A clinical series of resuscitative endovascular balloon occlusion of the aorta for hemorrhage control and resuscitation

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BACKGROUND:	A requirement for improved methods of hemorrhage control and resuscitation along with the translation of endovascular specialty skills has resulted in reappraisal of resuscitative endovascular balloon occlusion of the aorta (REBOA) for end-stage shock. The objective of this report was to describe implementation of REBOA in civilian trauma centers.					
METHODS:	Descriptive case series of REBOA (December 2012 to March 2013) used in scenarios of end-stage hemorrhagic shock at the					
	University of Maryland, R. Adams Cowley Snock Trauma Center, Baltimore, Maryland, and Herman Memorial Hospital, The Texas Trauma Institute. Houston, Texas.					
RESULTS:	REBOA was performed by trauma and acute care surgeons for blunt (n 4) and penetrating (n 2) mechanisms. Three cases were REBOA in the descending thoracic aorta (Zone I) and three in the infrarenal aorta (Zone II). Mean (SD) systolic blood pressure at the time of REBOA was $59(27)$ mm Hg and mean (SD) have deficit was $13(5)$. Atterial access was accomplished					
	using both direct cutdown (n 3) and percutaneous (n 3) access to the common femoral artery. REBOA resulted in a mean (SD) increase in blood pressure of 55 (20) mm Hg, and the mean (SD) aortic occlusion time was 18 (34) minutes. There were no REBOA-related complications and there was no hemorrhage-related mortality.					
CONCLUSION:	REBOA is a feasible and effective means of proactive aortic control for patients in end-stage shock from blunt and penetrating mechanisms. With available technology, this method of resuscitation can be performed by trauma and acute care surgeons who have benefited from instruction on a limited endovascular skill set. Future work should be aimed at devices that allow easy, fluoroscopy-free access and studies to define patients most likely to benefit from this procedure. (<i>J Trauma Acute Care Surg.</i> 2013;75: 506–511. Copyright © 2013 by Lippincott Williams & Wilkins)					
LEVEL OF EVIDENCE:	Therapeutic study, level V.					
KEY WORDS:	Trauma; hemorrhagic shock; endovascular surgery; resuscitation; balloon aortic occlusion.					

The use of endovascular technology in the management of trauma has increased over two decades.^{1–5} Improved outcomes using these techniques is not surprising, as a favorable trend has occurred with endovascular approaches to vascular disease.^{6–8} Outcomes following ruptured abdominal aortic aneurysm have improved, in part, because of the use of resuscitative endovascular balloon occlusion of the aorta (REBOA).^{9–11} In the setting of ruptured aneurysm, this technique may be initiated in the emergency department or operating room providing proactive aortic control. Similar to thoracotomy with aortic clamping for traumatic arrest, REBOA supports proximal aortic pressure and minimizes hemorrhage until anesthesia can be induced and hemostasis obtained.^{12–14}

Concurrent with the expansion of endovascular techniques to manage vascular trauma have been observations from

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combat casualty care in Afghanistan and Iraq. Reports from the war have shown that the leading cause of death in casualties with otherwise survivable injuries has been hemorrhage.^{15–18} A recent study from Eastridge et al.¹⁸ suggests that a quarter of otherwise survivable deaths in the battlefield could have been prevented with improved methods of resuscitation and hemorrhage control. This burden of morbidity and mortality has laid bare an imperative to develop better methods and devices to manage vascular disruption and hemorrhagic shock.¹⁹

These proceedings have spurred a series of initiatives aimed at translating endovascular techniques and skills from the realm of age-related disease to trauma including hemorrhagic shock. Translational studies have demonstrated the efficacy of REBOA in models of shock, and a new fluoroscopy-free device has been proposed.^{20–23} A technical description for REBOA now exists, and the Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS) curriculum has been developed.^{24,25} Despite momentum in these areas, modern descriptions of the use of REBOA in the clinical setting are lacking. The objective of this report was to demonstrate preliminary clinical application of REBOA in two US civilian trauma centers.

PATIENTS AND METHODS

A clinical series of REBOA for trauma performed at the University of Maryland, R. Adams Cowley Shock Trauma

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Standard Form 298 (Rev. 8-98) Prescribed by ANSI Std Z39-18 Center, Baltimore, Maryland, and Herman Memorial Hospital, The Texas Trauma Institute, Houston, Texas (December 2012 to March 2013). The cases described in this series were conducted as a matter of routine clinical care, and observations related to reporting of the case series were made in a retrospective manner.

RESULTS

Case 1

A 63-year-old male presented after a fall with an examination revealing only tenderness of the right hip (Table 1). A plain film of the pelvis showed a right acetabulum fracture with hemitransverse fractures, an inferior pubic rami fracture, and a medially displaced wall of the acetabulum. Computed tomography (CT) showed this fracture and several pelvic hematomas. The patient was taken to the operating room for acetabular repair when he became hypotensive, requiring pressurized resuscitation with blood products and vasopressor therapy. These interventions were ineffective, and his blood pressure was 50 mm Hg. Repeat focused assessment with sonography for trauma (FAST) and chest x-ray revealed no abnormalities, and percutaneous access was gained to the left femoral artery. A 12 Fr sheath was placed over a wire using fluoroscopic guidance, and Zone 3 REBOA was performed using the Cook Coda balloon (Cook Medical, Indianapolis, IN). With REBOA, the blood pressure increased to 135 mm Hg,

TABLE 1.	Demographics and Summary of REBOA Use in
Six Patients	

Patient	1	2	3	4	5	6
Age, y	62	24	59	25	40	27
Sex	Male	Male	Male	Male	Male	Female
Mechanism of injury	MVC	GSW	GSW	MVC	MCC	ATV collision
Injury Severity Score (ISS)	28	50	9	25	48	43
SBP before REBOA, mm Hg	70	70	0	60	70	85
Cardiac arrest before REBOA	No	No	Yes	No	No	No
SBP after REBOA, mm Hg	135	122	100	110	130	125
Admission base deficit	12	4	NA	16	14	19
Time to occlusion, min	5	4	4	6	6	6
Time of occlusion, min	12	16	70	60	65	36
Surgery after REBOA	No	Yes	Yes	Yes	Yes	Yes
Pelvic embolization after REBOA	Yes	Yes	No	No	Yes	Yes
Complication of REBOA	No	No	No	No	No	No
Outcome	Alive	Alive	Alive	Alive	Brain death	Death (care withdrawn)

ATV, all-terrain vehicle; GSW, gunshot wound; MCC, motorcycle collision; MVC, motor vehicle collision; NA, not applicable.

and the patient required no additional vasopressor or blood transfusions. Arteriography in the operating room demonstrated extravasation from a division of the right internal iliac and deep circumflex iliac arteries. Coil embolization was performed, and the patient required minimal additional resuscitation. The sheath was removed with operative exposure and closure of the femoral artery, and the patient had an uneventful hospital course.

Case 2

A 24-year-old male presented with a gunshot wound to the right posterior axillary line at the level of the eighth rib (Table 1). On arrival, his pulse was 119 beats per minute (bpm) and his blood pressure 70/42 mm Hg. A subclavian vein sheath was placed, and the transfusion protocol was initiated. Percutaneous 5 Fr sheath access was gained to the right femoral artery for pressure monitoring. A right tube thoracostomy was placed for hemothorax with return of 700 mL of blood, and an abdominal x-ray demonstrated a missile overlying the midepigastrium. FAST finding was positive in the abdominal but not cardiac views. Rapid infusion of blood products failed to correct hypotension, and the femoral monitoring line was upsized to a 14 Fr sheath using a plain x-ray to confirm position. Zone I REBOA was performed using a Cook Coda balloon, and the patient's blood pressure increased to 122 mm Hg. The patient was intubated and taken for laparotomy, which revealed a complex injury to the hilum of the right kidney. Vascular control was obtained, REBOA was deflated, and a nephrectomy was performed. Additional hemorrhage was noted from the lumbar vertebral body where the missile had lodged. This was packed, and the patient taken to radiology for coil embolization. The patient was returned to the operating room for the removal of the femoral sheath with repair of the artery. The rest of the patient's course was uneventful.

Case 3

A 59-year-old male presented to the emergency department following a through-and-through gunshot wound to the pelvis (Table 1). On arrival, the pulse was 130 bpm, and the systolic blood pressure (SBP) was 60 mm Hg. The abdominal portion of the FAST finding was positive, and the patient soon manifest pulseless electrical activity. The patient was intubated, cardiopulmonary resuscitation was initiated, and a sheath was placed in the subclavian vein for transfusion of blood products. Open exposure of the right femoral artery was performed and a 14 Fr sheath placed over a 0.035-inch wire using x-ray to confirm position. Zone I REBOA was performed using a Cook Coda balloon again using x-ray for positioning. With REBOA and transfusion of products, there was return of a pulse, and the systolic pressure improved to 100 mm Hg. The patient was taken to the operating room for laparotomy, which revealed a hemoperitoneum and bleeding from the right iliac vein. Control was obtained at the vena cava and femoral vein, and the injury was ligated. REBOA was deflated, and the patient was maintained a pressure of greater than 100 mm Hg. Bowel injuries were resected, and a temporary abdominal closure was applied. The aortic balloon and sheath were removed with repair of the femoral artery access site. The patient is neurologically intact and recovering.



Figure 1. Pelvic binder in place with REBOA catheter in right groin. Binder was moved up and modified to facilitate placement of REBOA.

Case 4

A 25-year-old male presented following a motor vehicle collision with a heart rate of 130 bpm and a blood pressure of 60 mm Hg (Table 1). The patient was intubated, and a subclavian vein sheath was placed for resuscitation with blood products. Chest x-ray demonstrated no intrathoracic pathology, and the pelvic film showed an open book fracture. The FAST finding was positive in the abdomen, and after the blood pressure failed to respond to transfusion, Zone I REBOA was performed through an open femoral artery exposure and placement of a 14 Fr sheath (Fig. 1). Positioning of the wire, sheath, and Cook Coda balloon was confirmed with x-ray in the resuscitation room. The patient was taken to the operating room for laparotomy, which revealed a hemoperitoneum emanating from the pelvis. An extraperitoneal bladder rupture was repaired, and the pelvis was packed with the application of temporary abdominal closure. REBOA was deflated with no hemorrhage, and the balloon and sheath were removed, followed by the closure of the arterial access site. The patient's hospital course has since been uneventful.

Case 5

A 40-year-old male presented to the emergency department following motorcycle collision with a heart rate of 130 bpm and a blood pressure of 70 mm Hg (Table 1). On examination, he had an unstable pelvis, and a binder was placed. The patient received resuscitation with blood products with no response in blood pressure. Zone I REBOA was performed through an open exposure of the femoral artery and a placement of a 12 Fr sheath. With inflation of the Cook Coda balloon, the SBP increased to 130 mm Hg. The patient was able to undergo CT imaging, which demonstrated splenic injury with occlusive Zone I REBOA (Fig. 2). Intraparenchymal cerebral contusions with hemorrhage were noted on head CT. The patient was taken to the operating room for exploratory laparotomy, splenectomy, packing of the pelvis, and temporary abdominal closure. The patient was transported to interventional radiology for pelvic arteriography and embolization of branches of the left gluteal artery. The patient was taken back to the operating room where the aortic occlusion balloon, wire, and sheath were removed with repair of the arterial access site. The patient subsequently had care withdrawn in the intensive care unit after confirmation of a lethal brain injury.

Case 6

A 27-year-old female was transported to the emergency department following a high-speed all-terrain vehicle collision with a truck (Table 1). The patient had been intubated on scene and was noted to have gross deformity of the pelvis with soft tissue degloving injuries. The patient arrived with a SBP of 60 mm Hg, a heart rate of 128 bpm, and a base deficit of 19. A subclavian vein sheath was placed for resuscitation including administration of blood products. Chest x-ray showed no intrathoracic pathology, and the pelvic film demonstrated a Type III anteroposterior compression injury, with 10 cm of separation at the pubic symphysis. The abdominal component of FAST result was positive, and a binder was placed with reduction of the pubic diastasis.

Hemodynamics responded poorly, and the patient was taken for damage-control laparotomy, which revealed a hemoperitoneum emanating from a pelvic hematoma. There were no intra-abdominal injuries, and the pelvic hematoma was packed as were extensive pelvic and perineal soft tissue wounds. The patient remained in shock, while a temporary abdominal closure was performed. The right femoral artery was accessed in a percutaneous fashion,



Figure 2. CT image showing REBOA in Zone 1 of aorta with no distal flow.

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Figure 3. Aortic zones related to REBOA. Zone I extends from the origin of the left subclavian artery to the celiac artery. Zone II extends from the celiac artery to the lowest renal artery and is a no-occlusion zone. Zone III extends from the lowest renal artery to the aortic bifurcation. Reproduced with permission from Stannard A, Eliason JE, Rasmussen TE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for hemorrhagic shock. *J Trauma*. 2011;71(6):1869 1872.

and Zone III was REBOA initiated using fluoroscopic guidance of the 0.035-inch wire and Cook Coda balloon. REBOA resulted in an increase in blood pressure from 85 mm Hg to 125 mm Hg with a decrease in heart rate from 143 bpm to 120 bpm. With improved hemodynamics, an external fixator was applied to the pelvis to further reduce pelvic volume while awaiting transport to interventional radiology.

In the interventional radiology, arteriography demonstrated contrast extravasation and vasospasm in areas of both internal iliac arteries and an abrupt cutoff of a right internal iliac artery branch suggesting thrombosis. Gelfoam embolization was performed to the areas of extravasation, and the anterior branch was treated with coil embolization. Following arteriography, the patient was returned to the operating room for removal of the balloon, wire, and sheath with local thrombectomy and closure of the femoral access site. CT imaging of the head revealed traumatic cerebral contusions, left internal carotid artery injury with ischemic stroke, and multiple acute pulmonary emboli. The patient never regained neurologic function, and care was withdrawn on hospital Day 6.

DISCUSSION

This clinical series represents the largest contemporary report of REBOA for hemorrhage control and resuscitation following trauma. This report represents the preliminary application of this technique extending a considerable amount translational research work, which has been accomplished on this topic during the past number of years. Observations from this series demonstrate the feasibility of REBOA using existing endovascular and imaging technology in patients with shock. The procedure in each case was performed emergently as a resuscitative adjunct by the trauma surgeon. Completion of ESTARS training preceded performance of REBOA for three surgeons, while three had basic endovascular skills obtained as part of residency augmented with cadaver-based endovascular laboratories. Despite severity of injury and adverse physiology, all patients survived hemorrhagic shock without REBOArelated complications. Two patients progressed to brain death caused by nonsurvivable neurologic injuries.

REBOA as an adjunct for shock was reported by Hughes²⁶ during the Korean War. Although not new, REBOA has received a reappraisal because of the military's imperative to develop better ways to manage hemorrhagic shock. To date, these efforts in damage-control resuscitation have focused on training, hemostatic dressings, extremity and junctional tourniquet devices, and balanced resuscitation using all blood components and tranexamic acid.^{27–29} The impetus behind REBOA stems from a need to develop mechanical or procedural adjuncts to improve survival from shock. The reappraisal of this technique also takes place in an endovascular era in which devices and skills are advanced and shown to benefit patients with ruptured aortic aneurysm.^{9–11}

Stannard et al.²⁴ published a description of REBOA in which occlusion zones were defined (Fig. 3) to facilitate understanding of the technique and to provide a framework with which to refine its use. Zone I is the descending thoracic aorta between the origins of the left subclavian and celiac arteries. Zone I REBOA is akin to aortic clamping otherwise performed during resuscitative thoracotomy. Zone II is the paravisceral segment and was proposed as a potential no-occlusion zone, while Zone III represents the infrarenal aorta extending from the lowest renal artery to the bifurcation. Despite the plausibility of description of Stannard et al., it was not a clinical report, and until the current series, the feasibility and utility of this nomenclature remained in question. The rationale behind REBOA is that aortic occlusion supports myocardial and cerebral perfusion until resuscitation can be initiated and hemostasis obtained. These are the same goals of open aortic cross clamping, but REBOA is performed in a less invasive manner, sparing a compromised patient additional morbidity.^{20,30,31} In the current series, REBOA was accomplished quickly and resulted in an average increase in blood pressure of 55 mm Hg. The average aortic occlusion time was 18 minutes, which allowed hemorrhage control maneuvers to be accomplished. By defining zones, Stannard et al. acknowledged that some cases of shock may be amenable to distal occlusion, allowing perfusion to the proximal aorta and its intercostal, visceral, and lumbar branches during REBOA. In this series, three cases comprised Zone III REBOA, while the remaining cases required proximal Zone I aortic occlusion.

The decision whether to perform a resuscitative thoracotomy with aortic clamping, REBOA, or rush to the operating room for laparotomy requires judgment. In each of the current cases, the surgeon felt that the patient had already arrested or that cardiac arrest was imminent and that aortic occlusion was required. Familiarity with the recent literature and a current understanding of the needed endovascular skills led to REBOA in these cases. The effectiveness of REBOA and a recognition that endovascular technologies will improve have caused the faculty at these centers to undergo an evolution in thought. Most agree that REBOA will replace resuscitative thoracotomy with aortic clamping as a means for proactive aortic control in cases of exsanguinating hemorrhage.

It is worth noting that arterial access was accomplished quickly in all cases. Through a variety of methods including blind and ultrasound-guided percutaneous access as well as rapid cutdown, the provider in each case was able to place a 12 Fr to 14 Fr sheath in the femoral artery. The variety of approaches speaks to the appropriateness of this technique in the hands of surgeons with a range of operative skills and a willingness to apply them in the emergent setting. It is also worth noting that basic imaging was used including basic spot films of the abdomen and or chest. This improvised but smart use of portable x-ray demonstrates that REBOA does not require extensive fluoroscopic imaging but instead select images to confirm wire and balloon position.

All cases in this series were performed by trauma and acute care surgeons without certification in interventional or vascular specialties. Each provider who performed REBOA did have the required training and experience in vascular disease, anatomy, and surgery to be certified as a general surgeon by the American Board of Surgery. In this context, trauma and acute care surgeons are not starting from scratch as they apply this skill set. In addition to board certification, three of the providers had undergone training in the ESTARS course. The surgeons who had not attended the ESTARS course had basic skills obtained as part of surgical residency augmented with cadaverbased endovascular laboratories.

The ESTARS course is a novel 2-day curriculum involving a structured syllabus consisting of didactic teaching, live tissue, and simulator components. As part of ESTARS, participants are required to demonstrate proficiency through completion of a pretest and posttest including examination of hand-on skills with both animal and simulator modules. The military is not alone in initiating programs to develop basic skills among trauma and acute care surgeons. Novel programs involving simulators and cadaveric laboratories have been initiated at the University of Maryland Shock Trauma Center and the University of Texas at Houston, Texas Trauma Institute. Observations from the current cases demonstrate the value of basic endovascular skills taught to boarded surgeons at ESTARS and these other venues and their application in clinical scenarios.

Limitations

Observations from this series should be interpreted cautiously because these successes may not translate to future scenarios. Blind placement of wires, sheaths, and catheters within the arterial circulation is not without risk and is not recommended under elective circumstances. These maneuvers and inflation of a balloon within the aorta may result in damage to the aorta and its branch vessels or end organs such as the viscera or brain from embolization or dissection. However, it is worth noting that each of the tools or devices used in these cases is designed for endovascular placement including a compliant aortic occlusion balloon. As such, it is reasonable to consider that their use by board-certified surgeons during REBOA provides an alternative to thoracotomy with aortic clamping. Finally, performance of REBOA does not portend an ability for trauma and acute care surgeons to perform more complex endovascular procedures. On the contrary, the ability to accomplish REBOA represents a limited skill set, which should be performed when other alternatives are limited.²⁴ More complex endovascular procedures would require more comprehensive endovascular training, possibly within the skill set of a new generation of acute care surgeons.

CONCLUSION

REBOA is a feasible and effective means of proactive aortic control for patients in end-stage shock from blunt and penetrating mechanisms. With the use of existing technology, this method of resuscitation can be performed by acute care surgeons who have benefited from brief instruction on a limited endovascular skill set. Future work should be aimed at the development of devices that minimize complications and facilitate access as well as studies to define populations in which this adjunct is beneficial.

AUTHORSHIP

M.L.B. contributed in the literature search, study design, data collection, data analysis, and writing. L.J.M. contributed in the literature search, study design, data collection, data analysis, and writing. J.J.D. contrib uted in the literature search, study design, data collection, data analysis, and writing. G.H.T. contributed in the study design, data collection, data analysis, and writing. M.K.M. contributed in the data collection, data analysis, and writing. J.B.H. contributed in the data collection, data analysis, and writing. J.B.H. contributed in the data collection, data analysis, and writing. J.B.H. contributed in the study design, data collection, data analysis, and writing. J.B.H. contributed in the study design, data collection, data interpretation, writing, critical revision, and obtaining study funding. T.M.S. contributed in the study design, data collection, data interpretation, writing, critical revision, and obtaining study funding. T.E.R. contributed in the study design, data collection, data interpretation, writing, critical revision, and obtaining study funding.

DISCLOSURE

The authors declare no conflicts of interest.

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