happens in isolation, which has significant local and systemic effects. Hemorrhage and tissue injury can result in both



hypo- and hypercoagulable states, a source of considerable concern when implanting an endo-prosthesis. In the current study, the isolated injury was anti-coagulated with both heparin and dual antiplatelet agents – circumstances rarely permissible in trauma care, especially in the setting of a concomitant head injury.

Despite these limitations, the current study adds to the evidence base surrounding this emerging intervention, by demonstrating the feasibility of bare-metal stenting in occlusive vascular trauma. The methods and models used in this study now need extending to more complex lesions, including significant blood loss, different types of graft, with and without anticoagulation and/or platelet inhibitors and for longer follow-up periods.

## CONCLUSIONS

The present study demonstrates that bare-metal stent implantation appears to perform well in the setting of a standardized ovine model with a short follow-up period. Minimal morbidity was incurred and the ovine arterial tree appears well suited to endovascular research. However, this conduit requires comparison with other methods of revascularization and a longer term of study in order to better appreciate its role in traumatic vascular occlusion.

## REFERENCES

- [1] Rasmussen TE, Tai NRM. Rich's Vascular Trauma. 3<sup>rd</sup> ed. Philadelphia: Elsevier; 2016.
- [2] Teixeira PG, Inaba K, Hadjizacharia P, et al. Preventable or potentially preventable mortality at a mature trauma center. *J Trauma*. 2007;63:1338–46.
- [3] Branco BC, DuBose JJ, Zhan LX, et al. Trends and outcomes of endovascular therapy in the management of civilian vascular injuries. *J Vasc Surg*. 2014;60:1297–307.
- [4] DuBose JJ, Savage SA, Fabian TC, et al. The American Association for the Surgery of Trauma PROspective Observational Vascular Injury Treatment (PROOVIT) registry: multicenter data on modern vascular injury diagnosis, management, and outcomes. *J Trauma Acute Care Surg*. 2015;78:215–22.
- [5] Avery LE, Stahlfeldt KR, Corcos AC, et al. Evolving role of endovascular techniques for traumatic vascular injury: a changing landscape? *J Trauma Acute Care Surg*. 2012;72:41–6.
- [6] DuBose J, Recinos G, Teixeira PG, Inaba K, Demetriades D. Endovascular stenting for the treatment of traumatic internal carotid injuries: expanding experience. *J Trauma*. 2008;65:1561–6.
- [7] Reuben BC, Whitten MG, Sarfati M, Kraiss LW. Increasing use of endovascular therapy in acute arterial injuries: analysis of the National Trauma Data Bank. *J Vasc Surg*. 2007;46:1222–6.
- [8] Jacks R, Degiannis E. Endovascular therapy and controversies in the management of vascular trauma. *Scand J Surg*. 2014;103:149–55.
- [9] Reva VA, Morrison JJ, Denisov AV, et al. Development of an ovine model of occlusive arterial injury for the evaluation of endovascular interventions. *Vascular*. 2016;24:501–9.
- [10] Karlander LE, Lidman D, Franzén L. The effect of severe contusion on the vessels of the femoral region. An experimental morphological study. *Scand J Plast Reconstr Surg Hand Surg*. 1991;25:1–4.
- [11] Scola E, Holch M. [Experimental over-stretching of the femoral artery in the sheep in situ]. *Unfallchirurg*. 1990;93:15–8. German.
- [12] Panetta TF, Hunt JP, Buechter KJ, Pottmeyer A, Batti JS. Duplex ultrasonography versus arteriography in the diagnosis of arterial injury: an experimental study. *J Trauma*. 1992;33:627–35.
- [13] Su WF, Chen LE, Seaber AV, Urbaniak JR. The effect of exposure time on microsurgical anastomoses of experimentally crushed arteries. *Int Angiol*. 1995;14:243–7.
- [14] Liu P, Peng X, Liu J, et al. Surgical treatment for rabbits' femoral arteries subjected to gunshot wounds combining with seawater immersion. *Chin J Traumatol*. 2005;8:311–6.
- [15] Burkhardt GE, Spencer JR, Gifford SM, et al. A large animal survival model (*Sus scrofa*) of extremity ischemia/reperfusion and neuromuscular outcomes assessment: a pilot study. *J Trauma*. 2010;69:S146–53.
- [16] Cejna M, Virmani R, Jones R, et al. Biocompatibility and performance of the Wallstent and several covered stents in a sheep iliac artery model. *J Vasc Interv Radiol*. 2001;12:351–8.
- [17] Cejna M, Virmani R, Jones R, et al. Biocompatibility and performance of the Wallstent and the Wallgraft, Jostent, and Hemobahn stent-grafts in a sheep model. *J Vasc Interv Radiol*. 2002;13:823–30.
- [18] Teigen C, Stanley JR, Johnson P, Gross C. Preclinical evaluation of the InCraft aortic endograft in a sheep model. *Vascular*. 2014;22:13–9.
- [19] Tang AL, Diven C, Zangbar B, et al. The elimination of anastomosis in open trauma vascular reconstruction. *J Trauma Acute Care Surg*. 2015;79:937–42.
- [20] Tepe G, Bantleon R, Brechtel K, et al. Management of peripheral arterial interventions with mono or dual antiplatelet therapy – the MIRROR study: a randomised and double-blinded clinical trial. *Eur Radiol*. 2012;22:1998–2006.
- [21] Robertson L, Ghouri MA, Kovacs F. Antiplatelet and anticoagulant drugs for prevention of restenosis/reocclusion following peripheral endovascular treatment. *Cochrane Database Syst Rev*. 2012;CD002071.
- [22] Connell JM, Khalapyan T, Al-Mondhiry HA, Wilson RP, Rosenberg G, Weiss WJ. Anticoagulation of juvenile sheep and goats with heparin, warfarin, and clopidogrel. *ASAIO J Am Soc Artif Intern Organs*. 1992. 2007;53:229–37.
- [23] Fleser PS, Nuthakki VK, Malinzak LE, et al. Nitric oxide-releasing biopolymers inhibit thrombus formation in a sheep model of arteriovenous bridge grafts. *J Vasc Surg*. 2004;40:803–11.
- [24] Ortenwall P, Bylock A, Kjellstrom BT, Risberg B. Seeding of ePTFE carotid interposition grafts in sheep and dogs: species-dependent results. *Surgery*. 1988;103:199–205.
- [25] Kohler TR, Kirkman TR. Dialysis access failure: a sheep model of rapid stenosis. *J Vasc Surg*. 1999;30:744–51.
- [26] Spanos HG. Aspirin fails to inhibit platelet aggregation in sheep. *Thromb Res*. 1993;72:175–82.

# Creating an Educational Program in the Endovascular and Hybrid Intervention; Experiences from the Japanese Society of Diagnostic and Interventional Radiology in Emergency, Critical Care, and Trauma (DIRECT)

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Diagnostic and interventional radiology (IR) techniques have recently shown significant efficacy in trauma care when combined with surgical procedures. A multifaceted approach to traffic accidents has reduced the number of trauma patients in Japan, which has necessitated simulation education to provide practical experience and ensure proficiency. The objective of this paper is to report the educational development of endovascular and hybrid workshops in Japan. The Japanese Society of Diagnostic and Interventional Radiology in Emergency, Critical care, and Trauma (DIRECT) was established in 2011 to maximize the benefit of diagnostic and IR in emergency or trauma settings. DIRECT conducts trauma endovascular workshops for emergency medicine physicians, acute care surgeons, and IR physicians. From July 2011 to June 2016, DIRECT has conducted 14 simulator workshops, six endovascular workshops using a porcine model, and four hybrid trauma management workshops, of which two were conducted with porcine models. The simulation workshop was designed for novice learners and included resuscitative endovascular balloon occlusion of the aorta (REBOA) deployment using a pressurized silicone model, catheter and guidewire manipulation with a three-dimensional (3D) vessel silicone model and virtual fluoroscopic simulator, and metallic coil deployment. Porcine simulations for intermediate-level physicians were conducted and endovascular tools included different occlusion materials. In the hybrid strategy model, by using a porcine model of injury, the participants combined both surgical and endovascular procedures such as REBOA, selective balloon occlusion, and N-butyl cyanoacrylate embolization. DIRECT is a vital bridge between emergency/trauma and IR, and workshops are essential for improved trauma care.

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## INTRODUCTION

Trauma care was established primarily by surgeons; thus, surgical procedures are historically considered the preferred methods of treatment [1]. Additional resources have recently become available. Current advances in diagnostic and interventional radiology (IR) have shown significant efficacy in endovascular hemostasis in trauma cases. Time is a critical factor in severe trauma patients [2,3]. However, it is difficult for in-house IR physicians to be available around the clock, particularly at night and on the weekends. Unacceptable delays in the treatment of exsanguinating patients may arise because the IR physicians must travel to the hospital, evaluate diagnostic images, and confer with the emergency medicine (EM) physician and/or acute care surgeon (ACS). Early activation of the trauma radiology team results in more accurate diagnostic imaging and more rapid deployment of IR procedures [4]. In this context, the Japanese Society of Diagnostic and Interventional Radiology in Emergency, Critical care, and Trauma (DIRECT) was created in 2011 to promote time-conscious trauma care. The objective of this paper is to report the development of the endovascular and hybrid educational workshop in Japan. This paper reviews the historical background of surgical and endovascular procedure training, as well as the formation of DIRECT and its training activities.

### ***Dramatic Decrease in Trauma and the Necessity of Educational Workshops***

A multifaceted approach to traffic accidents in Japan has dramatically reduced not only fatalities but also the number of trauma patients since 1970 [5,6]. Laws against illegal drugs and driving while intoxicated have contributed to a reduction in motor vehicle accident fatalities from 16,765 in 1970 to 4,117 in 2015 [7–10]. In addition, restrictions on firearm ownership resulted in a negligible number of trauma incidents involving gunshots, while there were 29,989 fatalities in the United States in 2014. The successful decrease in trauma has had a high impact on trauma education in Japan. The dearth of trauma cases has necessitated the use of cadavers, simulators, and porcine models to simulate trauma incidents to provide practical experience for clinically uncommon procedures.

The Advanced Trauma Life Support guidelines (ATLS) [1] have been paramount to the standardization of initial assessment and resuscitation, which are focused

on appropriate surgical intervention. They paved the way for a number of surgical skill improvement workshops using human cadavers or porcine models, which predate endovascular procedure workshops. Advanced Surgical Skills for Exposure in Trauma (ASSET) [11] and the Trauma Exposure Course (TEC) [12] are cadaver-using courses, while the Advanced Trauma Operative Management (ATOM) course (since 1998, United States) [13], Definitive Surgical Trauma Care (DSTC) course (since 1997, Australia and South Africa) [14], and Surgical Strategy and Treatment for Trauma (SSTT) course (since 2009, Japan) [15] use porcine models.

Human cadavers and porcine models have been used in endovascular procedures. Recently, approaches using synthetic materials and virtual reality simulators have become more popular [16,17]. Two trauma-specific workshops, Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS) and Basic Endovascular Skills for Trauma (BEST), were reported in the United States and have been offered since 2013 [18,19]. These courses cover the fundamental procedures of resuscitative endovascular balloon occlusion of the aorta (REBOA).

### ***Trauma Radiology and DIRECT: EM/ACS-IR Bridge and Synergies***

Acutely time-conscious intervention is the primary prerequisite to realizing the benefits of IR following a traumatic event. The concept of damage control, usually applied to surgery, may also result in successful outcomes [20] and requires the use of highly time-conscious strategies. Previous literature [4] has also included the concept of the Prompt and Rapid Endovascular Strategies in Trauma Occasion (PRESTO) concept and the damage control IR (DCIR) algorithm, whereby a rapidly-deployed trauma radiology team resulted in improved practice decisions in endovascular and hybrid interventions.

In July 2011, DIRECT was formed to maximize the benefits of radiology in emergency and/or trauma settings, and to serve as a bridge between surgical and IR specialists. From July 2011 to June 2016, DIRECT has conducted numerous workshops, including the following: 1) diagnostic imaging courses (acute disease, 12 times; trauma, 10 times; up to 20 participants); 2) 14 endovascular workshops using simulators (18–20 learners, 7–12 instructors and several instructor candidates); 3) six endovascular workshops using porcine models (8 or 16 learners, 7–10 instructors and several instructor candidates, 8 learners/porcine); and 4) four hybrid

trauma management workshops using a porcine model (6 learners/porcine, 9–12 instructors). In total, over 250 students have been trained in the simulator workshops, 70 in the porcine model workshops, and 24 in the hybrid workshops. The participation fee was 10,000 JPY for the diagnostic imaging course and the simulator IR workshop and 50,000–60,000 JPY for the porcine IR workshop.

### **Training Endovascular Physicians for Trauma in DIRECT**

There are two primary approaches to implementing endovascular techniques in trauma: IR priority and EM/ACS priority. Both groups of physicians contribute different skills and knowledge. IR physicians may exhibit a relative lack of knowledge in traumatology; whereas, EM physicians/ACs often lack the technical skills routinely possessed by IR physicians. Additionally, ineluctable inter-departmental conflicts may cause concern regarding the appropriate qualifications and board certification. However, the understanding that time is of the essence is of crucial importance: lost time increases blood loss, and blood loss causes loss of life.

By transcending potential inter-departmental conflicts, we are certain that a combined IR–EM management strategy will be able to improve trauma care. Accordingly, DIRECT does not restrict admission to its workshops due to a participant's primary specialty; we have shared the concepts of trauma physiology and trauma IR with IR physicians, and likewise, we have taught endovascular techniques and pitfalls to EM/ACS personnel.

#### *Trauma radiology lectures and time-conscious management*

Workshop lectures consist of the following topics: 1) the basic theory and pitfalls of REBOA; 2) embolic materials such as gelatin sponges, metallic coils and N-butyl cyanoacrylate (NBCA); 3) virtual fluoroscopic imaging for IR procedure navigation with a 3D workstation using arterial phase CT data from trauma panscans (known as pre-procedural planning, PPP); and 4) trauma coagulopathy and trauma IR concepts, including DCIR.

#### *Endovascular training using simulators*

The simulation workshop is designed primarily for novice learners of IR and comprises the following: 1) REBOA deployment using a pressurized silicone model (Endo Vascular Evaluator (EVE), BR Biomedicals, Pvt. Ltd., New Delhi, India); 2) catheter and guidewire manipulation using a 3D vessel silicone model and a Vascular Intervention System Trainer (VIST)-C, (Mentice, Evanston, IL, USA); and 3) metallic coil deployment training (fibered detachable coil or water-pressured bare detachable coil) (Table 1).

REBOA, as opposed to resuscitative thoracotomy, has gained increasing acceptance as a less-invasive aortic occlusion method [21]. In Japan, REBOA has been used since the late 1990s in clinical settings [22]; However, standardized courses did not exist prior to DIRECT. In current practice, 7 Fr and 10 Fr sheath-compatible devices are commercially available in Japan [23] and are also used in the workshop. Training focuses on obtaining arterial access, manipulating the guidewire and catheter, and using imaging to confirm the guidewire within the aorta (ultrasound, X-ray) to obviate potential complications. Self-evaluation after the workshop indicated a significantly improved understanding of the lecture material and all endovascular procedures (Table 2).

#### *Endovascular skill simulation using a porcine model*

IR simulations, using a porcine model have been conducted by intermediate-level IR physicians (Table 1). NBCA is infrequently used in elective cases; therefore, porcine simulation is quite useful. All faculty and students attended a mandatory ethics and animal welfare lecture before undertaking any clinical procedures.

After placing the animals under general anesthesia, the bilateral femoral arteries were selected as the access routes. Participants subsequently prepared embolic materials. They next practiced catheters and guidewires manipulation with faculty assistance. The intercostal, internal iliac arteries, and some branches of the renal arteries were selected as the target vessels. PPP acquired from the pre-scanned CT data of each porcine model provided the anatomical information to accurately navigate to the target vessel (Figure 1). Vascular injury models were made by piercing the vessel wall against the stiff edge of the guidewire and/or balloon catheter. Workshop students alternately acted as the operator or the attendant, thereby gaining valuable insights into the complexities and nuances of the procedure (Figure 2). Self-evaluation after the workshop revealed significant improvement in understanding the selection of embolic materials, catheter manipulation, and gelatin sponge embolization (Table 2).

#### *Hybrid strategy model in porcine injury*

Recently, hybrid approaches (combined surgical and endovascular procedures) in trauma treatment have gained greater acceptance as advanced, feasible hemostatic interventions [24]. Even though specialized equipment is necessary to fully utilize hybrid treatment, this approach will change trauma strategies.

In the hybrid approach workshops, vascular accesses were established and a laparotomy was performed on a porcine model. The hybrid workshop focused on damage control endovascular procedures such as NBCA injection, REBOA, and selective balloon occlusion, which were combined with surgical approaches. Finally, the

**Table 1** Program in the DIRECT workshop.

Time	Lecture and Simulation
<i>Simulator Workshop</i>	
11:55–12:05	Introduction
12:05–12:50	Session 1
13:00–13:45	Session 2
13:55–14:40	Session 3
15:00–15:45	Session 4
15:55–16:40	Session 5
16:40–17:00	Debrief and questions
Booth	Practice materials
1	REBOA; lecture and simulation
2	Catheter manipulation using a silicone model and a virtual simulator
3	Metallic coil embolization using a flow conduit
4	Pre-procedural planning; lecture and practice
5	Trauma coagulopathy and interventional radiology (lecture)
<i>Porcine Endovascular Workshop</i>	
8:30–9:30	Introduction, pre-test, ethical lecture
9:30–11:30	Metallic coil and NBCA (lecture) and NBCA preparation
11:30–13:30	Metallic coil and NBCA embolization (Lunch break, 30 min)
13:30–14:30	REBOA procedure
14:30–16:30	Embolization for vascular injury model
16:30–17:00	Debrief and questions
17:00–17:30	Post-test
<i>Porcine Hybrid Workshop</i>	
9:30–10:30	Introduction, pre-test, ethical lecture
10:30–12:00	NBCA preparation and embolization 1
12:00–13:20	REBOA and selective balloon occlusion catheter (Lunch break, 25 min)
13:20–14:50	NBCA preparation and embolization 2
14:50–15:30	Injury Case Scenario 1
15:30–16:10	Injury Case Scenario 2
16:10–16:30	Debrief and questions

REBOA, resuscitative endovascular occlusion of the aorta; NBCA, N-butyl cyanoacrylate; IR, interventional radiology.

liver, kidney, spleen, and iliac arteries were injured so that the students could strategize and implement interventions. Participants worked under the direct supervision of endovascular and surgical faculty members, thereby benefiting from a multidisciplinary approach in this crucial field (Figure 3).

### **Global Endovascular Workshops and Future Directions in Trauma Management**

Most participants in BEST or ESTARS courses are trauma surgeons or ACSs. However, and unfortunately, there are few experienced trauma surgeons in Japan because the number of trauma cases is decreasing and most general surgeons are unwilling to actively pursue ACS. Thus, EM physicians usually conduct the initial assessment and resuscitation. Consequently, some EM physicians have begun to choose IR fellowships as their subspecialty to perform trauma IR quickly and DIRECT

acts as a bridge to that training. In Sweden, the Endovascular hybrid Trauma and bleeding Management (EVTM) workshop began in 2015 [25], encompassing both surgical and endovascular approaches. The EVTM faculty and DIRECT collaboratively designed the workshop from the outset and such activity is spreading internationally.

In a limited number of non-standard, leading-edge “hybrid ER” facilities in Japan, CT scans, angiography, and surgery can be performed without patient transfer [26]. The use of CT as an aid to diagnosis, even in hemodynamically unstable patients in the trauma bay, may lead to a new era in trauma care.

DIRECT has taken a critical first step toward rapid radiological intervention in trauma cases. We strongly believe that sharing the knowledge and experience of trauma radiology among multidisciplinary professionals, multi-institutional staff, and internationally, will result in dramatic improvements in hybrid trauma management

**Table 2** Self-evaluation before and after the workshop.

	Before	After	P
<b>Simulator Workshop (n = 18)</b>			
Trauma IR concept	3.61 ± 2.17	6.61 ± 1.65	<0.001
Trauma coagulopathy	5.78 ± 2.69	8.78 ± 1.31	<0.001
Time consciousness in trauma care	5.83 ± 2.73	8.72 ± 1.23	<0.001
REBOA knowledge	3.44 ± 2.55	6.61 ± 1.88	<0.001
REBOA procedures	2.72 ± 2.30	6.17 ± 2.26	<0.001
Angiography catheter manipulation	1.78 ± 1.48	4.44 ± 1.72	<0.001
Microcatheter manipulation	1.39 ± 0.78	3.61 ± 1.69	<0.001
Gelatin sponge embolization	1.44 ± 1.10	2.94 ± 1.35	<0.001
Coil embolization	1.50 ± 1.10	3.39 ± 1.38	<0.001
NBCA-embolization	1.22 ± 0.55	2.28 ± 1.32	0.003
<b>Porcine Workshop (n = 12)</b>			
Selection of embolic materials	3.25 ± 2.30	4.67 ± 2.15	<0.001
Catheter manipulation	4.08 ± 2.11	6.25 ± 1.22	<0.001
Gelatin sponge embolization	3.83 ± 2.25	5.42 ± 1.83	<0.001
Coil embolization	3.17 ± 2.25	3.42 ± 2.43	0.191

IR, interventional radiology; REBOA, resuscitative endovascular occlusion of the aorta; NBCA, N-butyl cyanoacrylate.

**Figure 1** Pre-procedural planning.

After CT scanning, pre-procedural planning (PPP) processed the data and traced out a virtual angiographic catheter route toward each target site. This virtual angiographic image gives the operator detailed anatomical information such as the root of the vessel or position of extravasation. The process can be attained within 5 minutes or less by a “conductor” doctor.

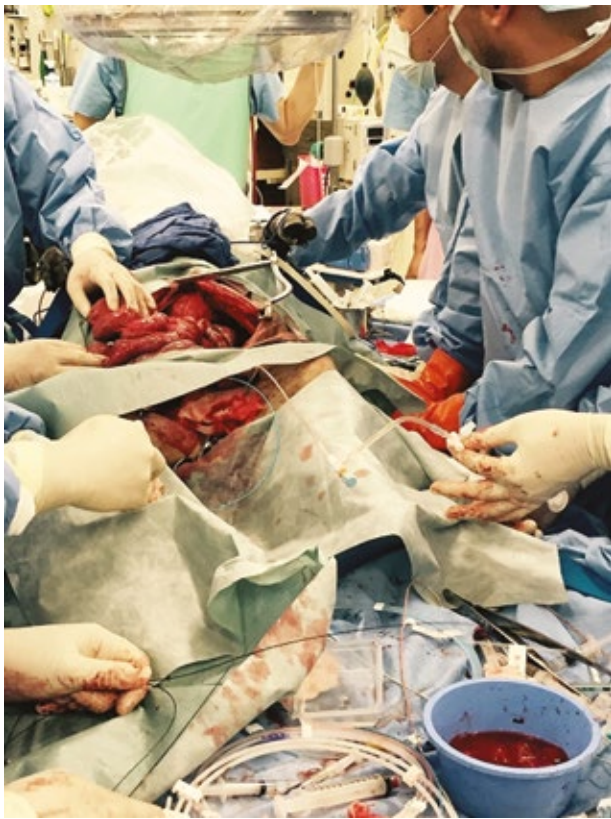
in the very near future. To objectively demonstrate the effect of the training package and the benefit to the patient, the EVT training material should be standardized and an accumulation of international experience should be established.

This paper has several limitations. First, our data could not provide exact data on how the participants changed before and after the workshop experience from evaluation of the questions because the program has

**Figure 2** Interventional radiology team with the conductor-operator-attendant system.

The conductor orchestrates and guides the operator during the procedure. This eliminates the operator's decision-making time while performing catheterization and optimizes procedural efficiency while minimizing human error in a time of haste. The attendant anticipates the subsequent maneuvers of the operator and prepares appropriate devices and embolization materials in a timely fashion.

improved gradually and was not able to accumulate the statistical results from the post-course questionnaire. Second, as trauma care systems vary widely among each institute or country, our experience may not be applicable in other countries. Despite these limitations, our experience in the development of an endovascular trauma workshop should be shared.



**Figure 3** Hybrid approach simulation in a porcine model. Resuscitative endovascular balloon occlusion of the aorta (REBOA) was first placed in a simulated visceral injury and stabilized hemodynamics temporarily. The fluoroscopy above the operating theater made the procedure safe and rapid. Then surgical faculty assisted peri-hepatic packing. Finally, a trauma interventional radiology team consisting of participants performed angiography and embolized the remaining arterial extravasation.

## CONCLUSION

The necessity of simulation education in trauma is widely recognized. This paper reported how to create an educational program in the endovascular and hybrid workshops in Japan. DIRECT was established to bridge the gap between EM/ACS and IR. We strongly believe multidisciplinary collaborative approaches offer improved trauma care, and that sharing the educational experience internationally will accelerate the improvement of endovascular and hybrid approaches in trauma settings.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This is a review article and does not contain any original human or animal data, therefore an ethics committee approval and consent to participate statement do not apply to this manuscript. The educational use of porcine received ethical approval from each institution and all

participants took mandatory ethics and animal welfare lectures and received approval.

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## REFERENCES

- [1] ATLS Subcommittee, American College of Surgeons' Committee on Trauma, International ATLS working group. Advanced trauma life support (ATLS(R)): the ninth edition. *J Trauma Acute Care Surg.* 2013;74:1363–6.
- [2] Lerner EB, Moscati RM. The golden hour: scientific fact or medical "urban legend"? *Acad Emerg Med.* 2001;8:758–60.

- [3] Howell GM, Peitzman AB, Nirula R, et al. Delay to therapeutic interventional radiology postinjury: time is of the essence. *J Trauma*. 2010;68:1296–300.
- [4] Matsumoto J, Lohman BD, Morimoto K, Ichinose Y, Hattori T, Taira Y. Damage control interventional radiology (DCIR) in prompt and rapid endovascular strategies in trauma occasions (PRESTO): A new paradigm. *Diagn Interv Imaging*. 2015;96:687–91.
- [5] Kaimila B, Yamashina H, Arai A, Tamashiro H. Road traffic crashes and fatalities in Japan 2000–2010 with special reference to the elderly road user. *Traffic Inj Prev*. 2013;14:777–81.
- [6] Nakahara S, Katanoda K, Ichikawa M. Onset of a declining trend in fatal motor vehicle crashes involving drunk-driving in Japan. *J Epidemiol*. 2013;23:195–204.
- [7] Christophersen AS, Morland J, Stewart K, Gjerde H. International trends in alcohol and drug use among vehicle drivers. *Forensic Sci Rev*. 2016;28:37–66.
- [8] Reducing gun violence: facts are stubborn things. *Lancet*. 2013;381:2055.
- [9] Liu C, Huang Y, Pressley JC. Restraint use and risky driving behaviors across drug types and drug and alcohol combinations for drivers involved in a fatal motor vehicle collision on U.S. roadways. *Inj Epidemiol*. 2016;3:9.
- [10] Cabinet Office GOJ. White Paper on Traffic Safety in Japan. <http://www8caogojp/koutu/taisaku/kou-wphtml>. 2015.
- [11] Bowyer MW, Kuhls DA, Haskin D, et al. Advanced Surgical Skills for Exposure in Trauma (ASSET): the first 25 courses. *J Surg Res*. 2013;183:553–8.
- [12] Gunst M, O’Keeffe T, Hollett L, et al. Trauma operative skills in the era of nonoperative management: the trauma exposure course (TEC). *J Trauma*. 2009;67:1091–6.
- [13] Jacobs LM, Burns KJ, Kaban JM, et al. Development and evaluation of the advanced trauma operative management course. *J Trauma*. 2003;55:471–9; discussion 9.
- [14] Boffard KD. *Manual of Definitive Surgical Trauma Care 3E*. CRC Press; 2011.
- [15] Watanabe H, Idoguchi K, Mizushima Y, et al. Training system of trauma surgery for young acute care surgeons: Surgical Strategy and Treatment for Trauma (SSTT) course. *Journal of Abdominal Emergency Medicine*. 2012;32:919–26.
- [16] Neequaye SK, Aggarwal R, Van Herzeele I, Darzi A, Cheshire NJ. Endovascular skills training and assessment. *J Vasc Surg*. 2007;46:1055–64.
- [17] Nesbitt CI, Birdi N, Mafeld S, Stansby G. The role of simulation in the development of endovascular surgical skills. *Perspect Med Educ*. 2016;5:8–14.
- [18] Brenner M, Hoehn M, Pasley J, Dubose J, Stein D, Scalea T. Basic endovascular skills for trauma course: bridging the gap between endovascular techniques and the acute care surgeon. *J Trauma Acute Care Surg*. 2014;77:286–91.
- [19] Villamaria CY, Eliason JL, Napolitano LM, Stansfield RB, Spencer JR, Rasmussen TE. Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS) course: curriculum development, content validation, and program assessment. *J Trauma Acute Care Surg*. 2014;76:929–35; discussion 35–6.
- [20] Roberts DJ, Bobrovitz N, Zygun DA, et al. Indications for use of damage control surgery in civilian trauma patients: A content analysis and expert appropriateness rating study. *Ann Surg*. 2016;263:1018–27.
- [21] Stannard A, Eliason JL, Rasmussen TE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for hemorrhagic shock. *J Trauma*. 2011;71:1869–72.
- [22] Inoue J, Shiraishi A, Yoshiyuki A, Haruta K, Matsui H, Otomo Y. Resuscitative endovascular balloon occlusion of the aorta might be dangerous in patients with severe torso trauma: A propensity score analysis. *J Trauma Acute Care Surg*. 2016;80:559–67.
- [23] Teeter WA, Matsumoto J, Idoguchi K, et al. Smaller introducer sheaths for REBOA may be associated with fewer complications. *J Trauma Acute Care Surg*. 2016;81:1039–45.
- [24] Holcomb JB, Fox EE, Scalea TM, et al. Current opinion on catheter-based hemorrhage control in trauma patients. *J Trauma Acute Care Surg*. 2014;76:888–93.
- [25] ABO Trauma registry. <https://www.abotraumaregistry.com>.
- [26] Wada D, Nakamori Y, Yamakawa K, Fujimi S. First clinical experience with IVR-CT system in the emergency room: positive impact on trauma workflow. *Scand J Trauma Resusc Emerg Med*. 2012;20:52.



# Successful and Unsuccessful Blind Placement of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Catheters Through Damaged Arteries: A Report of Three Cases

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**Background:** Patients who receive resuscitative endovascular balloon occlusion of the aorta (REBOA) for temporization of exsanguinating hemorrhage may have occult injuries sustained to the iliac arteries or aorta which may pose increased risks in performing REBOA. Caution is essential in performing REBOA in these patients as the injuries are not clearly defined on admission. REBOA is currently performed in select centers without fluoroscopy, leading to blind placement of devices and an essential reliance on tactile feedback.

**Methods:** Patients admitted between February 2013 and July 2017 at a tertiary center who had a successful or unsuccessful blind placement of a REBOA catheter or wire through a damaged iliac artery or aorta were included.

**Results:** Three patients were identified. Two patients had successful placement of the REBOA catheter; one sustained injury to the external iliac artery and the other sustained injury to the abdominal aorta. Confirmation of catheter placement was obtained before balloon inflation, and the damaged vessels were identified upon immediate operative intervention. One patient had unsuccessful placement of the REBOA catheter during cardiac arrest despite accurate access of the common femoral artery (CFA).

**Conclusions:** Emergent, blind placement of wires and catheters past arterial injuries is possible but may result in procedural abandonment and/or arterial injury. Physical exam and/or tactile feedback should alert the surgeon to the possibility of arterial injury. Imaging confirmation should precede balloon inflation if at all possible.

**Keywords:** *Resuscitative Endovascular Balloon Occlusion of the Aorta; REBOA; Aortic Occlusion; Aorta; Trauma; Arterial Injury; Complication*

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**Author contributions:** Study conception and design: PW, DS, TS, MB. Acquisition of data: PW, WT, PH. Analysis and interpretation of data: PW, MB. Drafting of manuscript: PW, MB. Critical revision: PW, WT, PH, DS, TS, MB.

**Conflicts of interest:** Dr M Brenner is a clinical advisory board member of Prytime Medical Inc.

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## INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is utilized as a temporary bridge to hemostasis by providing proximal control of the aorta for hemorrhage below the diaphragm. REBOA is utilized in trauma patients who sustain severe injuries causing non-thoracic torso hemorrhage. Given the critical condition of these patients, REBOA may be warranted immediately upon presentation to the hospital. In the pre-operative setting, it is frequently not feasible to perform REBOA under fluoroscopic guidance and placement of REBOA catheter and wires may be performed blindly without knowledge of potential major vascular injuries.

Prior to balloon inflation, imaging confirmation of the wires/catheters is highly recommended; however, expedient imaging confirmation may be deferred in patients in cardiac arrest actively undergoing chest compressions. In one multi-institutional study, 35% of patients did not receive imaging confirmation of device placement; and the majority of these cases were patients in arrest in whom closed chest compressions were not paused to obtain imaging [1].

Occult injuries to the femoral or iliac arteries, and even to the aorta, may lead to difficulty with successful blind placement of catheters and/or wires across these injuries. Despite a growing body of literature describing REBOA use in trauma patients [1–4], there is a paucity of literature describing successful or unsuccessful blind placement of catheters or wires across arterial injuries.

The objective of this study was to describe a single institution's experience with placement of endovascular devices blindly through injured vessels.

## METHODS

This study is a retrospective case series using prospectively collected data and was approved by the Institutional Review Board of the University of Maryland, Baltimore.

Demographics and hospital course data were collected prospectively on all trauma patients, age  $\geq 18$  years old, who underwent REBOA at the University of Maryland Shock Trauma Center. Patients admitted between February 2013 and July 2017 at a tertiary center who underwent REBOA and were found to have aortoiliac injury within the trajectory of the devices were included. Patients who had unsuccessful REBOA attempts that were ultimately abandoned due to inaccurate placement as a result of original vascular injury were also included. Demographics and hospital course data were extracted from the medical record. REBOA related timing metrics were captured by available time-stamped videography in the resuscitation areas and operating theaters. REBOA was initially performed using a 12 French (Fr) sheath and the CODA<sup>®</sup> catheter (Cook Medical, Bloomington, IN). During the study period, there was a transition to using a smaller 7 Fr

sheath with the FDA approval of a smaller profile catheter, ER-REBOA<sup>™</sup> (Prytime Medical, Boerne, TX), which occurred in February 2016.

## RESULTS

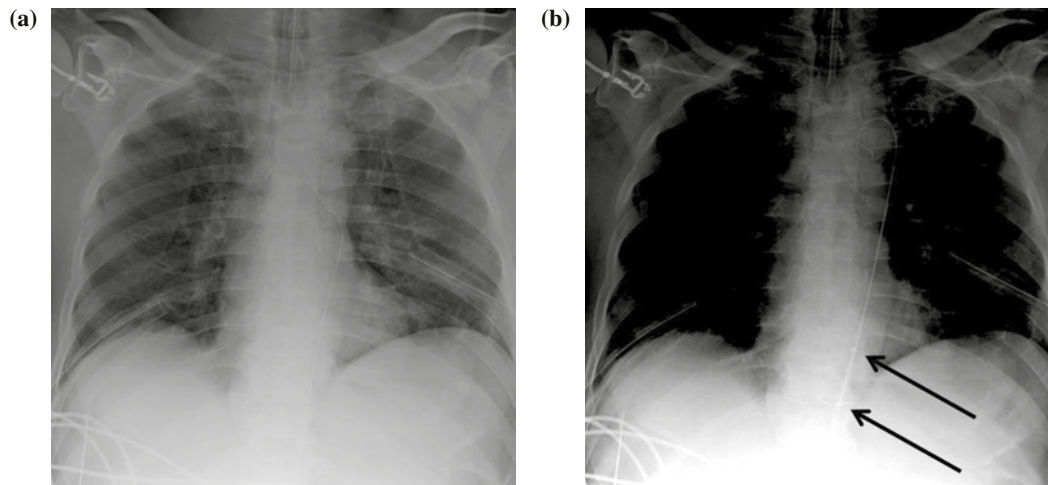
### Case 1

A 67-year-old male presented after being a pedestrian struck by a motor vehicle and was intubated in the field. Transport time to the hospital was 28 minutes. Upon arrival, the patient had bilateral chest tubes placed for decreased breath sounds with minimal output. Plain films of the chest and pelvis were negative. The patient's abdominal FAST exam was negative, but he had a distended abdomen. A femoral arterial line was placed and the patient was persistently hypotensive despite aggressive resuscitation. The arterial line was upsized for a 12 Fr sheath and a 0.035" Amplatz Super Stiff<sup>™</sup> (Boston Scientific, Marlborough, MA) guidewire was measured and inserted using external landmarks. A plain radiograph was obtained (Figure 1a) showing the wire in the appropriate location, and a CODA<sup>®</sup> catheter was inserted based on external landmarks. A plain radiograph was obtained (Figure 1b) showing the catheter with its radiopaque balloon markers in the appropriate position in zone 1 of the aorta (descending thoracic aorta). The balloon was then inflated. The patient's blood pressure improved from 50/30 mmHg immediately before balloon inflation to 80/48 mmHg and the patient was taken to the operating room emergently. The time from admission to the operating room was 75 minutes. An exploratory laparotomy demonstrated a large left-sided retroperitoneal hematoma. A left medial visceral rotation revealed a near transection of the aorta at the level of the left renal artery. The balloon catheter provided proximal control of the hemorrhage while the aortic transection was repaired primarily and the patient was able to tolerate total deflation of the REBOA balloon.

REBOA was performed intermittently, with a total occlusion time of 101 minutes. Unfortunately, while sheath removal and common femoral arterial repair was being performed the patient suffered cardiac arrest and subsequently expired due to extensive physiologic devastation despite transfusion of 35 units of blood products.

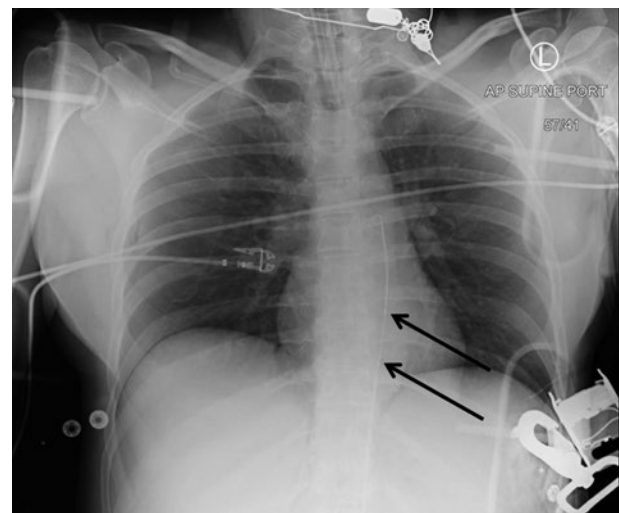
### Case 2

A 48-year-old female presented after sustaining multiple gunshot wounds, including two bullet wounds in her left anterior flank and right lower quadrant of her abdomen. The patient suffered cardiac arrest en-route with successful return of spontaneous circulation, and was intubated by EMS in the field. On arrival, the patient was hypotensive and suffered cardiac arrest again 1.7 minutes after admission and subsequently underwent closed chest compressions in conjunction with REBOA. Severe



**Figure 1** Chest X-ray confirmation of successful wire and catheter placement traversing a near-total abdominal aorta transection for REBOA. Image **a** demonstrates appropriate positioning of the wire before the CODA<sup>®</sup> catheter is inserted (Image **b**). Black arrows show the radiopaque markers of the balloon portion of the CODA<sup>®</sup> catheter, which provided supra-celiac aortic occlusion.

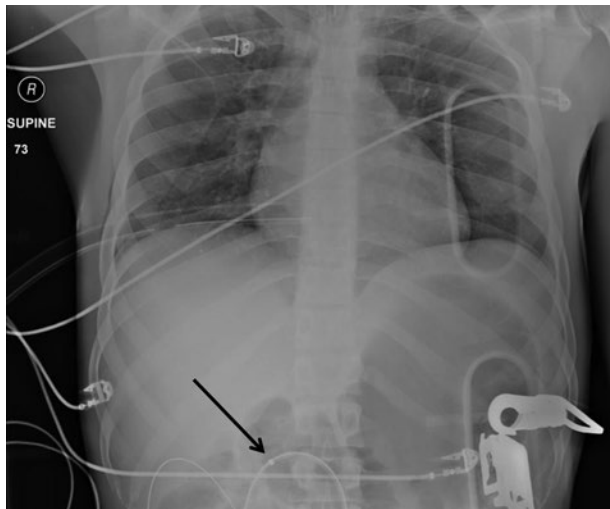
intra-thoracic hemorrhage was ruled out with an eFAST exam. A right femoral cut-down was performed and a 7 Fr sheath was inserted over a wire into the common femoral artery (CFA). Using external landmarks, an ER-REBOA<sup>™</sup> catheter was inserted in zone 1, flushed, and connected to a systemic arterial line monitoring device. The balloon was inflated without radiography. The time from the start of the femoral cut-down to aortic occlusion by REBOA was 7.55 minutes. Chest compressions and advanced cardiovascular life support continued for approximately 3 minutes after balloon inflation until the return of spontaneous circulation occurred. Radiography at this time confirmed appropriate positioning of the ER-REBOA<sup>™</sup> catheter in zone 1 of the aorta (see Figure 2), and the patient was taken emergently to the operating room where exploratory laparotomy demonstrated a large retroperitoneal hematoma. The balloon catheter was successfully deflated after a number of attempts with continued resuscitation (40 units of blood products). Upon successful balloon deflation, significant bleeding was identified from the abdominal right lower quadrant bullet wound. Exploration of the wound revealed injury to the anterior right external iliac artery. The ER-REBOA<sup>™</sup> catheter was visualized traversing the injury and the posterior wall of the artery was intact. Vessel loops were placed proximal and distal to the injury and the REBOA catheter was removed. A shunt was placed in the right external iliac artery, the patient was left in discontinuity and abdomen was left open. The patient was transferred to an intensive care unit (ICU) with severe physiologic devastation and on vasopressors. The patient's family arrived soon after transfer to the ICU; and after conversation regarding the patient's guarded condition and prognosis, the decision to withdraw care was made and the patient expired soon after.



**Figure 2** Chest X-ray demonstrating ER-REBOA<sup>™</sup> catheter placement through a damaged external iliac artery and in the descending thoracic aorta. Black arrows show the radiopaque markers of the balloon portion of the ER-REBOA<sup>™</sup> catheter, which provided supra-celiac aortic occlusion.

### Case 3

A 22-year-old male sustained a gunshot wound to his lower back and was found unresponsive and transported to the hospital with ongoing CPR. On arrival, the patient had decreased breath sounds on the right, and a chest tube was placed with minimal output. An arterial line was placed in the right CFA and upsized to a 12 Fr sheath. A 0.035" Amplatz Super Stiff<sup>™</sup> guidewire and CODA<sup>®</sup> catheter were inserted. Abnormal tactile feedback was not noted while advancing the guidewire and catheter or with balloon inflation. A chest



**Figure 3** Plain film demonstrating unsuccessful appropriate CODA<sup>®</sup> catheter placement with the catheter coiled intra-abdominally. The black arrow demonstrates the CODA<sup>®</sup> catheter coiled within the abdomen.

x-ray was performed, which revealed incorrect placement of the CODA<sup>®</sup> catheter and guidewire (see Figure 3). The eventual position of the REBOA catheter and guidewire was attributed to an occult iliac artery injury given successful access and placement of the sheath in the CFA. Given the prolonged duration of cardiac arrest and unknown downtime without the return of spontaneous circulation, efforts ceased. Pelvic x-ray and a FAST exam were not performed. An autopsy report was not available.

## DISCUSSION

### **Blind Catheter Placement and Balloon Inflation**

Given the moribund status of these patients, REBOA is frequently warranted before specific injuries can be identified. Blind placement of catheters using external landmarks in CT imaging [5] and cadaver-based [6] studies is feasible. Successful blind placement and balloon inflation in the setting of injured and pathologic arteries (ruptured aortic aneurysms) has been previously reported [7,8]. Our institutional protocol recommends blind placement of the devices using external landmarks with imaging confirmation before balloon inflation, which has been largely successful and without complication [9]. Exceptions to this are patients in cardiac arrest at the time of REBOA, where the radiograph confirming device placement is obtained after the return of spontaneous circulation, or during a brief pause for a pulse check.

Although it is possible to accurately place devices blindly, inaccurate placement should be ruled out before balloon inflation is performed. Studies [8,10–12] have demonstrated the feasibility of transabdominal

**Table 1** Factors potentially associated with the ability to blindly place a catheter across arterial injuries.

### **Successful or Unsuccessful Blind Placement of Catheter Across Arterial Injury**

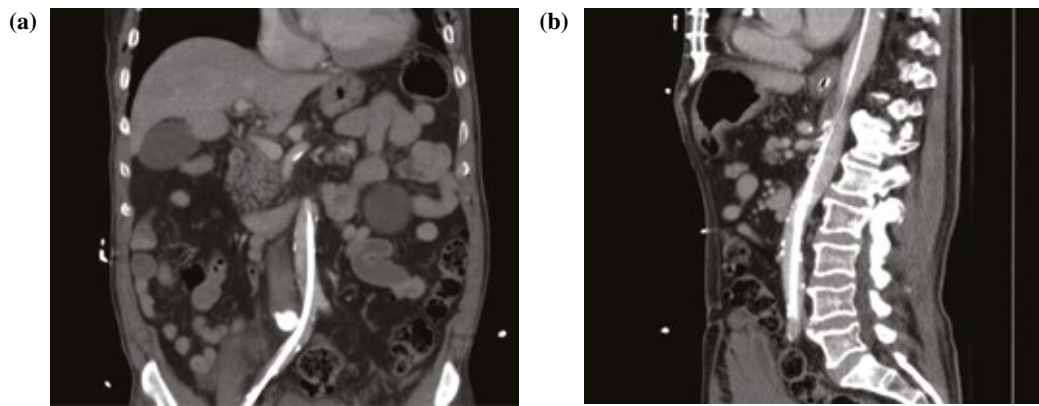
Specific location of injury compared to trajectory of path of wire/catheter
Size, degree of tortuosity, and degree of stiffness or non-compliance of the vessel
Degree of injury to the vessel (transmural vs. non-transmural)
Percentage of the circumference involved, including complete transection
Alignment of proximal and distal injury-free segments
Intraluminal obstruction: presence of retained foreign bodies, severe atherosclerosis, thrombus
Presence of surrounding structures to allow injury to be contained (retroperitoneal vs. peritoneal)

ultrasonography (including with the subxiphoid view), as well as transesophageal ultrasonography in placement confirmation. Despite previous reports of success [7,8] every attempt should be made to confirm catheter placement before balloon inflation.

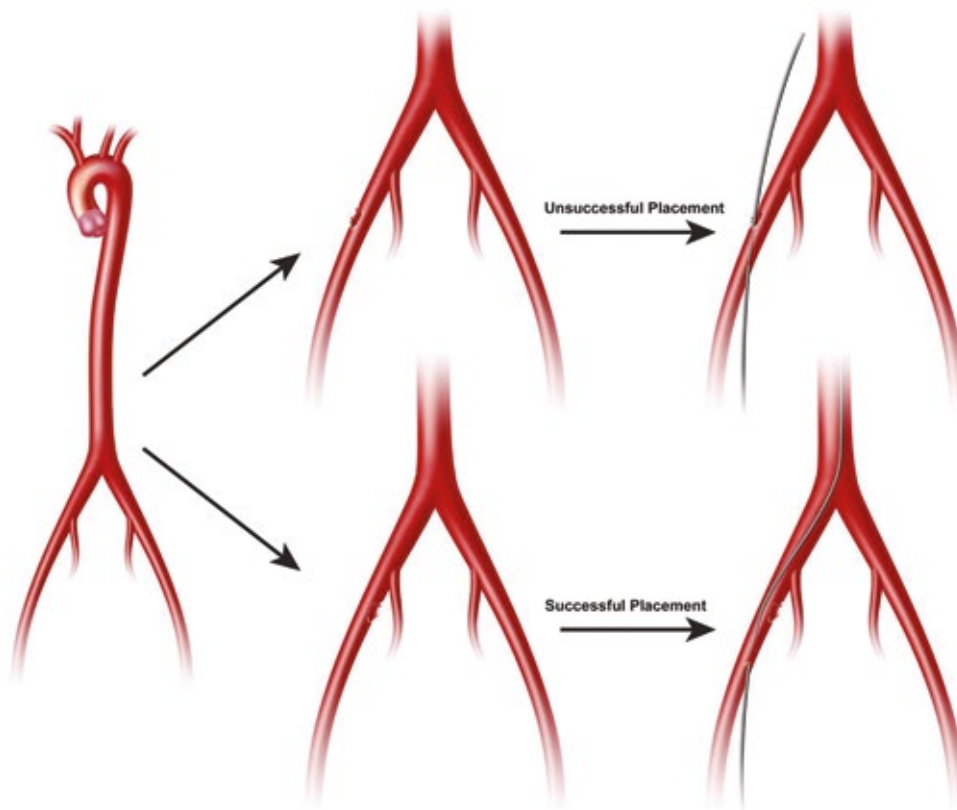
Blind placement of wires or catheters in any patient is associated with risks including incorrect placement, initial or further damage of vessels including dissection and/or embolization, and additional injury could occur with blind inflation of an incorrectly placed REBOA catheter [13].

### **Considerations in the Ability to Successfully and Blindly Traverse Injured Arteries**

The incidence of arterial injuries that may adversely affect catheter placement in patients who meet criteria for REBOA, as well as factors that allow a catheter to successfully traverse an injured artery, have not been well studied. In our institutional experience, we have placed REBOA catheters in 104 patients with only the cases described in this series having this type of arterial injury. This suggests that the incidence of occult arterial injury preventing successful placement of the catheter may be low and therefore should not be a major deterrent in the decision to perform REBOA when the degree of suspicion of aortic or iliac arterial injury is not high. Physical exam and attention to the mechanism of injury and missile trajectory can suggest injuries to the iliac arteries. A decreased femoral pulse on one side, large pelvic retroperitoneal hematoma seen on eFAST exam, or open wounds with active bleeding in the pelvis can alert the physician to potential injury and avoidance of that side when performing REBOA. During the procedure, tactile feedback is the most important factor to ensure the safety of REBOA, and resistance or atypical behavior of indwelling devices should prompt troubleshooting, attempting from the contralateral groin, and/or abandonment of the procedure altogether.



**Figure 4** Coronal (image a) and sagittal (image b) CT images showing the course of the wire and CODA<sup>®</sup> catheter as it travels through the iliac artery and aorta. Note that the balloon was fully deflated during this CT scan. It demonstrates that at different points in the wire and catheter’s course, it abuts different parts of the lumen wall while not abutting any part of the lumen wall at other locations.



**Figure 5** Illustration of how different injuries may potentially allow for successful vs. unsuccessful blind wire/catheter placement past the injuries.

Multiple factors are likely involved with the ability of a catheter or wire to traverse an arterial injury, as listed in Table 1. The specific characteristics of the patient and their arteries vary from patient to patient. These factors change with age, gender, and cardiovascular comorbidities, among other factors [5,14]. The course of a patient’s arteries, as well as the properties of the catheter or wire, result in the catheter or wire abutting different aspects of

the lumen wall at different locations, as seen in Figure 4. This may explain, in part, the ability of wires and catheters to traverse some arterial injuries, but not others, as illustrated in Figure 5. The incidence of arterial injury preventing accurate placement of catheters and wires for REBOA may be low. Nevertheless, efforts should be made to confirm catheter and wire placement before balloon inflation.

### Considerations in Performing REBOA via Brachial or Common Femoral Arterial Access

Blind advancement of wires or catheters through the brachial artery into the aortic arch may lead to inaccurate placement such as into the ascending aorta, left ventricle, coronary arteries, as well as other branches of the aortic arch. The platform guidewire utilized for REBOA would require an additional steering catheter to ensure correct cannulation into the descending aorta. This angle from left subclavian to descending aorta is acute and without at least visualization under fluoroscopy, as well as additional steps and devices, is not feasible in the resuscitation area. The ER-REBOA is a wire-free device which is not steerable and intended to be inserted into relatively linear projectiles. Additionally, the performance of REBOA through brachial artery access has led to embolic events [7]. Obtaining access to the brachial artery is more difficult than accessing the CFA due to diameter and anatomy [14,15]. In addition, both percutaneous and open surgical brachial artery access is an unfamiliar skillset to most acute care surgeons. The safest access for REBOA given the patient population, available devices, skillset of the providers, and location of the procedure, is the CFA.

Only in the rarest of circumstances can REBOA via brachial access be safe and effective. Current clinical data supports CFA access as the preferred method as complications have been relatively minor, and almost all attempts through the CFA have resulted in successful aortic occlusion [1,16].

### CONCLUSIONS

Blind placement of wires and catheters through arterial injuries for REBOA is feasible but may require procedural abandonment or result in iatrogenic arterial injury. Physical exam and tactile feedback should alert the surgeon to the possibility of arterial injury and possible unsuccessful placement of devices.

### REFERENCES

- [1] DuBose JJ, Scalea TM, Brenner M, et al. The AAST prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: Data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). *J Trauma Acute Care Surg.* 2016;81:409–19.
- [2] Brenner ML, Moore LJ, DuBose JJ, et al. A clinical series of resuscitative endovascular balloon occlusion of the aorta for hemorrhage control and resuscitation. *J Trauma Acute Care Surg.* 2013;75:506–11.
- [3] Moore LJ, Brenner M, Kozar RA, et al. Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage. *J Trauma Acute Care Surg.* 2014;79:523–32.
- [4] Moore LJ, Martin CD, Harvin JA, Wade CE, Holcomb JB. Resuscitative endovascular balloon occlusion of the aorta for control of noncompressible truncal hemorrhage in the abdomen and pelvis. *Am J Surg.* 2016;212:1222–30.
- [5] MacTaggart JN, Poulson WE, Akhter M, et al. Morphometric roadmaps to improve accurate device delivery for fluoroscopy-free resuscitative endovascular balloon occlusion of the aorta. *J Trauma Acute Care Surg.* 2016; 80:941–46.
- [6] Linnebur M, Inaba K, Haltmeier T, et al. Emergent non-image-guided resuscitative endovascular balloon occlusion of the aorta (REBOA) catheter placement: A cadaver-based study. *J Trauma Acute Care Surg.* 2016; 81:453–57.
- [7] Matsuda H, Tanaka Y, Hino Y, et al. Transbrachial arterial insertion of aortic occlusion balloon catheter in patients with shock from ruptured abdominal aortic aneurysm. *J Vasc Surg.* 2003;38:1293–96.
- [8] Lai CH, Wu HY, Kan CD. Resuscitation for an octogenarian with ruptured abdominal aortic aneurysm using endovascular balloon. *Am J Emerg Med.* 2008;26:967.
- [9] Brenner M, Teeter W, Hoehn M, et al. Use of resuscitative endovascular balloon occlusion of the aorta for proximal aortic control in patients with severe hemorrhage and arrest. *JAMA Surg.* 2017; *In Press.* doi: 10.1001/jamasurg.2017.3549.
- [10] Guliani S, Amendola M, Strife B, et al. Central aortic wire confirmation for emergent endovascular procedures: As fast as surgeon-performed ultrasound. *J Trauma Acute Care Surg.* 2015;79:549–54.
- [11] Ball CG, Wilson SR, Cattle P. Ultrasonography for resuscitative endovascular balloon occlusion of the aorta. *J Trauma Acute Care Surg.* 2016;81:616–17.
- [12] Chaudery M, Clark J, Morrison JJ, Wilson MH, Bew D, Darzi A. Can contrast-enhanced ultrasonography improve Zone III REBOA placement for prehospital care? *J Trauma Acute Care Surg.* 2016;80:89–94.
- [13] Davidson AJ, Russo RM, Reva VA, et al. The pitfalls of REBOA. *J Trauma Acute Care Surg.* 2017; *In Press.* doi: 10.1097/TA.0000000000001711.
- [14] Kamenskiy A, Miserlis D, Adamson P, et al. Patient demographics and cardiovascular risk factors differentially influence geometric remodeling of the aorta compared with the peripheral arteries. *Surgery.* 2015;158: 1617–27.
- [15] Dibble CT, Shimbo D, Barr RG, et al. Brachial artery diameter and the right ventricle: The multi-ethnic study of atherosclerosis-right ventricle study. *Chest.* 2012;142: 1399–405.
- [16] Brenner M, Teeter W, Hoehn M, et al. Use of resuscitative endovascular balloon occlusion of the aorta for proximal aortic control in patients with severe hemorrhage and arrest. *JAMA Surg.* 2017; *In Press.* doi: 10.1001/jamasurg.2017.3549.

# Effect of Severe Traumatic Hemorrhage on Large Arterial Diameter as Determined by Computed Tomography

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**Background:** The objective of this study was to investigate changes in the diameters of major arteries in trauma patients at the time of severe intravascular volume depletion.

**Methods:** Patients admitted from January 2008–June 2017 in extremis or in arrest who had an immediate computed tomography (CT) scan in the resuscitation period and at least one subsequent CT scan after hemodynamic stabilization and admission to the intensive care unit were included. Diameter in millimeters (mm) of the common carotid, subclavian, common iliac, external iliac, common femoral arteries, and aorta at the following locations were obtained: ascending, proximal descending, and mid-descending thoracic and supra-celiac, renal, and aortic bifurcation.

**Results:** Fourteen patients (93% male) were included. Mean injury severity score was  $37 \pm 8$  and age  $36 \pm 18$  years. Ten patients received a resuscitative endovascular balloon occlusion of the aorta and four patients received a resuscitative thoracotomy prior to the first CT. A maximum increase of the aorta of 63.6%, and 116.9% in the common carotid, subclavian, common iliac, external iliac, and common femoral arteries was observed. For patients aged 18–39 years, increases in diameter were statistically significant ( $p < 0.05$ ) at all locations except the peri-renal aorta and left subclavian. Patients  $\geq 40$  years had a less robust change, with a significant diameter increase only with the proximal descending aorta ( $p = 0.02$ ).

**Conclusions:** Large arterial diameters in the setting of severe hemorrhage are significantly reduced particularly in younger patients. This has significant implications for emergent placement of endovascular devices such as introducer sheaths, balloon catheters, and stent grafts where the determination of arterial diameter is critical.

**Keywords:** Resuscitative Endovascular Balloon Occlusion of the Aorta; REBOA; Aortic Occlusion; Resuscitative Thoracotomy; Hemorrhagic Shock; Diameter

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## INTRODUCTION

The prevalence of endovascular and catheter-based interventions in trauma has been increasing, as evidenced by the paradigm shift in treatment of blunt thoracic aortic injuries (BTAI) from open surgical repair to thoracic endovascular repair (TEVAR) [1–3], as well as a significant increase in the usage of resuscitative endovascular balloon occlusion of the aorta (REBOA) [4,5]. The ability to predict and/or measure arterial diameter is critical in these contexts. A substantial transient decrease in arterial diameter, such as with hemorrhagic shock, may have important implications for emergent placement of endovascular devices, such as introducer sheaths, balloon catheters, and stent grafts. An underestimation of arterial diameter may lead to inappropriate stent sizing,

which may increase the risk for complications such as endoleak, endograft malposition, migration, or collapse. The inflation diameter with balloon catheters required to occlude the aorta may be reduced, which may be significant especially in the setting of blind inflation. Lastly, decreased arterial diameters may potentially exacerbate the flow-limiting effects of indwelling introducer sheaths.

Hypovolemia from hemorrhagic shock and sympathetic activation from trauma results in a decrease in the diameters of the aorta and other large arteries; however, this phenomenon has yet to be adequately characterized. Porcine models of hemorrhagic shock have demonstrated that the diameter of the aorta can substantially decrease, up to 61%, and that the pulsatility (change in diameter between systole and diastole) of the aorta is also diminished [6,7], and may ultimately lead to the underestimation of these diameters at baseline. A few studies [8–10] have demonstrated that arterial diameters, as measured by computed tomography (CT) imaging acquired near admission, are reduced in comparison to subsequent CT imaging in humans. However, it remains unclear what the upper limits of this effect are on the diameters of the aorta and large arteries in trauma patients. In addition, there is a paucity of literature examining what the effects of aging or cardiovascular disease may be.

We sought to investigate this phenomenon by examining patients who underwent procedures typically reserved for patients in extremis such as REBOA or resuscitative thoracotomy. These patients likely represent a cohort of the most severely injured and potentially treatable patients.

## METHODS

This retrospective case series was approved by the University of Maryland Medical Center Institutional Review Board. Patients, age  $\geq 18$  years old, admitted to the University of Maryland Shock Trauma Center, between January 2008 and June 2017, who underwent REBOA or resuscitative thoracotomy in the resuscitation area or were taken to the operating room emergently and had REBOA or thoracotomy were included. Patients who had a CT scan of the thorax and/or abdomen/pelvis immediately before or after intervention, as well as a subsequent CT, were included. The comparison CT, defined as the “baseline” or “reference” CT, was required to be obtained within 1 year of the CT obtained at the time of injury. Patients were excluded if they had a CT scan performed with the REBOA balloon partially or fully inflated. Demographics and hospital course data were collected from medical records.

All images were reviewed and vessel measurements were taken by a board-certified trauma radiologist with 25 years expertise in trauma imaging, who was blinded to the purpose of the study. Images were reviewed using

IMPAX Software (AGFA Healthcare, Mortsel, Belgium). Two diameter measurements were taken at each location (one in the anterior–posterior dimension, and the other in the left–right or cranial–caudal dimension). Diameter measurements were taken of the left and right common carotid and subclavian arteries within 1 cm of their origins to the aorta/innominate artery. Measurements were taken of the ascending aorta (at the level of the manubrium-sternal joint), proximal descending thoracic aorta (just distal to the left subclavian artery origin), mid-descending thoracic aorta (at the level of the left pulmonary artery), supra-celiac aorta (immediately proximal to the origin of the celiac artery), peri-renal aorta (immediately adjacent to the renal arteries), and the aortic bifurcation (immediately proximal to the aortic bifurcation). The common iliac arteries were measured immediately proximal to the origin of the internal iliacs. The external iliacs were measured immediately adjacent to the origin of the inferior epigastric arteries. Lastly, the common femoral arteries were measured immediately proximal to the bifurcation of the superficial femoral and profunda femoris arteries. All measurements were taken using axial images except for the right subclavian artery, which required coronal imaging. No patients had significant tortuosity and/or angulation requiring reformatting of imaging to obtain appropriate diameter measurements perpendicular to the long axis of the vessels. Diameter measurements and comparisons were only included if it was possible to obtain measurements at both CT scan time points.

Patients were analyzed in total and divided into two groups, those aged 18–39 years and those over 39 years old. The diameters of the CT adjacent to the time of injury and reference CT were compared. The eccentricity of the arteries at each location was calculated and analyzed for potential changes. The value of eccentricity ranges from 0 (a perfect circle) to 1 (a straight line). Statistical analysis was performed using R Software (version 3.3.0, R Development Core Team, Vienna, Austria). A paired two-sample *t*-test was used for mean comparison of diameter and eccentricity changes between CT scans at both time points.

An unpaired one-sided *t*-test was used for mean comparison of the relative increase in arterial diameters between the younger (18–39 years) and older ( $\geq 40$  years) age groups. For patients who underwent REBOA, the change in the common femoral artery that was accessed and manipulated was compared to the contralateral common femoral artery using a paired two-sided *t*-test. Fisher’s exact test was used for proportion comparison of demographic characteristics between age groups. Statistical significance was defined as a *p*-value of 0.05 or less.

## RESULTS

Fourteen patients were included. See Table 1 for a description of patient demographics and characteristics.



**Table 1** Demographics and characteristics.

Variable	Value
<i>n</i>	14
ISS (mean $\pm$ standard deviation)	37 $\pm$ 8
Penetrating/blunt	57%, 43%
Gender	93% male, 7% female
Age (years)	36 $\pm$ 18
REBOA	<i>n</i> = 10
Resuscitative thoracotomy	<i>n</i> = 4
Time from admission to CT scan, median [inter-quartile range]	281 [191–673] minutes
Time from CT imaging near point of injury to comparison (baseline) CT	16 [10–28] days
Initial admission hemoglobin (mean $\pm$ standard deviation)	11.6 $\pm$ 1.8 g/dL
24 hour nadir hemoglobin	8.7 $\pm$ 1.9 g/dL
24 hour highest lactate	9.1 $\pm$ 5.1 mmol/L
Initial admission lactate	9.0 $\pm$ 5.2 mmol/L
24 hour nadir pH ABG	7.10 $\pm$ 0.18
24 hour nadir base deficit	–13.8 $\pm$ 6.8

The majority (93%) of patients were male. Mean injury severity score (ISS) was ( $\pm$  SD) 37  $\pm$  8 and mean age was 36  $\pm$  18 years. Three patients presented in cardiac arrest. For patients with a spontaneous rhythm, the admission systolic blood pressure was 97  $\pm$  32 mmHg and heart rate was 113  $\pm$  23. An additional three patients subsequently developed cardiac arrest in the resuscitation bay before operative intervention. Patients suffered severe hemorrhage as evidenced by their low hemoglobin laboratory values on admission and the lowest values within the first 24 hours of admission. The demographic and injury characteristics of the patients age 18–39 years old were similar to that of the patients 40 years old or over with the exception that the majority (60%) of patients in the older group had a history of hypertension compared to no patients in the 18–39 year-old group ( $p = 0.03$ ).

As seen in Table 2, there was a significant increase in arterial diameters in the aorta and large arteries between the initial/admission CT scan and the reference CT scan. The mean increase in diameter size ranged from 1.4 (right subclavian) to 2.7 millimeters (mm) (mid-descending thoracic aorta), with a maximum increase of the aorta (ascending aorta) of 8.1 mm and up to a maximum of 5.2 mm (left common carotid) in the other arteries. The maximum increase of the aorta (at the aortic bifurcation) was 63.6%, and the maximum increase of the other arteries ranged between 48.1 and 116.9%. While many patients had significant increases in the diameters of the various arteries, some had minimal to no change and in some cases, there was even a small decrease in size.

Changes in arterial diameters were compared between younger (aged 18–39 years) and older (aged  $\geq$ 40 years) patients, as seen in Table 3. The patients in the younger group had large, statistically significant, increases in their arterial diameters at almost all levels (except the left subclavian and peri-renal aorta,  $p = 0.056$  and 0.093, respectively). In contrast, patients in the older group had a less dramatic increase, with statistical significance only

being achieved in the proximal descending thoracic aorta. When compared, the younger group had a statistically significant larger increase in their arterial diameters at several locations, including the right common carotid, right subclavian, bilateral common iliac, and left common femoral arteries. The substantial difference between the two age groups in changes of arterial diameter from the initial/admission CT to the reference CT can be further visualized in Figure 1. Figure 1 also highlights the distribution of the diameter measurements and the degree of eccentricity for each group and CT measurement time point. Overall, most measurements of the arteries revealed some eccentricity with slight changes from the reference CT; however, no consistent pattern of increasing or decreasing eccentricity was identified across the different locations.

For all patients undergoing REBOA with complete data for both common femoral arteries ( $n = 6$ ), there was no significant difference between the manipulated/ accessed common femoral artery compared to the artery that was not accessed (23.9% vs. 19.7% increase, respectively;  $p = 0.62$ ). Interestingly, younger patients (18–39 years,  $n = 3$ ) did have a larger increase in arterial diameter on the side that was accessed vs. not accessed (54.4% vs. 37.7%, respectively;  $p = 0.14$ ).

## DISCUSSION

Large arterial diameters in the setting of severe hemorrhage are dramatically reduced, particularly in younger patients. The findings of a statistically significant and consistent decrease in diameter throughout the various locations of the aorta at the time of hemorrhage and injury, with an attenuated effect in older patients, have not been previously demonstrated [9,10]. In addition, the mean and maximum changes in the aorta of our series are greater than the cohorts of patients previously described [9,10], and may serve

**Table 2** Arterial measurement characteristics for all patients.

	N (n = 14)	M1	M2	Mean difference (mm)	Difference (% increase)	Range (%)	p-value
Right common carotid	12	6.9 ± 1.3	8.3 ± 1.7	2.2 ± 1.3	31.6 ± 34.8	-24.7–103.2	0.04
Left common carotid	12	6.8 ± 1.2	8.3 ± 1.4	1.9 ± 1.4	26.5 ± 35.0	-15.2–116.9	0.02
Right subclavian	12	6.6 ± 1.2	7.9 ± 1.6	1.4 ± 1.2	20.3 ± 23.4	-6.9–79.1	0.01
Left subclavian	13	8.6 ± 1.2	9.7 ± 1.7	1.7 ± 1.2	14.9 ± 23.1	-12.9–58.0	0.04
Ascending aorta	13	25.1 ± 3.9	27.0 ± 3.4	2.4 ± 2.2	8.5 ± 10.9	-10.0–31.6	0.02
Proximal descending aorta	13	20.2 ± 3.0	22.7 ± 2.5	2.6 ± 2.0	13.8 ± 12.2	-1.6–29.2	0.001
Mid- descending thoracic aorta	13	19.2 ± 3.0	21.6 ± 2.5	2.7 ± 1.9	13.6 ± 14.1	-10.9–37.0	0.003
Supra-celiac aorta	13	18.2 ± 3.8	19.8 ± 2.3	2.4 ± 1.6	11.7 ± 16.9	-10.8–50.6	0.03
Peri-renal aorta	11	15.8 ± 3.1	17.2 ± 2.4	1.9 ± 1.5	11.4 ± 16.0	-7.0–48.3	0.03
Aorta at aortic bifurcation	11	14.4 ± 3.1	16.2 ± 1.9	2.5 ± 2.0	16.0 ± 23.0	-13.1–63.6	0.057
Right common iliac	10	10.3 ± 3.5	10.9 ± 2.1	2.4 ± 1.4	12.2 ± 28.8	-25.1–52.0	0.52
Left common iliac	11	9.8 ± 3.1	11.0 ± 1.5	2.6 ± 1.2	18.8 ± 28.7	-23.1–57.9	0.19
Right external iliac	7	6.6 ± 1.6	8.9 ± 1.3	2.4 ± 1.2	39.7 ± 27.7	-1.7–76.8	0.004
Left external iliac	10	7.0 ± 2.2	9.2 ± 1.7	2.5 ± 1.6	38.9 ± 33.1	-13.6–91.8	0.006
Right common femoral	8	7.8 ± 3.1	8.7 ± 1.5	1.9 ± 1.4	6.8 ± 31.2	-27.5–78.7	0.30
Left common femoral	10	7.8 ± 2.6	8.9 ± 1.6	1.6 ± 1.0	22.3 ± 19.8	-5.4–48.1	0.12

M1: Admit CT measurement (mean ± std. dev. mm). M2: Comparison CT measurement (mean ± std. dev. mm).

**Table 3** Arterial measurement characteristics for patients aged 18–39 years and patients age ≥40 years.

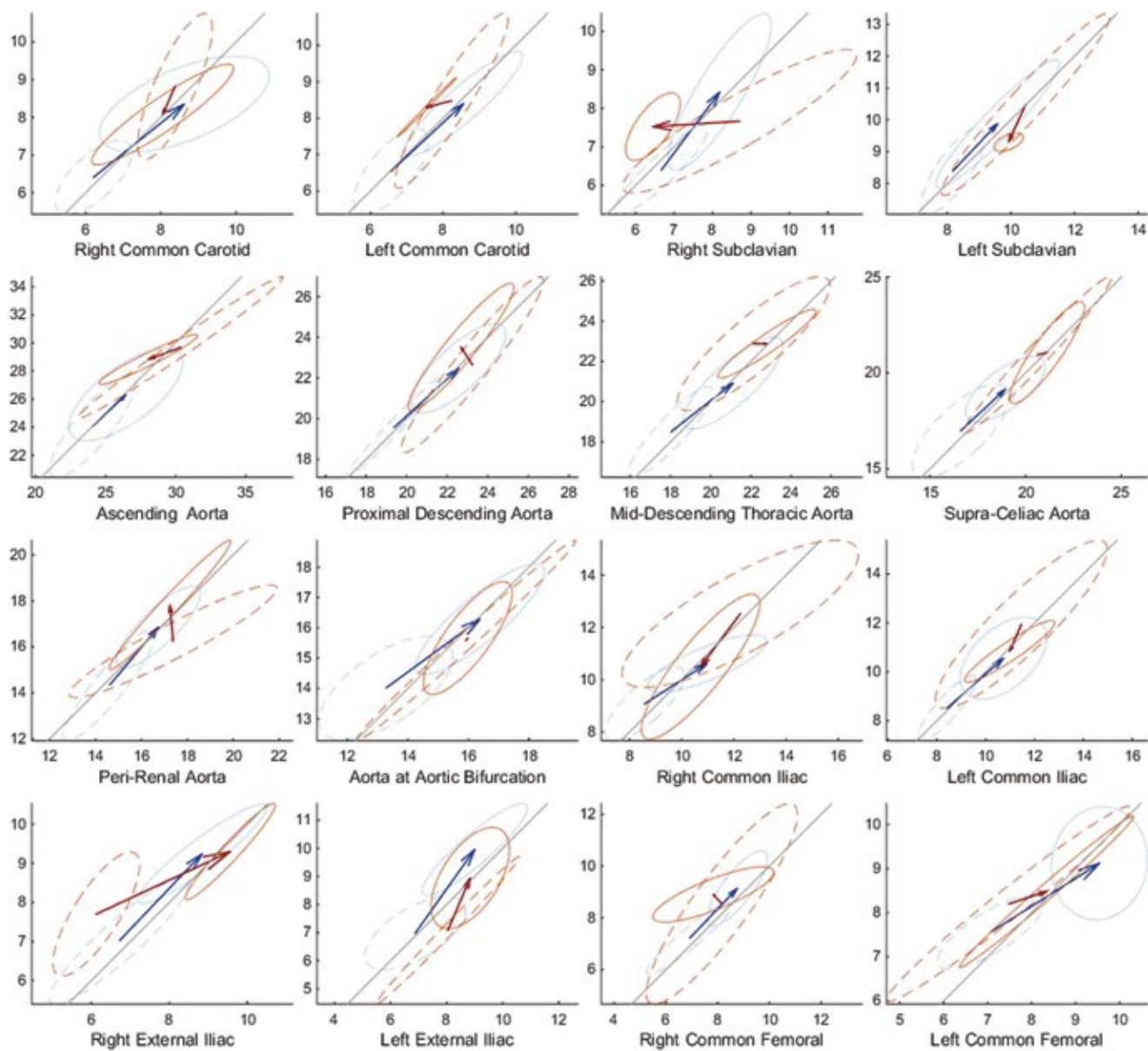
	Difference (% increase) 18–39 years	N (n = 9)	p-value (18–39 years M1 vs. M2)	Difference (% increase) ≥40 years	N (n = 5)	p-value (≥40 years M1 vs M2)	p-value comparison 18–39 vs. ≥40
Right common carotid	37.3 ± 33.9	8	0.013	1.1 ± 24.4	4	1.000	0.044
Left common carotid	36.0 ± 38.3	8	0.018	7.5 ± 18.4	4	0.497	0.098
Right subclavian	30.8 ± 21.7	8	0.001	-0.7 ± 5.3	4	0.702	0.009
Left subclavian	18.6 ± 25.1	9	0.056	6.3 ± 18.0	4	0.596	0.199
Ascending aorta	10.3 ± 12.1	9	0.047	4.4 ± 7.3	4	0.291	0.195
Proximal descending aorta	16.7 ± 13.7	9	0.004	7.2 ± 4.3	4	0.018	0.104
Mid-descending thoracic aorta	16.3 ± 15.7	9	0.013	7.5 ± 8.2	4	0.111	0.160
Supra-celiac aorta	16.9 ± 18.3	8	0.024	3.3 ± 11.4	5	0.758	0.085
Peri-renal aorta	16.3 ± 20.3	6	0.093	5.4 ± 6.5	5	0.182	0.139
Aorta at aortic bifurcation	25.8 ± 21.9	6	0.017	4.1 ± 20.1	5	0.951	0.062
Right common iliac	37.3 ± 14.1	5	0.004	-12.9 ± 9.7	5	0.083	<0.001
Left common iliac	34.5 ± 18.3	6	0.005	-0.2 ± 28.7	5	0.553	0.019
Right external iliac	48.6 ± 24.9	5	0.003	17.5 ± 27.2	2	0.541	0.101
Left external iliac	51.6 ± 31.5	5	0.012	26.2 ± 32.7	5	0.225	0.123
Right common femoral	33.5 ± 29.4	5	0.026	-2.0 ± 22.2	3	0.647	0.062
Left common femoral	33.3 ± 13.7	5	0.002	11.3 ± 19.8	5	0.357	0.038

as a guide to the potential upper limit of change in arterial diameters. These findings deserve consideration when performing endovascular interventions within these patient populations.

The observations of decreased arterial diameters in the setting of intra-arterial volume depletion are likely a function of arterial compliance. The aorta is very compliant, especially in younger patients, and significant changes in diameter occur between systole and diastole [11]. Numerous studies have demonstrated that the compliance of the aorta and large arteries decreases with age, and may be related to cardiovascular

disease [12–14]. We hypothesize that the finding that older patients have a less dramatic decrease in arterial diameters secondary to trauma and hemorrhage is likely related to decreased arterial compliance secondary to the effects of aging including cardiovascular disease.

Some endograft-specific complications may be related to under or over-sizing the stent based upon the initial admission CT (which frequently can be the only CT available). If a CT scan is performed on a severely injured patient on admission, the measurements may be underestimated in comparison to a healthy state and therefore the endograft stent may be under-sized, lead-



**Figure 1** Changes in arterial diameters from the initial CT and reference CT are depicted. Each ellipsoid represents the two-dimensional Gaussian distribution (1 standard deviation) of arterial diameters made at the initial (dashed line) and reference (solid line) CTs. Patients aged 18–39 years are represented in light blue, and patients aged  $\geq 40$  years are represented in orange. The average increases for each group are represented by arrows starting at the centroid of the initial CT and ending (arrowhead portion) at the centroid of the reference CT. The axes are measured in millimeters. For all locations except the right subclavian artery, the Y axis is the anterior–posterior arterial diameter and the X axis is the right–left arterial diameter. For the right subclavian, the Y axis is the cranial–caudal arterial diameter and the X axis is the anterior–posterior arterial diameter. The solid gray lines depict equal diameter measurements of both axis and therefore represent an eccentricity of 0 (perfect circle). Overall, most measurements of the arteries revealed some eccentricity which slightly changed with the reference CT; however, no consistent pattern of increasing or decreasing eccentricity was identified across the different locations.

ing to potential complications. Given the findings of our series, it is clear that not all patients undergoing endovascular repair should have their endograft stents oversized to the same degree, based upon their admission CT scan, and the potential change in arterial dimensions is significantly greater than previously thought. Further imaging modalities such as intravascular ultrasound (IVUS) in the operating room just prior to endograft

placement can give a more accurate aortic diameter [17,18]. The use of IVUS in the resuscitation bay prior to REBOA is not a feasible or safe option.

Arterial access and the management of arterial sheaths may be affected by a decrease in arterial diameters. The presence of an arterial sheath obstructs (at least partially) the arterial lumen and limits flow distal to the sheath. A study examining the degree of obstruction

to the external iliac artery caused by introducer sheaths in endovascular aneurysm repairs (EVAR) demonstrated that the sheaths caused a mean functional stenosis of 70% [19], and cases of lower extremity ischemia secondary to the presence of an introducer sheath in the common femoral artery have been reported in the EVAR literature [19,20]. According to Poiseuille's law, the amount of flow through a pipe is related to the radius to the fourth power and therefore the decrease in diameters of the common femoral and external iliac arteries may dramatically increase the degree of flow limitation to the lower extremity. In addition, although our findings did not reach statistical significance, we suspect that the mere act of manipulating and accessing the common femoral artery may cause a further reduction of arterial size, especially in younger patients. Lower extremity ischemia in the setting of hemorrhage and severe trauma secondary to prolonged usage (28 hours) of a sheath in the common femoral artery has been described in a patient who underwent REBOA [21]. Anecdotally, we have encountered a patient (18-year-old female in profound hemorrhagic shock) in whom a 7 French sheath was totally occlusive of the common femoral artery at time of sheath removal after performing REBOA. Given these findings, our experience has led us to remove arterial sheaths as soon as possible, typically in the index operation or shortly thereafter once coagulopathy has improved.

The inflation diameter with balloon catheters required to occlude the aorta may be reduced in patients suffering from hemorrhage, which is especially important in relation to blind inflation. Adequate inflation of balloon catheters, such as for REBOA, is imperative to avoid potential complications of over-inflation including arterial injury or balloon rupture [22,23]. In addition, blind inflation in REBOA is typically performed in moribund patients before arrival to the operating room [5]. The amount of volume to achieve aortic occlusion in this setting may be less than previously thought, and is the focus of ongoing clinical investigations. Morphometric analyses have guided clinical estimates for inflation volumes for aortic occlusion; however, these images and measurements were collected from euvoletic patients. This data may help refine clinical protocols and procedure specifications.

### Limitations

This study has several limitations. The study is a retrospective case series with a relatively small number of patients included. The CT imaging analyzed was not ECG gated, and therefore represents a confounding variable that we could not control for. The inability to control for exactly when the images were captured during the cardiac cycle is likely responsible for some variance in measurements and it is apparent in the findings that in some comparisons the arterial diameters

were slightly larger during hemorrhage than during the reference imaging.

### CONCLUSION

The diameters of major arteries, especially in younger patients, are temporarily decreased by severe trauma and hemorrhage. This has significant implications for emergent placement of endovascular devices such as introducer sheaths, balloon catheters, and stent grafts where the determination of arterial diameter is critical.

### REFERENCES

- [1] Demetriades D, Velmahos GC, Scalea TM, et al. Operative repair or endovascular stent graft in blunt traumatic thoracic aortic injuries: results of an American Association for the Surgery of Trauma Multicenter Study. *J Trauma*. 2008;64:561–71.
- [2] DuBose JJ, Leake SS, Brenner M, et al. Contemporary management and outcomes of blunt thoracic aortic injury: a multicenter retrospective study. *J Trauma Acute Care Surg*. 2015;78:360–369.
- [3] Shackford SR, Dunne CE, Karmy-Jones R, et al. The evolution of care improves outcome in blunt thoracic aortic injury. *J Trauma Acute Care Surg*. 2017;83:1006–13.
- [4] Brenner ML, Moore LJ, DuBose JJ, et al. A clinical series of resuscitative endovascular balloon occlusion of the aorta for hemorrhage control and resuscitation. *J Trauma Acute Care Surg*. 2013;75:506–11.
- [5] DuBose JJ, Scalea TM, Brenner M, et al. The AAST prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). *J Trauma Acute Care Surg*. 2016;81:409–19.
- [6] Jonker FHW, Mojibian H, Schlosser FJ, et al. The impact of hypovolaemic shock on the aortic diameter in a porcine model. *Eur J Vasc Endovasc Surg*. 2010;40:564–71.
- [7] Jonker F, van Keulen J, Schlosser F, et al. Thoracic aortic pulsatility decreases during hypovolemic shock: implications for stent-graft sizing. *J Endovasc Ther*. 2011;18:491–6.
- [8] van Prehn J, van Herwaarden JA, Muhs BE, Arnofsky A, Moll FL, Verhagen HJM. Difficulties with endograft sizing in a patient with traumatic rupture of the thoracic aorta: the possible influence of hypovolemic shock. *J Vasc Surg*. 2008;47:1333–6.
- [9] Hoffman JR, Chowdhury R, Johnson LS, et al. Posttraumatic resuscitation affects stent graft sizing in patients with blunt thoracic aortic injury. *Am Surg*. 2016;82:75–8.
- [10] Jonker FHW, Verhagen HJM, Mojibian H, Davis KA, Moll FL, Muhs BE. Aortic endograft sizing in trauma patients with hemodynamic instability. *J Vasc Surg*. 2010;52:39–44.
- [11] van Prehn J, Vincken KL, Sprinkhuizen SM, et al. Aortic pulsatile distention in young healthy volunteers is asymmetric: analysis with ECG-gated MRI. *Eur J Vasc Endovasc Surg*. 2009;37:168–74.

- [12] Bulpitt CJ, Rajkumar C, Cameron JD. Vascular compliance as a measure of biological age. *J Am Geriatr Soc.* 1999;47:657–63.
- [13] Millasseau SC, Kelly RP, Ritter JM, Chowienczyk PJ. Determination of age-related increases in large artery stiffness by digital pulse contour analysis. *Clin Sci (Lond).* 2002;103:371–7.
- [14] Bulpitt CJ, Cameron JD, Rajkumar C, et al. The effect of age on vascular compliance in man: which are the appropriate measures? *J Hum Hypertens.* 1999;13:753–8.
- [15] Kasirajan K, Dake MD, Lumsden A, Bavaria J, Makaroun MS. Incidence and outcomes after infolding or collapse of thoracic stent grafts. *J Vasc Surg.* 2012;55:652–8.
- [16] Jonker FHW, Schlosser FJ, Geirsson A, Sumpio BE, Moll FL, Muhs BE. Endograft collapse after thoracic endovascular aortic repair. *J Endovasc Ther.* 2010;17:725–34.
- [17] Jánosi RA, Gorla R, Rogmann K, et al. Validation of intravascular ultrasound for measurement of aortic diameters: comparison with multi-detector computed tomography. *Minim Invasive Ther Allied Technol.* 2015;5706:1–7.
- [18] Blasco A, Piazza A, Goicolea J, et al. Intravascular ultrasound measurement of the aortic lumen. *Rev Española Cardiol.* 2010;63:598–601.
- [19] Jonsson T, Larzon T, Jansson K, Arfvidsson B, Norgren L. Limb ischemia after EVAR: an effect of the obstructing introducer? *J Endovasc Ther.* 2008;15:695–701.
- [20] Manning BJ, Agu O, Richards T, Ivancev K, Harris PL. Temporary axillobifemoral bypass as an adjunct to endovascular aneurysm repair using fenestrated stent grafts. *J Vasc Surg.* 2011;53:867–9.
- [21] Okada Y, Narumiya H, Ishi W, Ryoji I. Lower limb ischemia caused by resuscitative balloon occlusion of aorta. *Surg Case Rep.* 2016;2:130.
- [22] Søvik E, Stokkeland P, Storm BS, Åsheim P, Bolås O. The use of aortic occlusion balloon catheter without fluoroscopy for life-threatening post-partum haemorrhage. *Acta Anaesthesiol Scand.* 2012;56:388–93.
- [23] Davidson AJ, Russo RM, Reva VA, et al. The pitfalls of REBOA. *J Trauma Acute Care Surg.* 2017; *In Press.* doi: 10.1097/TA.0000000000001711.

# First Use of the Manta Closure Device in Ruptured Abdominal Aortic Aneurysm Patients and its Potential Usage for Urgent Endovascular Procedures: A Short Report

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Arterial closure after endovascular procedures can be managed by manual compression, fascia suture, closure devices or surgical cut-down with direct vessel suture. We describe the first successful usage of the Manta closure device for large access closure in three cases of ruptured abdominal aortic aneurysm. This large-bore access closure device has the potential for use in other endovascular procedures and might be especially beneficial in emergent endovascular surgery.

**Keywords:** Closure Device; Endovascular; EVAR; Vascular Access

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## INTRODUCTION

Correct closure of a large-bore access at the end of an endovascular procedure is of high importance, especially in emergency procedures such as endovascular aortic repair (EVAR) for ruptured abdominal aortic aneurysm (rAAA). However, this may be challenging and complications, such as excess bleeding, might cause further delay as well as increase the risk of infections.

In an acute setting, time is of the essence in the hemodynamically unstable patient [1]. During EVAR and other procedures, such as thoracic endo-grafts and transfemoral valve replacements, there are several closure devices used for large-bore access. The majority of devices have relatively low failure rates and are considered safer than manual compression, but require considerable pre-procedural preparation before being used [2]. Other vessel closure possibilities are fascia suture and the surgical cut-down procedure [3]. All these procedures have pros and cons but the optimal access closure in urgent procedures should be fast, simple and have a low failure rate [1]. Manta (Essential Medical Inc, Malvern, USA) is a recently developed percutaneous closure device intended for large-bore access sheaths between 10 and 25 Fr. It consists of a delivery system attached to a closure unit consisting of a sheath with introducer and a puncture location dilator. The closure unit works by using an intraluminal toggle that seals the vessel from the inside which is then connected by a polyester suture to an extravascular hemostatic bovine collagen pad with a fluoroscopically visible lock. The components of the closure unit will all be reabsorbed within 6 months, except for the stainless-steel suture

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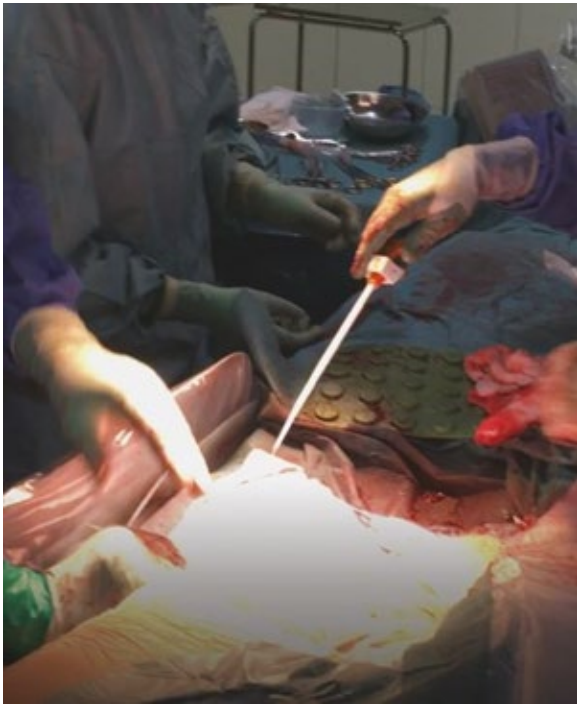
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**Author contributions:** TMH drafted the manuscript, all other authors helped draft the manuscript.

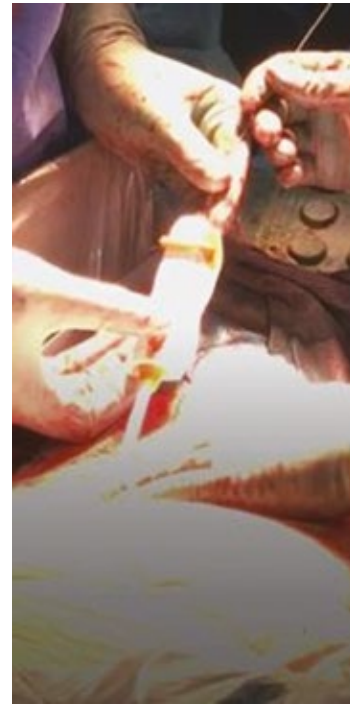
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**Figure 1** Manta sheath introduced on a wire at the end of the procedure.

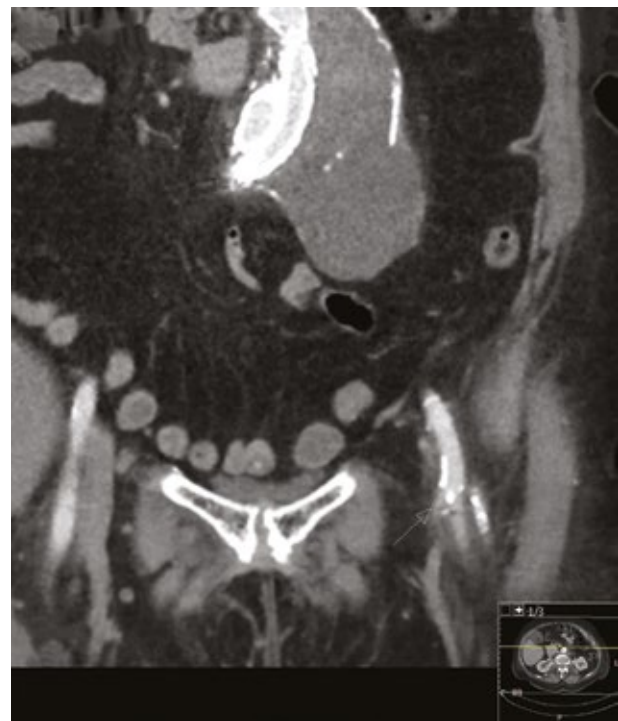


**Figure 2** Manta device deployment.

lock which allows for future x-ray identification of the puncture site [4]. We describe three consecutive cases of rAAA treated by EVAR, where the EVAR procedure was terminated successfully with bilateral femoral access closure using the Manta closure device.

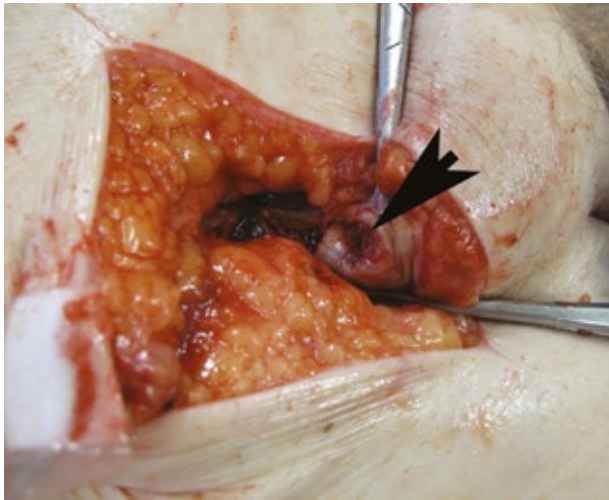
### Case Descriptions and Usage of the Device

After receiving a short instruction on its use, the team successfully used Manta in an elective EVAR with bilateral femoral access (12 Fr and 16 Fr sheaths, GORE stent-graft system). Thereafter, the first rAAA case in which it was used was an 87-year-old woman admitted with a three-week history of abdominal pain. On admission, due to accentuation of abdominal pain, a computed tomography (CT) was performed and revealed an 8 cm rAAA. The patient was hemodynamically stable and transferred to the hybrid operating room immediately for urgent EVAR according to our hospital routines [5]. The procedure started with percutaneous ultrasound assisted access with a 7 Fr sheath and measurement of the vessel depth as described in the Manta instructions for use (IFU). EVAR was performed successfully with a 32 mm GORE C3 system (W.L. Gore & Associates, Flagstaff, AZ, USA) with a surgical time of around 45 minutes. At the end of the procedure, Manta was used to close the femoral access using a Lunderquist wire (Cook, Bloomington, IN, USA). Manta 16 Fr was used for the 16 Fr access and Manta 14 Fr for the 12 Fr access (Figures 1 and 2). At the end of the procedure, ultrasound was conducted to ensure distal perfusion



**Figure 3** Post-procedural CT with Manta in place in the left femoral artery. Marked with the arrow.

and normal flow was observed in the femoral arteries. The patient recovered without complications and the ankle-brachial index and clinical status were normal. The CT performed two days later showed open femoral arteries bilaterally with no stenosis (Figure 3).



**Figure 4** Autopsy photo of the femoral artery in the third patient. The arrow points to the intravascular Manta toggle.

The following day, the same procedure was performed on a 79-year-old man who presented with a 9 cm rAAA. This patient was circulatory stable with a systolic blood pressure (SBP) of 150 mmHg upon arrival which remained stable during the procedure. EVAR was successfully performed with a 6 mm Chimney graft to the left renal artery (BeGraft, Bentley InnoMed GmbH, Germany) and a 34 mm C3 GORE system. The total surgical time was 190 minutes. Manta 16 Fr and 14 Fr were used to close the bilateral femoral arterial accesses without any complications and normal clinical status. The control CT did not show any stenosis of the femoral arteries.

A third patient, with an aneurysm after a previous open aortic tube-graft reconstruction several years earlier, presented to the emergency department with abdominal pain and an SBP of 70 mmHg. CT showed a 7 cm rAAA. Delayed repair was performed 12 hours later with a Nellix 10 mm endo-graft system (Endologix, Irvine, CA, USA) and a 6 mm Chimney graft (BeGraft) to the left renal artery. The closure device was used successfully but the patient died some hours later due to multi-organ failure. Autopsy revealed the Manta toggle correctly positioned within the femoral artery (Figure 4).

During October 2017, we have used Manta in a total of 7 patients without any complications (three urgent EVAR for rAAA and four elective EVAR for AAA, using Gore and Cook endo-grafts).

## DISCUSSION

The usage of closure devices has been described for rAAA, but the devices commonly used require time and

preparation prior to the endovascular procedure [6]. Cut-down or fascia suture procedures are also time-consuming [3]. In this small series, we used the Manta closure device successfully to terminate the EVAR procedure in three rAAA patients, without any reported complications at the 3-month follow-up. The major advantage of the Manta closure device is that it is easy to use, fast and can be used for large-bore accesses. An important limiting factor of total percutaneous EVAR for rAAA is the need for fast closure of the femoral arterial access. Pre-procedural measurement is recommended for Manta, however not compulsory, to estimate the depth of the femoral artery for correct device placement and may be performed rapidly. There is insufficient published data regarding the failure rate of this specific device, which must be taken into account before adopting it into clinical practice. Theoretically, failure of Manta could occur and the remaining stainless-steel lock could potentially cause complications, especially in calcified arteries. This was, however, not observed in this current series. The use of the reported closure device in these three cases demonstrated that the procedure can be performed safely and rapidly, thus facilitating rapid total procedure time.

## CONCLUSION

Manta can be used in urgent EVAR procedures and might have the potential to be used in other endovascular procedures where large-bore access is required.

## REFERENCES

- [1] Kahlert P, Al-Rashid F, Weber M, et al. Vascular access site complications after percutaneous transfemoral aortic valve implantation. *Herz*. 2009;34:398–408.
- [2] Ben-Dor I, Looser P, Bernardo N, et al. Comparison of closure strategies after balloon aortic valvuloplasty: suture mediated versus collagen based versus manual. *Catheter Cardiovasc Interv*. 2011;78:119–24.
- [3] Larzon T, Geijer H, Gruber G, Popek R, Norgren L. Fascia suturing of large access sites after endovascular treatment of aortic aneurysms and dissections. *J Endovasc Ther*. 2006;13:152–7.
- [4] van Gils L, Daemen J, Walters G, et al. MANTA, a novel plug-based vascular closure device for large bore arteriotomies: technical report. *EuroIntervention*. 2016;12: 896–900.
- [5] Mayer D, Aeschbacher S, Pfammatter T, et al. Complete replacement of open repair for ruptured abdominal aortic aneurysms by endovascular aneurysm repair: a two-center 14-year experience. *Ann Surg*. 2012;256:688–95.
- [6] Hon LQ, Ganeshan A, Thomas SM, et al. Vascular closure devices: a comparative overview. *Curr Probl Diagn Radiol*. 2009;38:33–43.



# Zone 1 or 3? Approach to Zone Selection and Pitfalls of REBOA Placement in Trauma

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The use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in cases of non-compressible torso hemorrhage is becoming increasingly more common. While prospective multicenter data is being collected, and case reports are many, there is still significant debate on the ideal place for REBOA in critically ill trauma patients. With each application of the technique, there are opportunities for lessons learned and opportunities to inform other users while consensus in the trauma community is obtained. We report on the successful use of REBOA for the management of hemorrhagic shock and discuss several such lessons that may improve outcomes in future patients.

**Keywords:** Trauma; Hemorrhage; Shock; Proximal Control; REBOA; Zone 1; Zone 3

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## INTRODUCTION

The use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in cases of non-compressible torso hemorrhage (NCTH) is becoming increasingly more common. While prospective multicenter data is being collected, and case reports are many, there is still significant debate on the ideal place for REBOA in critically ill trauma patients. While the technique has been liberally adopted at some centers, many question its widespread use preceding large evidence-based data supporting its use [1]. In addition, with the FDA approval of a streamlined device utilized through a 7 Fr sheath, REBOA use has increased in non-traumatic disease, in particular, those associated with high bleeding risk [2–4].

While the utility is debated, and may be for some time, early adopters of the technique are still on the upward

slope of the learning curve. With each application of the technique, there are opportunities for lessons learned, and opportunities to inform other users while consensus in the trauma community is obtained. We report on the successful use of REBOA for the management of hemorrhagic shock and discuss several such lessons that may improve outcomes in future patients.

## Case Report

This case involves a 45-year-old male, presenting to the trauma center after a reported fall from five stories (approximately 50 feet). The patient was awake upon arrival but confused. He had equal chest rise bilaterally. His initial vital signs included a systolic blood pressure (SBP) of 130 and a heart rate of 115. He had a fractured left pelvis and proximal left femur. His initial extended focused assessment with sonography (FAST) exam was negative for free fluid, but he had no lung sliding on the left side. His right chest was clear. At this point, after the primary survey, the patient became obtunded and a repeat SBP was 100 mmHg.

He was intubated and a left chest tube placed. He lost his radial pulse but had a palpable femoral pulse. Repeat blood pressure reported an SBP of 63 mmHg. Massive transfusion was initiated and the decision was made to use REBOA.

Ultrasound guidance was used to locate the right femoral artery and the access was obtained with an

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18-gauge finder needle. A 7 Fr sheath was placed over a wire. An ER-REBOA catheter (Prytime Inc.) was measured to zone 3, assuming a pelvic source of bleeding, and placed. The balloon was inflated with 5 cc of saline, no contrast was used. Unable to attach an arterial line, the contralateral femoral pulse was used to confirm adequate balloon inflation (loss of the pulse, 4 minutes total time to occlusion).

Despite ongoing blood product resuscitation and zone 3 occlusion, his blood pressure did not recover. After repeat BP measurements below an SBP of 90 mmHg, the balloon was deflated, advanced to 50 cm, and re-inflated with 8 cc of saline. At this point, the patient responded adequately. He was stable enough for axial imaging, with the goal of identifying an appropriate target for intervention (persistent negative FAST in the trauma bay and pelvic fracture). He tolerated this well, with expected imaging limitations due to balloon occlusion. Imaging revealed a large retroperitoneal hematoma, minimal free fluid, and no solid organ injury. He was taken directly from CT to the operating room (OR) for laparotomy.

In the OR, the abdomen was opened and packed. With close communication with the anesthesia team, the REBOA balloon was partially deflated. After recovery from some hemodynamic derangements, it was then deflated fully. Total balloon time at zone 1 was 32 minutes. Packing was removed sequentially. In the right lower quadrant the cecum and terminal ileum had been avulsed off of their vascular pedicle, and this was managed with resection and suture control of the mesenteric bleed. A retroperitoneal zone 3 hematoma was seen but determined not to be expanding. No other major vascular or solid organ injury was identified. In a damage control manner, his abdomen was left open with abdominal packing in the right lower quadrant. His deflated ER-REBOA catheter was removed in the OR but the sheath was left in place, flushed with heparinized saline.

Postoperatively the patient continued to be somewhat hemodynamically labile and minimally responsive to ongoing resuscitation. He underwent diagnostic angiography of the pelvis and mesenteric vasculature. Images were excellent, but no active blush or treatable lesion was identified. His sheath was again left in place and removed at the bedside the next day. His hemodynamics improved over the next 24 hours, and he underwent repeat laparotomy with restoration of intestinal continuity and abdominal closure. His orthopedic injuries were addressed. He remained hemodynamically stable for 10 days and then was transferred to his home hospital, neurologically intact, for further care and recovery.

## DISCUSSION

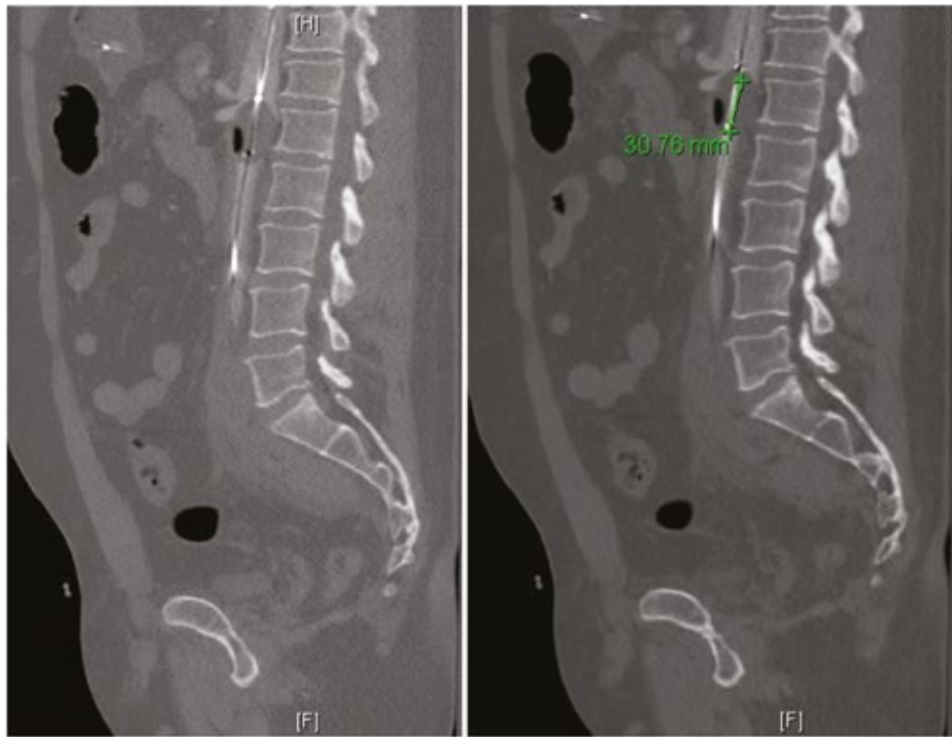
As stated above, the indications and scope of REBOA have yet to be fully elucidated. Regardless, we consider this case to be a success story. It also illustrates several

potential areas of improvement and pitfalls that other users should be aware of.

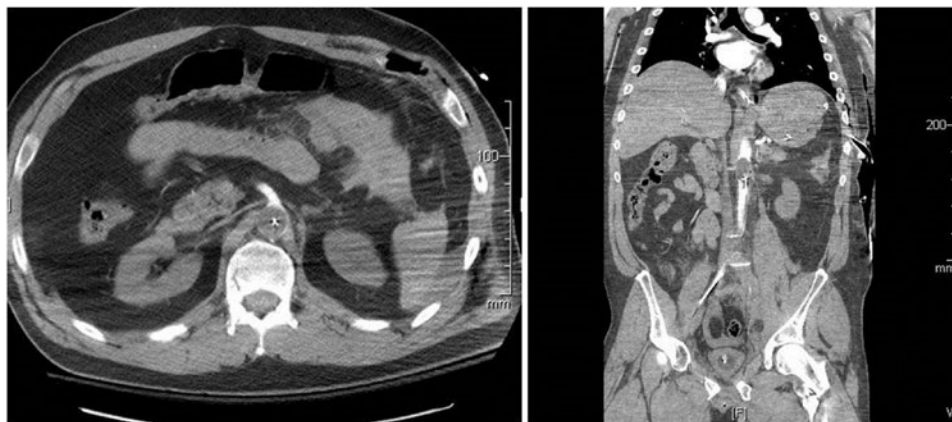
The first issue to point out is in the decision to place the balloon occlusion in zone 3. Although the mechanism was reported to be a fall from height and thus was likely to have a large deceleration component, a negative abdominal sonogram and a pelvic fracture on plain films led us to feel that a zone 3 deployment was appropriate. When the patient's blood pressure did not immediately respond to aortic occlusion at this level (as it nearly universally will in our experience), we deflated the balloon and 'blindly' advanced the balloon to zone 1. This was an estimated distance, and we chose 50 cm as the 'best guess' appropriate distance. This is consistent with anatomic and cadaver studies for a zone 1 placement (minimal zone 1 distance should be 46 cm [5-7]). In retrospect, it may have been preferable to have 'premeasured' both for zone 1 and 3 prior to placement. Taking a mental note of the zone 1 distance may have been of benefit, allowing accurate, patient-specific anatomic balloon deployment versus relying on population-based standards. We recommend that the premeasurement of both zones be incorporated into placement algorithms. It only takes a moment, and in our opinion is several seconds that are well spent in an effort to avoid misplacement. An alternative would be to utilize contrast in the balloon and confirm position radiographically. This is a standard approach in many institutions. However, if this approach is taken, we feel that some of the advantages (primarily speed) of the fluoroscopy free device may be lost.

Our second point is in regards to securing the catheter in place. While several guidelines emphasize the use of commercially available securing devices, these were not immediately available in this case and we used tape and occlusive dressings to secure the balloon at 50 cm. Between placement of the patient into the CT scanner and the images being acquired, the balloon migrated to 43 cm. This is in part a result of the patient's aortic pressure, but more due to the inadequacy of the securing of the device. A commercially available device can be found in any central venous line kit (universally found in emergency departments), individually purchased or can be found in the 'ER-REBOA™ Catheter Convenience Kit' [8] that has been marketed. Suturing the catheter is NOT advised, as kinking of the arterial line lumen is likely.

Finally, during CT imaging, the balloon had migrated to zone 2, providing the unusual opportunity to evaluate images of balloon occlusion in 'no man's land' (Figure 1). We feel that the true danger of a zone 2 deployment is the risk of missing proximal bleeding. Fortunately, this patient had no vascular disease or calcifications, in which case the consequences may have been more severe. We are, however, able to see that there is indeed some flow beyond the balloon and that the hemodynamic benefit of the balloon can be gained without complete occlusion of the vessel (Figure 2).



**Figure 1** REBOA balloon inflated at 43 cm, displaying zone 2 occlusion. As displayed on the right, the advancement of the balloon to the recommended 46 cm or 47 cm would still have left the balloon in Zone 2.



**Figure 2** Zone 2 occlusion in axial and coronal views, displaying near complete occlusion of the aorta with persistent or reconstituted flow to the mesenteric vasculature. Also displayed are abdominal free fluid and a left intertrochanteric femur fracture.

One benefit of having these images is to reinforce the second point above. The balloon in these images was documented at 43 cm. As stated, the minimum distance recommended in the literature is 46 cm or 47 cm. The addition of 3 cm of distance in this patient would not have advanced the balloon to zone 1. This reinforces that an actual anatomic measurement, specific to the patient, should be obtained if possible. We feel that fixed distance placement (46 cm for zone 1 and 27 cm for

zone 3) should be performed only in situations where anatomic distance cannot be measured.

## CONCLUSION

REBOA for NCTH has been reinvigorated through the enthusiasm of several large trauma centers and promotion by early adopters. As the trauma community continues to work toward the best solutions to NCTH,

continued case by case reflection on gaps, areas for improvement, and successes for REBOA is paramount. Until large multicenter data is available, we must rely on the clinical decisions of the frontline trauma surgeons to maximize patient outcomes, and we hope the above reflections assist in getting closer to that goal.

## REFERENCES

- [1] Biffi WL, Fox CJ, Moore EE. The role of REBOA in the control of exsanguinating torso hemorrhage. *J Trauma Acute Care Surg.* 2015;78:1054–8.
- [2] Weltz AS, Harris DG, O’Neill NA, O’Meara LB, Brenner ML, Diaz JJ. The use of resuscitative endovascular balloon occlusion of the aorta to control hemorrhagic shock during video-assisted retroperitoneal debridement or infected necrotizing pancreatitis. *Int J Surg Case Rep.* 2015;13:15–8.
- [3] Lee J, Kim K, Jo YH, et al. Use of resuscitative endovascular balloon occlusion of the aorta in a patient with gastrointestinal bleeding. *Clin Exp Emerg Med.* 2016; 3:55–8.
- [4] Rosenthal MD, Raza A, Markle S, Croft CA, Mohr AM, Smith RS. The novel use of resuscitative endovascular balloon occlusion of the aorta to explore a retroperitoneal hematoma in a hemodynamically unstable patient. *Am Surg.* 2017;83:337–40.
- [5] Okada Y, Narumiya H, Ishi W, Iiduka R. Anatomical landmarks for safely implementing resuscitative balloon occlusion of the aorta (REBOA) in zone 1 without fluoroscopy. *Scand J Trauma Resusc Emerg Med.* 2017;25:63.
- [6] [http://www.usaisr.amedd.army.mil/cpgs/REBOA\\_for\\_Hemorrhagic\\_Shock\\_16Jun2014.pdf](http://www.usaisr.amedd.army.mil/cpgs/REBOA_for_Hemorrhagic_Shock_16Jun2014.pdf). Accessed 2 October 2017.
- [7] Morrison J, Reva V, Lönn L, et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA). In: Hörer T, editor. *Top Stent – the Art of Endovascular Hybrid Trauma and Bleeding Management*. Sweden: Örebro University Hospital; 2017.
- [8] <http://prytime.com/product/convenience-kit/> Accessed 2 October 2017.

# Onyx Embolization in IA Endoleak to Prevent Rupture After Aortic Repair With the Nellix System

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An endoleak after endovascular aorta repair with the Nellix® system is potentially at high risk of rupture. As Nellix is a relatively new system with two parallel grafts, there are very few options for proximal extension of the graft as an endoleak treatment.

We describe in these photos the use of the Onyx® liquid embolization agent for treatment of a type IA endoleak in two elective Nellix cases in our institute, preventing rupture and following instructions for use, with good results at 30 days and 1 year follow up. The endoleak was treated directly peri-operatively in one case and after 30-days control in the other case.

The Onyx embolization agent can be used for other bleeders and has the advantage of being independent of the coagulation status as well as being used downstream in the vascular tree. Figure 1 shows a proximal (IA) endoleak (endoleak, black arrow; left renal artery, red arrow). Figure 2 shows a Bernstein 4Fr catheter (red arrow) in the aneurysm and Onyx embolization of the endoleak (white arrow) (usually via a micro-catheter). Figure 3 shows the completion angiography with no endoleak (red arrow) with the Bernstein catheter in place (white arrow). Figure 4 shows 1-year control after embolization with Onyx (black arrow) and no endoleak on computed tomography or contrast-enhanced ultrasound.

**Keywords:** *Embolization; Onyx; Nellix; Endovascular Aorta Repair; Endoleak*

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Figure 1

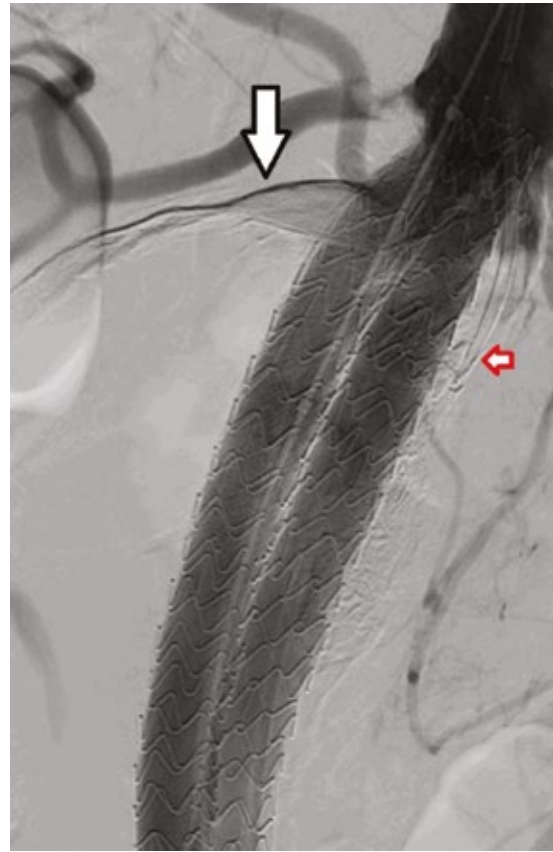


Figure 3

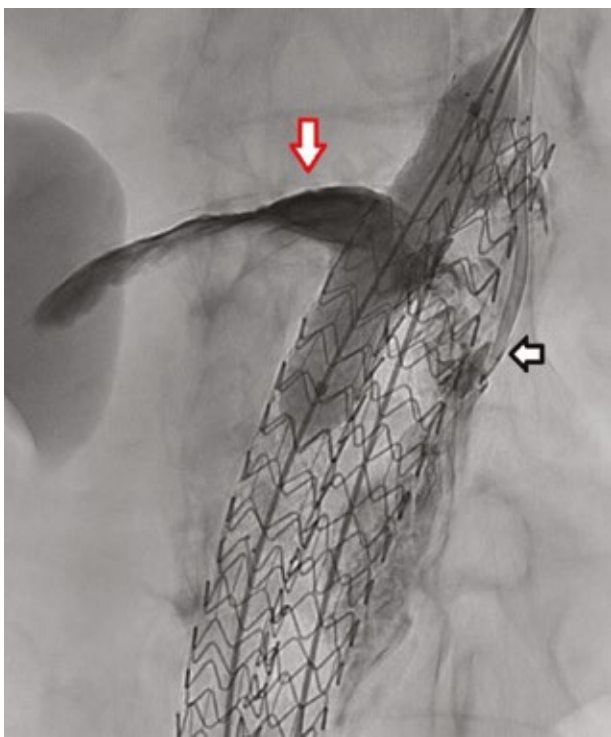


Figure 2

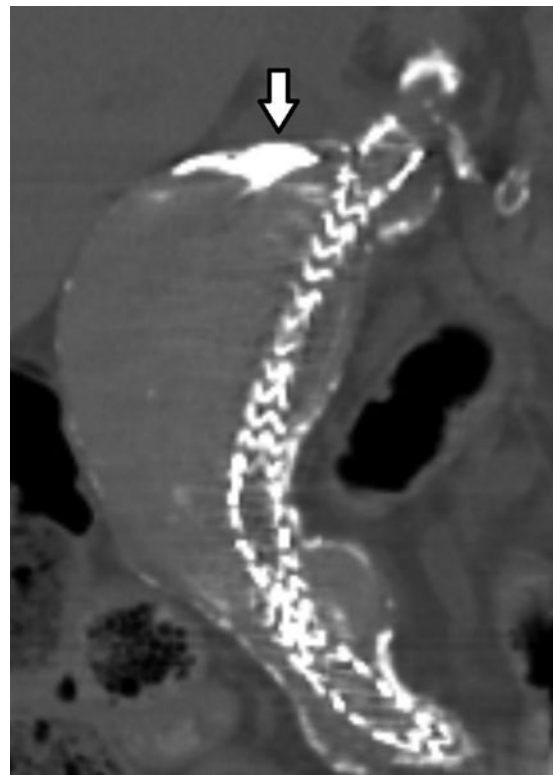


Figure 4

# Use of ER-REBOA™ to Reverse Traumatic Arrest After Non-Truncal Bleeding

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**Keywords:** REBOA; Hemorrhagic Shock; Blunt; Traumatic Arrest

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## INTRODUCTION

For select trauma patients, resuscitative endovascular balloon occlusion of the aorta (REBOA) is an alternative to emergency thoracotomy with aortic cross-clamping [1–3]. The principal indication for this procedure is uncontrolled exsanguination from known abdominal or pelvic injuries [4]. However, as the following case demonstrates, REBOA may also be useful as an adjunct to resuscitating trauma patients in cardiac arrest due to hemorrhagic shock without truncal hemorrhage.

## Case Report

A 41-year-old male was trapped in the cab of a semi-trailer truck following a front-impact, rollover collision

in rural Ohio. The vehicle traveled down an embankment becoming intertwined with a guardrail and trees. One passenger was ejected at the site of impact and was taken to a local hospital. The local emergency medical services (EMS) called for additional assistance with extrication secondary to difficult terrain and suspected injuries. The patient was found to have multiple deep lacerations and concern for a head injury. Extrication was prolonged (>2 hours) and EMS reported significant blood loss at the scene. After extrication, the flight nurse and paramedics obtained intraosseous access. Secondary to concerns for traumatic brain injury, the patient was intubated with a 7.5 mm endotracheal tube and given 100 mcg fentanyl IV, 100 mg ketamine IV, 100 mg rocuronium IV, 40 mg etomidate IV. During transport, the flight team infused 2 liters of normal saline and administered tranexamic acid.

The patient arrived in the emergency department with a Glasgow Coma Score of 3T. The primary survey revealed a patent airway (7.5 ET 24 cm at teeth), bilateral breath sounds and palpable pulses in four extremities. The patient was found to have a scalp laceration and multiple deep lacerations in the upper extremity and proximal thigh. The initial vital signs were consistent with those given during transport (Table 1). The primary focused assessment with sonography for trauma (FAST) exam was negative. A chest and pelvis x-ray were performed (Figure 1) and an extended arterial blood gas (ABG) was obtained. The initial ABG was pH 7.22, pCO<sub>2</sub> 30.2, PaO<sub>2</sub> 318, HCO<sub>3</sub> 12, base deficit 14.2, Hgb 6.2, K<sup>+</sup> 2, iCa<sup>2+</sup> 1.2, glucose 240, and lactate 6.9.

As the trauma evaluation progressed, the patient became increasingly hypotensive (Figure 2). His blood pressure was 81/38 mmHg with a heart rate of 95 bpm.

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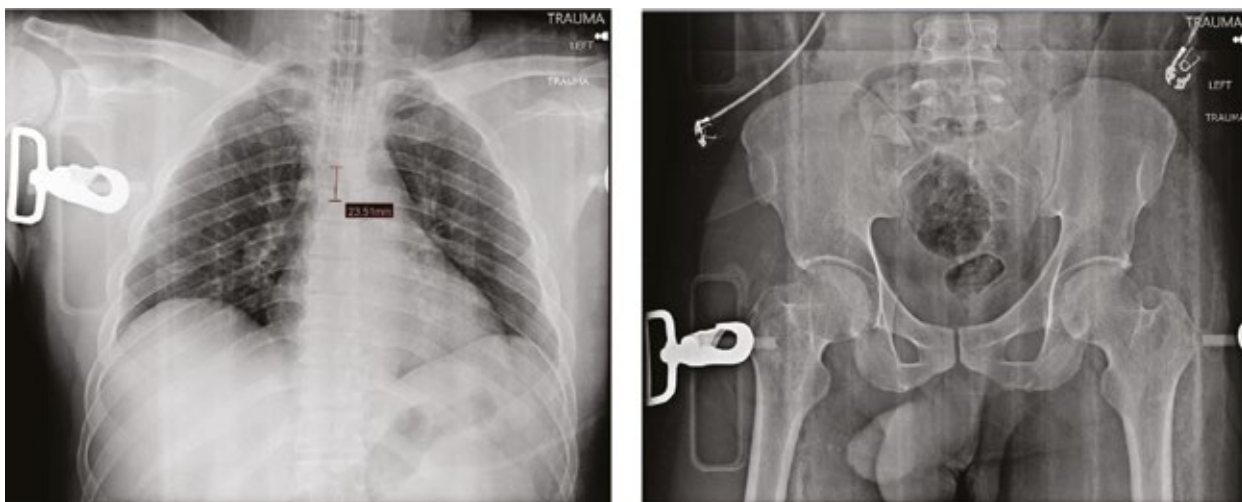
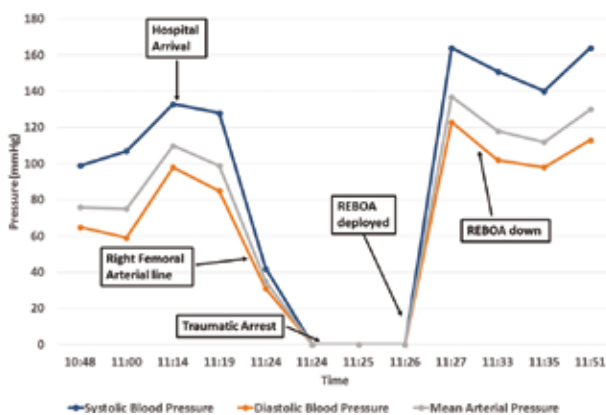
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**Table 1** Vitals throughout initial trauma care.

	Time	Heart Rate	Respiratory Rate	Blood Pressure
<b>Scene*</b>	10:48	108	22	99/65
<b>Transport*</b>	11:00	114	16	107/59
<b>ED arrival*</b>	11:14	109	12	133/98
<b>Prior to arrest</b>	11:24	122	26	42/31
<b>Arrest</b>	11:24	0	26	0/0
<b>REBOA: initial</b>	11:27	117	31	164/123
<b>REBOA: resuscitation</b>	11:33	104	14	151/102
<b>Balloon down</b>	11:35	112	13	140/98
<b>Prior to CT</b>	11:51	107	14	164/113

Note: Medflight team assumed care at 10:45 after >2 hours of extrication.

\*Automated blood pressure cuff placed on right upper extremity. The remaining vitals are recorded from the right femoral arterial line.

**Figure 1** Initial chest and pelvis imaging.**Figure 2** Blood pressure throughout trauma evaluation and resuscitation.

The trauma surgeon and advanced practice provider inserted a right femoral arterial line while the chief surgical resident placed a left subclavian 8.5 Fr single lumen resuscitation catheter. During placement of the arterial line, the patient's blood pressure dropped to

61/30 mmHg and the heart rate increased to 122 bpm. At approximately 10 minutes after arrival, the patient went into cardiac arrest (Figure 2). The patient had no arterial line waveform, but continued to have some cardiac activity on ultrasound evaluation.

Several team members worked in conjunction to expedite the resuscitation. The junior surgical resident started chest compressions while the nurse and chief resident started transfusion of two units of uncrossmatched packed red blood cells (PRBCs). The massive transfusion protocol (MTP) was initiated. The trauma surgeon upsized the femoral arterial line to a 7 Fr sheath and measured the catheter at 42 cm for Zone 1 deployment from the point of arterial access to the patient's sternal notch. An ER-REBOA™ catheter (Prytime Medical, Boerne, TX, USA) was inserted through the 7 Fr sheath after testing the balloon and flushing the catheter with the pressurized arterial line setup. The balloon was advanced and inflated with 11 ml of saline. The REBOA decision-to-inflation time was approximately 2.5 minutes, the time to secure the catheter was 3 minutes and the total occlusion time was 5 minutes. During the occlusion



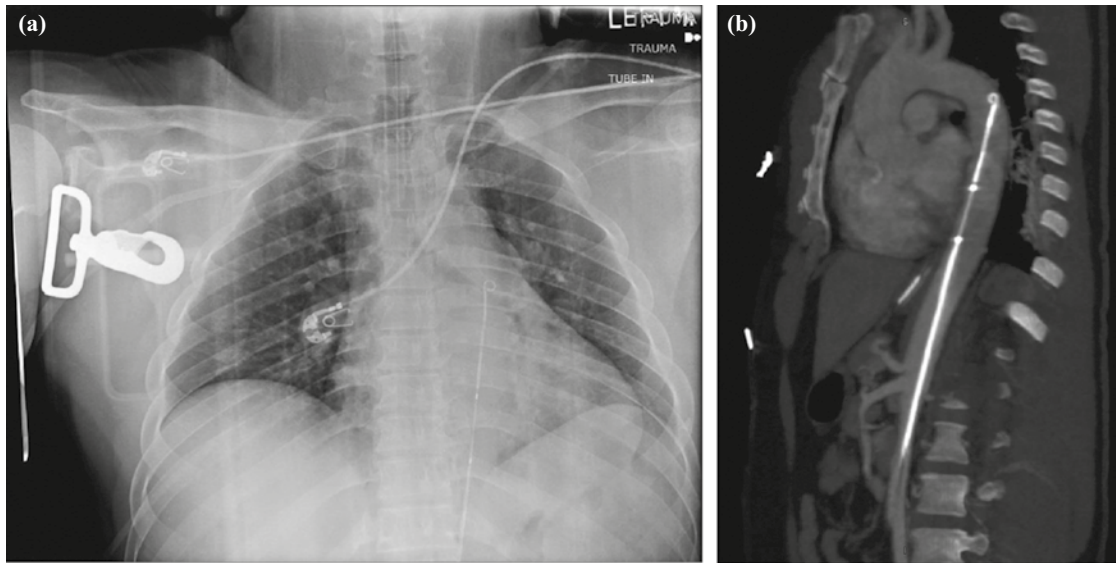


Figure 3 Portable chest x-ray (a) and CT chest (b) after Zone 1 ER-REBOA™ catheter placement.

period, the patient received two units of uncrossmatched PRBCs, 2 mg of epinephrine, 1 g of calcium, and 1 amp of sodium bicarbonate. Shortly after balloon inflation, the patient had return of spontaneous circulation (ROSC) with a narrow complex tachycardia.

After 5 minutes of resuscitation and monitoring, the ER-REBOA™ balloon was deflated. The institutional protocol is to slowly deflate the balloon while monitoring the proximal arterial pressure and waveform. In this case, the patient's mean arterial pressure remained >65 mmHg throughout deflation and the remaining time in the trauma bay. The trauma surgeon and chief resident ligated superficial unnamed bleeding vessels in the scalp, upper and lower extremity. Pressure was applied to the remainder of the wounds without continued significant blood loss. Repeat FAST examine and chest x-ray (Figure 3) revealed no further bleeding. The patient's resuscitation included four units of PRBC, no plasma or platelets and he received no further vasopressors. MTP was stopped after obtaining ROSC and confirming hemodynamic stability with balloon deflation. The patient was transferred for computed tomography (CT) scans (Figure 3). The images revealed no intracranial, aortic, thoracic, abdominal or retroperitoneal injuries.

The patient was transferred to the surgical intensive care unit (SICU). The REBOA catheter was removed and sheath pulled ensuring hemostasis with manual pressure for 30 minutes. The patient was extubated the following morning. There were no complications of the REBOA procedure. He received a plastic surgery consult for an upper extremity injury involving tendon damage and a complex scalp laceration. He went to the operating room for repair of these structures on hospital day one. He underwent physical, occupational, and speech therapy and was discharged to home with outpatient occupational therapy on hospital day three.

## DISCUSSION

The combination of the rural location, difficult extrication and multiple trauma patients at the scene significantly prolonged the prehospital time for this patient. This is an otherwise healthy trauma patient who suffered substantial blood loss from non-truncal sites, resulting in hemorrhagic shock that progressed to traumatic arrest from seemingly minimal injuries. This is not the only case such as this described in the literature. In 2005, a large case series of both blunt and penetrating extremity injuries progressing to traumatic arrest was performed [5]. In that series, the patients who received CPR or resuscitative thoracotomy all died. Most trauma centers have patients that have arrested from isolated extremity bleeding, and all students are taught that scalp lacerations bleed profusely. This case is an example of how combining these seemingly non-lethal injuries with prolonged transport time resulted in a near fatal outcome. This may represent a potentially avoidable scenario by earlier recognition of hemorrhagic shock, early use of blood product resuscitation, limiting the use of crystalloid during transport and thus avoiding acidosis. This case highlights a few of the difficulties in prehospital trauma care and potential opportunities for improvement as a trauma system.

The patient in our case, fortunately, did not arrest until shortly after arrival at the trauma center. We had recently instituted a REBOA training program for our physicians and staff. Our training program consisted of a lead trauma surgeon who demonstrated skills and interest in the technology. A small group of surgeons was chosen to attend the basic endovascular skills for trauma (BEST) course in Baltimore, MD. These individuals subsequently trained the remaining surgeons and hospital staff. Guidelines were adopted from the Joint

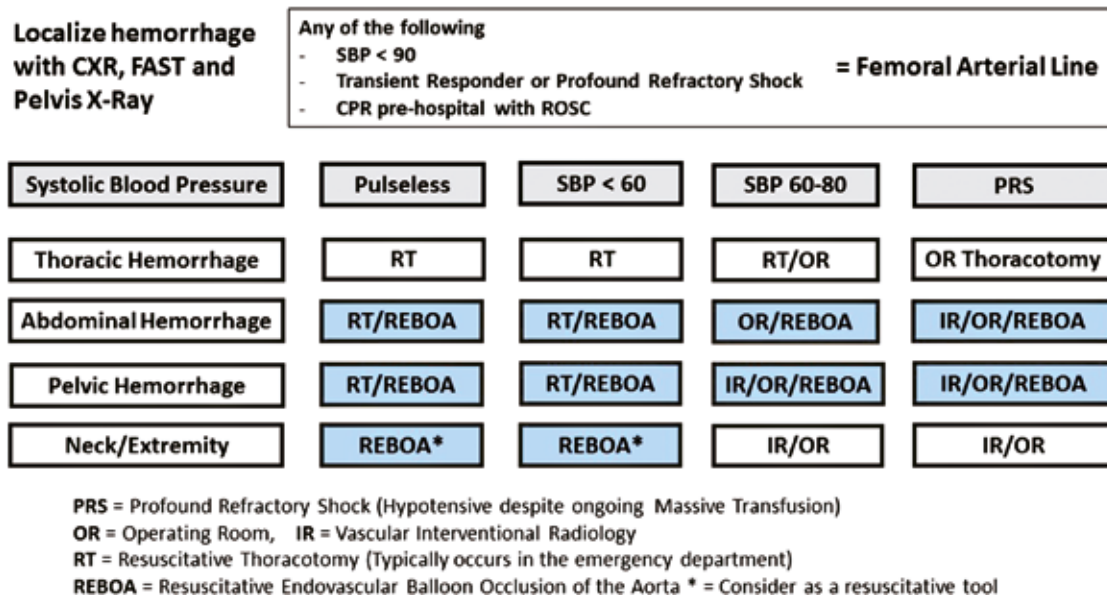


Figure 4 Guideline for approach to hypotensive trauma patients.

Trauma System Clinical Practice Guideline [6] and reviewed for implementation by leaders of our multidisciplinary trauma team (Figure 4). A combination of didactics and hands-on simulation were utilized to train providers. We included the emergency department physicians and staff, SICU and operating room staff, house staff, trauma advanced practice providers and nursing teams in REBOA training sessions. Initial implementation was complicated by difficulties in packaging an ER-REBOA kit, training trauma nursing staff to assist with the arterial line set up, and obtaining catheters for locations outside the trauma bay. After months of training, implementation and use throughout multiple hospital locations we learned that investment into REBOA specific procedure carts (much like “crash” carts) that include all necessary supplies for arterial access and deployment of an ER-REBOA was effective for deployment and efficient for restocking.

Our patient benefited from the location of arrest, preparation of the resuscitative team and continued simulation with the institutions REBOA protocol. The interesting aspect, in this case, is that he did not have truncal hemorrhage, the classic indication for REBOA. After repeat FAST exams, several CXRs and because of continued hemodynamic stability after REBOA placement, ultimately a CT revealed no evidence of intrathoracic, abdominal or pelvic injury, obviating the need for other invasive procedures. This case is a good example of how temporarily reducing a patient’s effective circulating volume along with blood product resuscitation enabled us to break the cycle of hemorrhagic shock while maintaining brain and cardiac perfusion. Similar results have been shown in aortic occlusion in non-traumatic

cardiac arrest animal models [7]. In these models, the occluded aorta was found to increase coronary and cerebral perfusion and associated with a significant increase in ROSC and good neurologic outcome. In our case, this resuscitative technique allowed more deliberate noninvasive interrogation and planning of next steps. Without the immediate hemorrhage control capability provided by the ER-REBOA™, this patient would have had a thoracotomy and likely a laparotomy, without identification of injury. Because we had trained our entire trauma team for rapid REBOA placement, this patient went home in three days with minimal morbidity. This case highlights use of the ER-REBOA™ in a non-traditional fashion, but demonstrates how this capability is evolving, and becoming part of the routine care we provide for bleeding patients.

**REFERENCES**

- [1] DuBose JJ, Scalea TM, Brenner M, et al. The AAST prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: Data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). *J Trauma Acute Care Surg.* 2016;81:409–19.
- [2] Brenner ML, Moore LJ, DuBose JJ, et al. A clinical series of resuscitative endovascular balloon occlusion of the aorta for hemorrhage control and resuscitation. *J Trauma Acute Care Surg.* 2013;75:506–11.
- [3] Morrison JJ, Ross JD, Houston R 4<sup>th</sup>, Watson JD, Sokol KK, Rasmussen TE. Use of resuscitative endovascular balloon occlusion of the aorta in a highly lethal model of noncompressible torso hemorrhage. *Shock.* 2014;41: 130–37.

- [4] Biff WL, Fox CJ, Moore EE. The role of REBOA in the control of exsanguinating torso hemorrhage. *J Trauma Acute Care Surg.* 2015;78:1054–58.
- [5] Dorlac WC, DeBakey ME, Holcomb JB, et al. Mortality from isolated civilian penetrating extremity injury. *J Trauma.* 2005;59:217–22.
- [6] Pasely J, Cannon J, Glaser J, et al. Joint Trauma System Clinical Practice Guideline: Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock. Retrieved from [http://www.usaisr.amedd.army.mil/cpgs/REBOA\\_%2006Jul2017CORRECTED.pdf](http://www.usaisr.amedd.army.mil/cpgs/REBOA_%2006Jul2017CORRECTED.pdf). Accessed July 2017.
- [7] Daley J, Morrison JJ, Sather J, Hile L. The role of resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct to ACLS in non-traumatic cardiac arrest. *American Journal of Emergency Medicine.* 2017;35:731–36.

# Resuscitative Endovascular Balloon Occlusion of the Aorta in Inter-Hospital Transfers: Two Case Reports

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Non-compressible torso hemorrhage (NCTH) remains a considerable source of potentially preventable death in both military and civilian trauma. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is one tool that can be used to treat or prevent hemodynamic collapse in hemorrhaging patients suffering from NCTH, but until now its use has been mostly as a bridge to definitive hemostasis within institutions and less so as temporizing intervention in the pre-hospital setting. The cases described here are the first reported uses of REBOA as a means of enabling inter-hospital transfer within a regionalized trauma system. This experience could help inform future patient selection, procedural technique and institutional readiness to fully realize the potential for REBOA in salvaging patients with NCTH.

**Keywords:** REBOA; bleeding; Trauma

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## INTRODUCTION

Military experience from the Global War on Terror identified hemorrhage as the most significant source of preventable deaths in combat [1]. Modifications in field care, tourniquets use and hemostatic dressings improved outcomes in patients with readily accessible sources

of hemorrhage while changes in resuscitation strategies better supported physiologic hemostasis in patients losing blood at a slower pace [2]. These improvements isolated a class of casualties who continued to die at alarming rates from what is still believed to be a preventable cause of death. By some estimates, non-compressible hemorrhage is responsible for up to fifty percent of preventable deaths in combat casualties [3,4], and the morbidity and mortality of this pattern of injury is similarly substantial in civilian trauma populations [5,6].

Non-compressible torso hemorrhage (NCTH) is formally defined by anatomic, physiologic and procedural contexts as shock secondary to pulmonary injury, solid organ injury, major vascular trauma and/or pelvic fracture requiring immediate intervention for hemorrhage control [7]. As recently as 2010, it had been believed that “a method for mechanically stopping non-compressible truncal hemorrhage before surgical hemostasis... remains in the distant future” [2]. However, beginning in 2012, Level I trauma centers in the US began to implement the technique known as resuscitative endovascular balloon occlusion of the aorta (REBOA) in patients with NCTH [8]. A clinical practice guideline for its use has since been incorporated into the military’s Joint Theater Trauma System [9], and the American College of Surgeons

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Committee on Trauma has both endorsed the Basic Endovascular Skills in Trauma course curriculum for teaching the REBOA insertion technique [10] and established a data repository for clinical experience with its use [11].

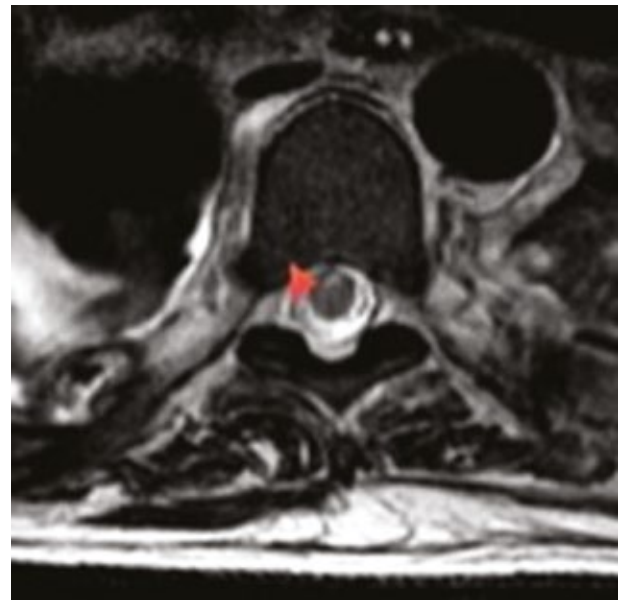
Until now, implementation of REBOA in the US has been as a temporizing bridge to definitive hemostasis within an institution. Limited experience with pre-hospital use has been described in both Japan [12] and the UK [13], although its role in field care remains largely undefined. Here, we describe the first reported uses of REBOA in the setting of inter-hospital transfer within a regional trauma system.

### Case 1

A 43-year-old male was involved in a high-speed motor vehicle collision in which he was ejected from his vehicle and subsequently struck by another car. He arrived at a Level II trauma center hypotensive, tachycardic with a GCS 15 but in respiratory distress. He was intubated and bilateral chest tubes were placed. He was diagnosed with a scalp avulsion, bilateral flail chest, a Grade III liver laceration, a Grade II left renal laceration and an open book pelvic fracture with hemorrhage (Injury Severity Score 66). Massive transfusion was initiated, and his hemodynamics transiently improved. Because of the need for both interventional radiology and pelvic reconstruction the patient was scheduled for transfer to the regional Level I trauma center. Just prior to air evacuation, the patient's blood pressure fell to 70s/40s with a heart rate of 150. A REBOA catheter (ER-REBOA, Prytime Medical, Boerne, TX) was placed percutaneously through the right common femoral artery and inflated in Zone 1 to partial occlusion such that a faint contralateral femoral pulse could still be palpated. Paramedics were instructed to inject an additional 4 mL of saline into the balloon if the patient became hypotensive during transport, as this, the referring surgeon determined, was the volume necessary to proceed from partial to complete aortic occlusion. This step did prove necessary en route, and the paramedics, having no previous training or experience with REBOA, executed the instructions as directed. Total fluid and transfusion volumes provided at the referring hospital and during inter-hospital transport included six liters of crystalloid, 12 units of packed red blood cells, 12 units of fresh-frozen plasma, and three 6-packs of platelets.

Upon the patient's arrival, surgeons at the Level I center discovered the previously undisclosed REBOA catheter in Zone I. Despite the intent of the referring surgeon to progress to complete occlusion for en-route hypotension, a faint but palpable contralateral femoral pulse was present on initial assessment at the receiving hospital. According to records, the REBOA had been in place for 113 minutes at the time of arrival.

The patient was taken urgently to a hybrid OR suite. Exploratory laparotomy with liver packing, pelvic



**Figure 1** T2 weighted axial MRI illustrating increased signal intensity in the anterior aspect of the spinal cord at the level of T6, consistent with ischemic spinal cord injury.

packing, supra-pubic catheter insertion, and renal fossa packing was performed. The pelvis was bound and the REBOA catheter gradually deflated over 10–12 minutes. Arteriography demonstrated vascular patency with three-vessel run-off to both lower extremities, and both the REBOA catheter and its 7 French sheath were removed. The following day, all packing was removed, external pelvic fixation and traction were applied, and his scalp wound was formally closed.

The patient's subsequent clinical course was complicated by early septic shock on post-injury day 2, prolonged adrenal insufficiency, and multisystem organ failure requiring renal replacement therapy and 127 hours of veno-venous extra-corporeal membrane oxygenation (VV-ECMO) for refractory hypoxemic, hypercapnic respiratory failure. Following medical stabilization, the patient preserved baseline mental acuity but suffered bilateral lower extremity paralysis without tissue loss or compartment syndrome (Figure 1). His renal function improved, and renal replacement therapy was discontinued on post-injury day 30. He was ultimately discharged to rehabilitation on post-injury day 68.

### Case 2

A man thought to be in his 60s was struck by a motor vehicle at a high speed. The patient presented to the outside hospital both hypotensive and tachycardic. Massive transfusion was initiated, and his hemodynamics transiently responded. A CT scan demonstrated a complex pelvic fracture with active arterial extravasation. The patient lost his pulses in radiology despite ongoing resuscitation. A REBOA catheter was placed percutaneously

through the right common femoral artery, and the balloon inflated. The patient was taken to the OR where his pelvis was packed, and his hemodynamics stabilized. The balloon was deflated but the catheter was left in place. Total occlusion time was 23 minutes. The surgeon then accompanied the patient to the Level 1 trauma center via air transport, guiding the ongoing resuscitation and prepared to manage the REBOA catheter en route, as needed. Shortly after arrival, the patient again lost pulses and required CPR. The REBOA balloon was re-inflated resulting in the immediate return of spontaneous circulation. The patient was taken to the OR for re-exploration, and his pelvis was re-packed. The REBOA balloon was slowly deflated over 8–10 minutes, and the catheter was ultimately removed. Total occlusion time for this episode was 24 minutes. Preparations were made for pelvic angioembolization, but in the interim the patient suffered a cardiac arrest not directly attributable to hypovolemia and could not be salvaged.

## DISCUSSION

In the first case of inter-hospital REBOA transfer, there is substantial room for improvement in the coordination between the sending and receiving facility. The patient was transferred with the balloon inflated, and the total occlusion time of nearly two hours is substantially longer than in any previously reported REBOA survivor in the US. The patient's tolerance of the prolonged balloon inflation may be due to the fact that the balloon was not completely occlusive as evidenced by the presence of a faint contra-lateral femoral pulse. Prolonged REBOA inflation may be possible with incomplete occlusion, although clearly this technique did not spare our patient from the consequences of distal ischemia. It can be argued that some of the more profound and more permanent consequences of prolonged aortic occlusion could have been avoided with timely laparotomy and judicious packing.

In its present state, REBOA should not be used as a means to defer operative hemostasis, as the highly morbid and potentially mortal metabolic consequences of aortic occlusion begin to accumulate the moment the balloon is inflated. Instead, REBOA is a tool that may enable carefully selected patients to survive to definitive hemostasis in a salvageable condition when they otherwise would have died before hemorrhage could be definitively controlled. The objective of REBOA, then, once deployed, is to achieve such hemostasis before the resulting metabolic derangement exceeds the patient's capacity to recover; otherwise all we would have accomplished with the investment of considerable resources is deferment of an early hemorrhagic death to a delayed but inevitable metabolic one. REBOA, however, may expand patient salvageability in the face of hemorrhage in the way balanced resuscitation, renal replacement therapy, and ECMO have expanded salvageability in

the face of metabolic derangement, and it may prove critical to realizing the full potential of each of these capabilities to recognize them all as part of one larger, more comprehensive, strategy in severely injured patients with sufficient physiologic resilience.

In most instances of NCTH, the factor most predictive of survival is the presence of measurable blood pressure upon arrival at a facility equipped to achieve definitive surgical or endovascular hemostasis [14]. Those that arrive with cardiopulmonary resuscitation in-progress secondary to hemorrhagic shock and exsanguination rarely survive. REBOA is a tool that unquestionably enables proximal blood pressure augmentation [15]. What remains to be seen is whether selective enhancement of proximal perfusion, shunting intravascular oxygen carrying capacity to the heart, lungs, and brain, could offer a potential for survival to grievously injured patients at an acceptable expense of transient spinal, splanchnic, and lower extremity ischemia [16].

Spinal cord ischemia secondary to aortic manipulation is multifactorial, incorporating risks associated with vascular obstruction, hypotension, and thromboembolization [17]. The anterior spinal artery is the major source of spinal cord perfusion; however, its variable caliber throughout its course makes it dependent on circulation through a system of radicular arteries derived from segmental branches of the aorta. The largest of these, the great radicular artery (also known as the artery of Adamkiewicz), is located between T9 and T12 in three-quarters of cases [18]. Collateral circulation to the distal portion of the anterior spinal artery is through the iliolumbar and lateral sacral branches of the internal iliac arteries [19]. With REBOA placement in Zone 1, there is inadequate flow to the anterior spinal artery through both radicular arteries and internal iliac collaterals, raising the risk of spinal cord ischemia particularly with long periods of occlusion. With Zone 3 placement, radicular arteries remain patent with conceivably augmented circulation owing to distal aortic occlusion, so risks of spinal cord ischemia should be negligible in the absence of systemic vascular disease. Lumbar drainage could be considered in patients with prolonged Zone 1 occlusion or those manifesting signs of spinal cord damage not explained by direct trauma [20], although it is unclear if such cerebrospinal fluid drainage truly protects patients from ischemic complications [21].

Partial REBOA (P-REBOA) is a technique postulated to augment proximal perfusion of the brain and heart while "creating permissive regional hypoperfusion to [distal] areas of uncontrolled hemorrhage" [22]. In this technique, the balloon is inflated to achieve full occlusion as indicated by the loss of a contralateral femoral pulse on palpation or the dissipation of an arterial waveform transduced through a distal arterial pressure line or through the sidearm of an upsized sheath around the REBOA catheter itself. After allowing 10 minutes for optimal resuscitation and clot formation at the site

of distal hemorrhage, the balloon is slowly deflated, 1 mL at a time, until a faint distal pressure is perceived on palpation or waveform analysis [23]. Current recommendations suggest 30 minutes of complete occlusion for Zone 1 REBOA placement and up to 60 minutes for Zone 3; however, these guidelines have not been scientifically validated and it remains unclear whether the P-REBOA technique would meaningfully extend these timelines by moderating the metabolic consequences of ischemia distal to complete aortic occlusion.

In the second case of inter-hospital REBOA transfer, communication, coordination, and oversight during transport were significantly improved, with clear communication between the referring and receiving surgeons, and surgeon accompaniment of the patient for air evacuation. Repeated aortic occlusion has been necessary in 9.6% of patients in the AAST Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery registry, including 4.3% of REBOA patients [11], but the cumulative physiologic stress of intermittent occlusion has not been studied. It is reasonable to conclude that REBOA did facilitate hemorrhage control, preventing the patient from exsanguinating. However, prolonged periods of aortic occlusion have been associated with higher degrees of coronary ischemia in animal studies, conceivably secondary to rapid fluctuations in afterload [24]. This patient's demise appeared more directly related to cardiac failure than hemorrhage, and while age is not an absolute determinant of REBOA eligibility, it is worth considering whether such a technique would have been employed were it known in advance that the patient was 87 years old.

Use of REBOA for inter-hospital transfer is not currently part of regional trauma management algorithms or informal arrangements amongst institutions. Our experience with such is purely a product of the specific circumstances surrounding these two particular patients. In both instances, it was the conclusion of the transferring surgeons that the patient's injuries would have been imminently non-survivable based on the capabilities of their institution and that transfer offered the most expeditious route to definitive hemostasis.

REBOA has been used in the military for the successful transfer of patients to higher echelons of care [25], but as the trauma community, both military and civilian, continues to explore the potential life-saving implications of endo-aortic occlusion, survival to transfer cannot be the intended goal of this intervention. Such an attitude would come with tremendous expenditure of resources without meaningfully impacting overall survival. Since ultimate survival is inversely proportional to balloon occlusion time [26], the planning for timely REBOA removal must commence with the decision to place the REBOA, and trauma system characteristics such as travel distance, evacuation time, and en-route capabilities must be considered in deciding when, where, and how to field REBOA beyond the walls of a single

institution. Military–civilian cooperation will be critical to the optimal incorporation of this technology in organized trauma systems and mission planning.

One animal study suggested that aortic occlusion should be limited to less than 40 minutes for there to be any survival advantage [24], and such considerations are essential to the responsible deployment of REBOA, particularly regarding pre-hospital and inter-hospital utilization. It is unclear whether this timeline can be extended with the technique of P-REBOA.

## CONCLUSION

We have reported here the first two instances of REBOA utilization for inter-hospital transfer. If the conclusions of the referring surgeons regarding the imminent death of both patients secondary to uncontrolled hemorrhage are accepted, then REBOA enabled the salvage of one and at least the opportunity of salvage for the other.

An ideal candidate for REBOA-facilitated inter-hospital transfer would be a patient estimated to possess the substantial physiologic resilience required to overcome profound metabolic disturbances associated with prolonged aortic occlusion. As illustrated in our lone survivor, this potentially life-saving intervention did accompany a period of physiologic decompensation and end organ injury, some of which proved irreversible. The implications of spinal cord ischemia must be included in the risk assessment along with bowel, kidney, and lower extremity malperfusion when considering partial or complete aortic occlusion.

The constellation of injuries for which REBOA-facilitated inter-hospital transfer could be considered includes sub-diaphragmatic injuries resulting in hemorrhagic shock that cannot be controlled sufficiently or more quickly with standard damage control surgical techniques.

An optimal referring provider would be one experienced with the technique of REBOA placement, but for whom the time to definitive hemostasis would be shorter through transfer to another facility than it would be to mobilize local institutional resources. REBOA should not defer the time to operative hemostasis but rather facilitate patient arrival in a physiologic state compatible with survival at a setting where definitive hemostasis can be reliably achieved.

An optimal receiving facility would be one well-versed in REBOA placement and removal, able to rapidly mobilize surgical or endovascular resources to minimize the time to definitive hemostasis, and prepared to provide the most elaborate means of life support for potentially prolonged periods of multi-system organ failure, including renal replacement therapy, cardiopulmonary bypass, and extra-corporeal life support.

If fully optimized in terms of patient selection, procedural technique, and efficiency of transport to definitive hemostasis, REBOA could provide a valuable tool in the management of non-compressible truncal hemorrhage,

which remains a source of considerable “preventable” mortality in both military and civilian trauma. New insights are required to harness the full capability of regionalized trauma systems for this pattern of injury, and any tool or technique with the potential to extend the reach of surgical and endovascular trauma management and delay the time from injury to hemodynamic collapse warrants aggressive exploration.

## REFERENCES

- [1] Martin M, Oh J, Currier H, et al. An analysis of in-hospital deaths at a modern combat support hospital. *J Trauma*. 2009;66:S51–60; discussion S-1.
- [2] Blackburne LH, Czarnik J, Mabry R, et al. Decreasing killed in action and died of wounds rates in combat wounded. *J Trauma*. 2010;69:S1–4.
- [3] Kelly JF, Ritenour AE, McLaughlin DF, et al. Injury severity and causes of death from Operation Iraqi Freedom and Operation Enduring Freedom: 2003–2004 versus 2006. *J Trauma*. 2008;64:S21–6; discussion S6–7.
- [4] Holcomb JB, McMullin NR, Pearse L, et al. Causes of death in U.S. special operations forces in the global war on terrorism: 2001–2004. *Ann Surg*. 2007;245:986–91.
- [5] Kauvar DS, Wade CE. The epidemiology and modern management of traumatic hemorrhage: US and international perspectives. *Crit Care*. 2005;9:S1–9.
- [6] Gomez D, Berube M, Xiong W, et al. Identifying targets for potential interventions to reduce rural trauma deaths: a population-based analysis. *J Trauma*. 2010;69:633–9.
- [7] Morrison JJ, Rasmussen TE. Noncompressible torso hemorrhage: a review with contemporary definitions and management strategies. *Surg Clin North Am*. 2012; 92:843–58, vii.
- [8] Moore LJ, Brenner M, Kozar RA, et al. Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage. *J Trauma Acute Care Surg*. 2015;79:523–30; discussion 30–2.
- [9] Pasley J, Cannon JW, Glaser J, et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA) for hemorrhagic shock (CPG ID: 38) 2017 [updated July 6, 2017]. Available from: [http://www.usaisr.amedd.army.mil/cpgs/REBOA\\_06Jul2017CORRECTED.pdf](http://www.usaisr.amedd.army.mil/cpgs/REBOA_06Jul2017CORRECTED.pdf).
- [10] Brenner M, Hoehn M, Pasley J, et al. Basic endovascular skills for trauma course: bridging the gap between endovascular techniques and the acute care surgeon. *J Trauma Acute Care Surg*. 2014;77:286–91.
- [11] DuBose JJ, Scalea TM, Brenner M, et al. The AAST prospective aortic occlusion for resuscitation in trauma and acute care surgery (AORTA) registry: data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). *J Trauma Acute Care Surg*. 2016;81:409–19.
- [12] Inoue J, Shiraishi A, Yoshiyuki A, et al. Resuscitative endovascular balloon occlusion of the aorta might be dangerous in patients with severe torso trauma: a propensity score analysis. *J Trauma Acute Care Surg*. 2016; 80:559–66; discussion 66–7.
- [13] Sadek S, Lockey DJ, Lendrum RA, et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA) in the pre-hospital setting: an additional resuscitation option for uncontrolled catastrophic haemorrhage. *Resuscitation*. 2016;107:135–8.
- [14] Gupta BK, Khaneja SC, Flores L, et al. The role of intra-aortic balloon occlusion in penetrating abdominal trauma. *J Trauma*. 1989;29:861–5.
- [15] Low RB, Longmore W, Rubinstein R, Flores L, Wolvek S. Preliminary report on the use of the Perccluder occluding aortic balloon in human beings. *Ann Emerg Med*. 1986; 15:1466–9.
- [16] Morrison JJ, Galgon RE, Jansen JO, et al. A systematic review of the use of resuscitative endovascular balloon occlusion of the aorta in the management of hemorrhagic shock. *J Trauma Acute Care Surg*. 2016;80:324–34.
- [17] Picone AL, Green RM, Ricotta JR, May AG, DeWeese JA. Spinal cord ischemia following operations on the abdominal aorta. *J Vasc Surg*. 1986;3:94–103.
- [18] Glociczki P, Cross SA, Stanson AW, et al. Ischemic injury to the spinal cord or lumbosacral plexus after aorto-iliac reconstruction. *Am J Surg*. 1991;162:131–6.
- [19] Rosenthal D. Spinal cord ischemia after abdominal aortic operation: is it preventable? *J Vasc Surg*. 1999;30:391–7.
- [20] Coselli JS, LeMaire SA, Koksoy C, Schmittling ZC, Curling PE. Cerebrospinal fluid drainage reduces paraplegia after thoracoabdominal aortic aneurysm repair: results of a randomized clinical trial. *J Vasc Surg*. 2002; 35:631–9.
- [21] Khan SN, Stansby G. Cerebrospinal fluid drainage for thoracic and thoracoabdominal aneurysm surgery. *Cochrane Database of Systematic Reviews*. 2012(10).
- [22] Johnson MA, Neff LP, Williams TK, DuBose JJ, Group ES. Partial resuscitative balloon occlusion of the aorta (P-REBOA): clinical technique and rationale. *J Trauma Acute Care Surg*. 2016;81:S133–S7 (Proceedings of the 2015 Military Health System Research Symposium).
- [23] DuBose JJ. How I do it: partial resuscitative endovascular balloon occlusion of the aorta (P-REBOA). *J Trauma Acute Care Surg*. 2017;83:197–9.
- [24] Avaro JP, Mardelle V, Roch A, et al. Forty-minute endovascular aortic occlusion increases survival in an experimental model of uncontrolled hemorrhagic shock caused by abdominal trauma. *J Trauma*. 2011;71:720–5; discussion 5–6.
- [25] Manley JD, Mitchell BJ, DuBose JJ, Rasmussen TE. A modern case series of resuscitative endovascular balloon occlusion of the aorta (REBOA) in an out-of-hospital, combat casualty care setting. *J Spec Oper Med*. 2017;17:1–8.
- [26] Martinelli T, Thony F, Decléty P, et al. Intra-aortic balloon occlusion to salvage patients with life-threatening hemorrhagic shocks from pelvic fractures. *J Trauma*. 2010;68:942–8.



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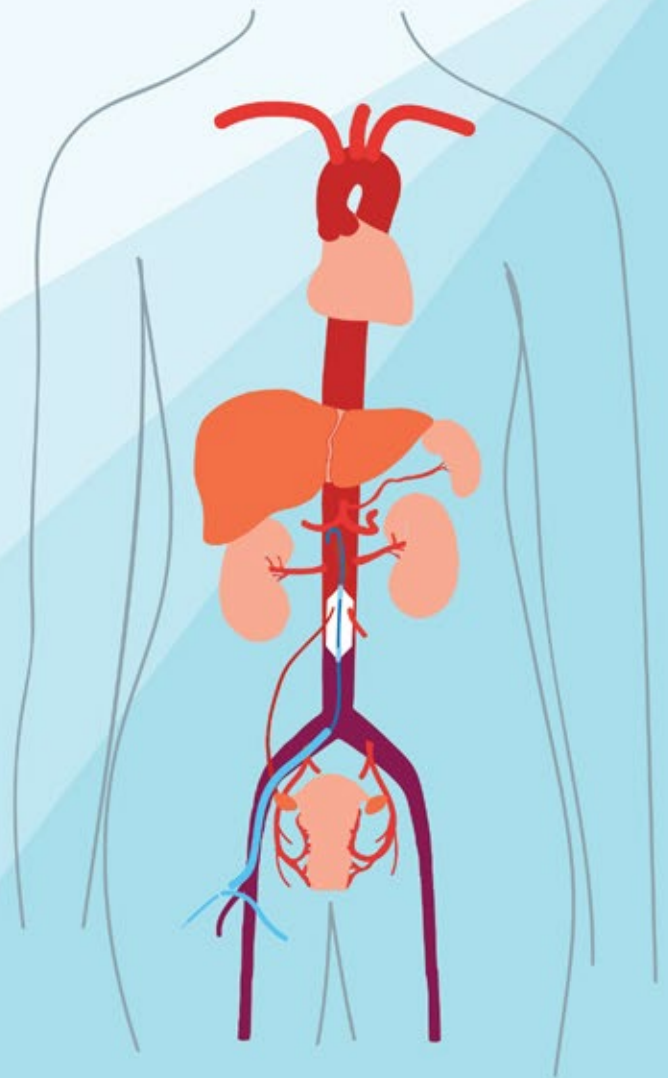
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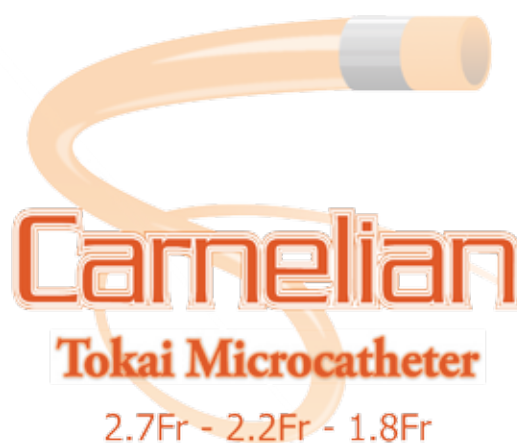
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