Original Article

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Contemporary Utilization of Zone III REBOA for Temporary Control of Pelvic and Lower Junctional Hemorrhage Reliably Achieves Hemodynamic Stability in Severely Injured Patients

Jason D Pasley DO FACS[1], Megan Brenner MD MS RVPI FACS[1], Amelia Pasley DO[1], Laura J Moore MD FACS[2], Thomas M Scalea MD FACS FCCM[1], Joseph Dubose MD RVPI FACS FCCM[1] and AAST AORTA Study Group

[1]R Adams Cowley Shock Trauma Center, Baltimore, MD, USA
[2]UT Houston, TX, USA

Background: Aortic occlusion is a valuable adjunct for the management of traumatic pelvic and lower extremity junctional hemorrhage.
Methods: The American Association for the Surgery of Trauma Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery registry was reviewed for patients requiring Zone III resuscitative endovascular balloon occlusion of the aorta (REBOA) from eight verified trauma centers. After excluding patients in arrest, demographics, elements of treatment, and outcomes were identified.
Results: From November 2013 to December 2016, 30 patients had Zone III REBOA placed. Median age was 41.0 (interquartile range, IQR, 38); median injury severity score was 41.0 (IQR 12). Hypotension (SBP < 90 mm Hg) was present on admission in 30.0% and tachycardia (HR > 100 bpm) in 66.7%. Before REBOA placement, vital signs changed in this cohort with hypotension in 83.3% and tachycardia noted in 90%. Median initial pH was 7.14 (IQR 0.22), and median admission lactate 9.9 mg/dL (IQR 5). Pelvic binders were utilized in 40%. Occlusion balloon devices included Coda™ (70%), ER REBOA™ (13.3%), Reliant™ (10%). After REBOA, hemodynamics improved in 96.7% and stability (BP consistently > 90 mm Hg) was achieved in 86.7%. Median duration of REBOA was 53.0 mins (IQR 112). Median PRBC and FFP requirements were 19.0 units (IQR (17) and 17.0 units (IQR 14), respectively. One amputation unrelated to REBOA utilization was required. Systemic complications included AKI (23.3%) and MODS (10%). REBOA specific complications included groin hematoma (3.3%) and distal thromboembolization (16.7%). Survival to discharge was 56.7%, with in-hospital deaths occurring in the ED 7.7%, OR 23.1%, ICU 69.2%.
Conclusions: This review discusses the specifics of the contemporary use of Zone III REBOA placement as well as local and systemic complications for patients in extremis with pelvic/junctional hemorrhage. Further review is required to determine optimal patient selection.

Keywords: *Zone III REBOA; Pelvic Bleeding; Junctional Hemorrhage*

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Corresponding author:
Jason Pasley, DO, FACS, 50 N Perry St, Pontiac, MI 48342, USA.
Email: jason.pasley@mclaren.org

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INTRODUCTION

Hemorrhage remains the leading cause of preventable death in both the civilian and military sectors, with a majority of patients having noncompressible torso hemorrhage (NCTH) in the truncal or junctional regions [1,2]. In patients with pelvic fractures or junctional bleeding, a multidisciplinary approach is necessary consisting of interventions performed in the pre-hospital setting, the trauma bay, the operating room (OR) and/or the angiographic suite.

Previously, in patients with exsanguinating pelvic hemorrhage, the only methods for immediate bedside control consisted of ongoing blood transfusion as well as pelvic wrapping with a binder or sheet. If the patient came into the trauma bay in cardiac arrest or progressed to cardiac arrest, open thoracic aortic cross-clamping has been used for proximal control with poor survival [3].

Balloon occlusion of the aorta, originally described for abdominal aortic rupture in the setting of vascular disease [4,5] has been modified to develop a similar strategy for NCTH [6]. The effectiveness of resuscitative balloon occlusion of the aorta (REBOA) for traumatic hemorrhage has been shown in multiple animal models [7] and through clinical experience [8].

In certain centers, REBOA has become an important adjunct in the treatment of life-threatening abdominal, pelvic, and junctional hemorrhage. In these centers, this procedure has essentially replaced emergency department thoracotomy with open aortic cross-clamping in traumatic arrest resulting from bleeding at these same locations [9].

The authors believe that Zone III REBOA offers a minimally invasive approach for proximal control in pelvic and junctional bleeding. In specific patients, arresting hemorrhage at the aortic bifurcation may stabilize patients, by decreasing bleeding and may facilitate hemodynamic stability for these patients to travel to more definitive care beyond the emergency department.

We utilized the American Association for the Surgery of Trauma (AAST) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) database to examine the contemporary utilization of distal (Zone III) REBOA for management of traumatic pelvic and lower extremity junctional hemorrhage.

METHODS

The AAST AORTA registry is a prospectively collected observational database, reporting aortic occlusion by endovascular and open means for all noncompressible torso trauma.

The prospective observational AORTA study was approved by the AAST Multicenter Trials Committee. All data were obtained from level I and level II trauma centers, as verified by the American College of Surgeons. All centers obtained individually local institutional review board approval before participation. Data were collected prospectively and entered by registrars, designated by individual centers, into the online data collection portal resource developed by AAST.

Adult trauma patients (age 18 or older) undergoing Zone III REBOA placement were examined. Data included patient's demographics, admission physiology, admission laboratory results, and injury severity score (ISS). The timing, type, delivery, and duration of Zone III balloon occlusion were recorded. The physiologic response was recorded with hemodynamic stability for the AORTA trial defined as SBP consistently >90 mm Hg after inflation. Patient transfusion requirements, subsequent systemic and local complications, as well as outcomes, were reviewed.

AORTA registry patients requiring Zone III REBOA from eight American College of Surgeons verified level I and level II trauma centers were examined. Patients presenting in cardiac arrest at the time of aortic occlusion (AO) were excluded from this study, as it is the opinion of the authors that Zone I REBOAs should be placed in this case for exsanguination below the diaphragm, whether the source is abdominal or pelvic/junctional. Demographics and elements of treatment and outcomes were identified.

Values are reported as means ± standard deviation (SD) for continuous variables with normal distributions as determined by the assessment of a skewness calculation. Continuous variables not possessing normal distribution are reported as median and interquartile range (IQR). Categorical variables are expressed as percentages. All analyses were performed using the Statistical Package for Social Sciences (SPSS Mac) version 22.0 (SPSS Inc, Chicago, IL).

RESULTS

From November 2013 to December 2016, 30 patients meeting the criteria were identified with Zone III REBOA placement, among eight contributing ACS level I and level II trauma centers. The majority of patients were male ($n = 25$, 83.3%), with a mean age of 41 (IQR 38) years. The most common mechanism was blunt ($n = 29$, 96.7%) with nearly a third ($n = 9$, 30%) injured by motor vehicle accident, followed by pedestrian versus automobile, motorcycle crash, fall, unknown blunt mechanism, and then gunshot wound. Hypotension (systolic blood pressure (SBP) < 90 mm Hg) was present on admission in 30.0% and tachycardia (heart rate (HR) > 100 bpm) in 66.7%. Before REBOA placement, vital signs changed in this cohort with hypotension noted in 83.3% and tachycardia noted in 90%. Mean initial pH was 7.14 (IQR 0.22), and mean admission lactate 9.9 mg/dL (IQR 5). The mean ISS was 38 (IQR 12). Patients had a mean intensive care unit (ICU) length of stay (LOS) of 15 (IQR 14) days and a mean hospital LOS of 26 (IQR 40) days (Table 1).

Table 1 Demographics of study population.

	N = 30
Age, *y* (IQR)	41 ± 38
Male, *n* (%)	25 (83.3)
Mechanism, *n* (%)	
Blunt	29 (96.7)
Motor vehicle accident	9 (30)
Pedestrian vs auto	6 (20)
Motorcycle crash	6 (20)
Fall	5 (16.6)
Unknown blunt mechanism	4 (13.3)
Penetrating	1 (3.3)
GSW	1 (3.3)
Admission parameters	
Hypotension < 90 mmHg, *n* (%)	9 (30)
Tachycardia >100 mmHg, *n* (%)	20 (66.7)
Admission pH	7.14 (0.22)
Admission lactate, mg/dL	9.9 (5)
Admission GCS	8 ± 5.63
Preplacement parameters	
Hypotension < 90 mmHg, *n* (%)	25 (83.3)
Tachycardia >100 mmHg, *n* (%)	27 (90)
ISS	38 (16.8)
Intubated on admission, *n* (%)	12 (40)
ICU LOS, d	15 (14)
Hospital LOS, d	26 (40)
Discharge disposition, *n* (%)	
Rehab/Nursing facility	16 (53.3)
Home	1 (3.3)
Mortality	13 (43.3)

GSW, gunshot wound; GCS, Glasgow coma score; ISS, injury severity score; ICU, intensive care unit; LOS, length of stay.

Table 2 REBOA placement.

	N = 30, *n* (%)
Location of AO attempt	
ER	20 (66.6)
OR	10 (33.3)
Technique for access	
Percutaneously with landmarks only	15 (50)
US	9 (30)
Fluoroscopy	3 (10)
Cut down	2 (6.6)
Not adequately described	1 (3.3)
Background of operator	
Trauma/ACS Attending	24 (80)
Trauma/ACS Fellow	1 (3.3)
Surgical Resident	1 (3.3)
Vascular Attending	1 (3.3)
Not adequately described	3 (10)
Imaging to facilitate positioning	
None/external landmarks	8 (26.7)
Plain film	15 (50)
C-arm fluoroscopy	5 (16.7)
Ultrasound	1 (3.3)
Not adequately described	1 (3.3)
Type of balloon	
Coda	21 (70)
ER REBOA	4 (13.3)
Reliant	3 (10)
Not adequately described	2 (6.6)

ER, emergency Room; OR, operating room; US, ultrasound; ACS, acute care surgery.

For REBOA placement, a majority (66.6%) were placed in the emergency department with the remainder in the OR. The operating physician was typically a Trauma/Acute Care Attending in 80%, followed by Trauma/Acute Care Fellow, Surgical Resident, and Vascular Attending. Techniques for access included percutaneous with landmarks in 50%, ultrasound guidance in 30%, with the remainder via fluoroscopy or cut down. Facilitating positioning was performed via plain film in 50%, fluoroscopy in 16.7%, and via ultrasound in 3.3%. No imaging (using external landmarks only) was the approach employed in 26.7%, and for 3.3% the approach utilized was not adequately described. Occlusion balloon devices included Coda™ (Cook Medical, Bloomington, IN) in a majority (70%), followed by ER REBOA™ (Prytime, Boerne, TX), and Reliant™ (Medtronic, Minneapolis, MN) (Table 2).

Zone III AO was successful in all patients (n = 30, 100%). Hemodynamics improved in 29 patients (96.7%). Hemodynamic stability consistently above 90 mm Hg was noted in 86.7% of patients. The median duration of occlusion was 53 minutes (IQR 112). Transfusions were required in all patients. The median number of packed red blood cells (PRBC) was 19 units (IQR 17) and fresh frozen plasma (FFP) 17 units (IQR 14), respectively (Table 3).

Pelvic binders were present on arrival in 30% of patients. Six patients (20%) had no additional documented procedures noted; however, two of these patients expired, one in the emergency department and the other in the OR. Ten patients (33.3%) had single modality treatment following Zone III REBOA, with six patients requiring exploratory laparotomy with associated

Table 3 Results of aortic occlusion at Zone III and associated procedures.

	N = 30, *n* (%)
AO successful	
yes	30 (100)
HD improved	
Yes	29 (96.7)
HD stable	
SBP consistently > 90 mm Hg	26 (86.7)
Duration of inflation, min (IQR)	53.0 (112)
Transfusion	
PRBC	19 (17)
FFP	17 (14)
Pelvic binder	12 (30)
Associated procedures	
None	6 (20)
Single modality	10 (33.3)
Ex Lap alone	6 (20)
PP alone	1 (3.3)
Ex Fix alone	2 (6.7)
AE alone	1 (3.3)
Multiple modality	14 (46.7)
Ex Lap/PP	2 (6.7)
Ex Lap/PP/Ex Fix	2 (6.7)
Ex Lap/PP/AE	3 (10)
Ex Lap/Ex Fix	4 (13.3)
Ex Lap/Ex Fix/AE	1 (3.3)
PP/AE	1(3.3)
Ex Fix/AE	1 (3.3)
Additional procedures	
Craniectomy	0 (0)
Thoracotomy	0 (0)

AO, aortic occlusion; HD, hemodynamics; SBP, systolic blood pressure; PRBC, packed red blood cells; FFP, fresh frozen plasma; Ex Lap, exploratory laparotomy and associated procedures; PP, pelvic packing; Ex Fix, pelvic external fixator; AE, angiographic embolization.

abdominal procedures alone, one patient requiring pelvic packing alone, two patients requiring external fixator alone, and one patient requiring angioembolization alone. Almost half of the patients (*n* = 14, 46.7%) required multimodal treatment following REBOA placement (Table 3). No patients in this sample size required craniectomy or thoracotomy for associated neurologic or cardiothoracic injuries.

Local complications were present in seven patients, most commonly distal embolization in five patients (16.7% of entire cohort). One of these patients also had a local hematoma, requiring no additional treatment. Infection locally, requiring antibiotics or surgery, was present in two patients (6.6% of entire cohort) (Table 4).

Table 4 Complications and mortality.

	N = 30, *n* (%)
Local	
Hematoma	1 (3.3)
Pseudoaneurysm	0 (0)
Extremity ischemia	0 (0)
Stenosis	0 (0)
Distal embolization	5 (16.7)
Infection requiring Abx and/or drainage	2 (6.6)
Need for patch angioplasty	3 (10)
Need for arterial bypass	0 (0)
Need for amputation	1 (3.3)
Systemic	
Any complication/death	20 (66.7)
AKI	7 (23.3)
Sepsis/septic shock	5 (16.7)
MODS	3 (10)
Bacteremia	2 (6.6)
Paraplegia	1 (3.3)
Survival to discharge	17 (56.7)
Hospital mortality	13 (43.3)
ED	1 (7.7)
OR	3 (23.1)
ICU	9 (69.2)

Abx, antibiotics; MODS, multiple organ dysfunction syndrome; AKI, acute kidney injury; ED, emergency department; OR, operating room; ICU, intensive care unit.

A majority of the patients (*n* = 20, 66.7%) experienced some type of systemic complication or death. Acute kidney injury (AKI) was the most common systemic complication (*n* = 7, 23.3%), followed by sepsis (*n* = 5, 16.7%), multiple organ dysfunction syndrome (MODS) (*n* = 3, 10%), bacteremia (*n* = 2, 6.6%), and paraplegia (*n* = 1, 3.3%). Seventeen patients (56.7%) survived until hospital discharge. Of the 13 deaths, initial GCS was 3 in nine patients (69.2%) with signs of life (pupillary response, organized cardiac rhythm, spontaneous movement) being completely absent in two patients (15.3%), 2/3 absent in four patients (30.7%) and 1/3 absent in three patients (23.1%) and only intact in four patients (30.7%). In regards to time to death, six patients (46.2%) died within the initial 24 hours of admission, and an additional three patients (23.1%) died within 48–72 hours of admission, and the remainder passed away between 6 and 16 days. A majority of

these survived to the ICU, where nine patients (69.2%) succumbed to their injuries, while three patients (23.1%) died in the OR and one patient (3.3%) in the emergency department (ED) (Table 4). The overall ISS trended slightly higher in the patients who died, with an increase in associated thoracic and neurologic injuries.

DISCUSSION

In our multi-institutional study, we describe the contemporary use of REBOA in Zone III for temporary control of pelvic and lower junctional hemorrhage. Pelvic fracture with associate shock has been reported in up to 14% of patients with associated mortality rates above 30% [10]. Although the source of hemorrhage may be from somewhere other than the pelvis in these polytrauma patients, REBOA may be considered as an adjunct for hemorrhage control. REBOA may be deployed rapidly, by trained personnel, anywhere along the continuum of care to arrest or decreased hemorrhage.

Non-invasive methods, such as the pelvic binder, can be placed by Emergency Medical Services at the point of injury, decreasing the volume of the pelvis and decreasing the potential space for blood loss. If not placed in the pre-hospital environment, this can also be placed in the ED. Depending on the patient's hemodynamics and response to transfusion, potential AO can occur as a more invasive adjunct to stabilize the patient for ongoing hemorrhage control.

Angioembolization is a key adjunct in patients with pelvic fracture. Overall, 26% of our patients had pelvic embolization, either alone or in combination therapy. This value is comparable to the results of Constantini et al. from the AAST multi-institutional trial on current management of hemorrhage for severe pelvic fractures, where angioembolization was required in 9.6% of all patients presenting to the centers and in 24.7% of those presenting in shock [10].

Pre-peritoneal packing performed via a low-midline incision or Pfannenstiel incision, initially described by Smith et al. [11] was performed in nine patients (30%) after REBOA utilization, either alone (n = 1, 3.3%) or in combination with another modality, most commonly exploratory laparotomy/pelvic packing/angioembolization.

Mortality in our group reached 43.3%. This rate is similar to the published reports of pelvic fracture with hemodynamic instability, ranging from 21 to 50% [12–16]. All of the patients that died had significantly elevated ISS scores (22–57) with at least one other significant associated injury in another body system, besides pelvic trauma.

The first clinical series of the use of REBOA following trauma was by Brenner et al. in 2013. This study used all CODA balloons with wires and 12 F sheaths. This study showed an increase mean SBP for patients requiring both Zones I and III placement; however, 12.5% (3/14) of patients required amputations due to ischemic limb complications after arterial access. Two of the three were associated with extensive associated extremity or pelvic injury and only one was a result of iatrogenic vascular injury following multiple attempts in an obese patient [17]. Our study showed one patient that required an amputation. This patient had Zone III occlusion performed with the 7 F ER REBOA. He presented with a SBP of 94 mm Hg and HR of 154 BPM with an ISS of 41. He required multiple operations initially, including exploratory laparotomy with bowel resection, as well as Ex-Fix placement. He had a prolonged hospital course (85 ICU days and 78 ventilator days) with many complications, including AKI (requiring dialysis), bacteremia, pneumonia, sepsis/septic shock requiring vasopressors, MODS, as well as local infection requiring antibiotics and surgery. No further details surrounding the amputation were noted in the registry.

In our study, a majority of the balloons were the CODA, delivered through a large 12 F sheath all of which require operative repair. Since this data was extracted, many centers have shifted to the lower profile ER REBOA catheters. Intuitively, a smaller device for delivery and deployment should have a lower complication profile than a larger, more obstructive device. The ER REBOA uses a smaller, 7 F sheath, requiring pressure to remove if done percutaneously, or a cut-down if done open. Teeter et al. showed that with the smaller device via 7 F sheath placement, no sheath related complications were identified in placement or removal during a 30 day follow-up period [18].

In regards to the variance in sheath sizes in our study, 7–12 F, local complications at the access site can occur. In the recently published Shock Trauma series, three minor reconstructions were required, due to low cannulation of the CFA, at the bifurcation or in the superficial femoral artery. Two of these complications were with the 12 F sheath, and one with the 7 F sheath [19]. Similarly, in our study, three patients required patch angioplasty, two from the 12 F group and one from the 7 F group.

This series represents contemporary practice at eight level I and level II trauma centers. With the option for endovascular AO, many centers are starting to place femoral arterial lines in an expedited fashion for any trauma patient with potential NCTH that may appear to be in shock. As seen by Hampton et al., the limiting factor in time to placement is initial arterial access, therefore in this patient population, once access is obtained, the sheath can be upsized and the catheter placed in a timely fashion [20].

This study has several limitations. The data was collected from eight level I and level II trauma centers, with their own capabilities and practice patterns. The data was predominantly taken from using the 12 F CODA, which is likely to be less commonly utilized in the era since the introduction of 7 F alternative platforms. As this is a review of registry data, several factors may not be captured, such as physician preference/perspective,

occlusion type (total, partial, intermittent occlusion) and institutional policies. Not all data fields were fully entered on every patient. Data points are also inserted as a single number and may not truly reflect the fluidity of the patient situation, specifically with hemodynamic instability. Bias in this sample population can be inferred since a significant number of patients had a high ISS with elevated AIS graded injuries in other body areas besides the abdomen with no patient undergoing a craniectomy or thoracotomy. Monitoring devices, such as an intracranial device were also not noted.

Through the AORTA registry, our experience shows that Zone III occlusion for pelvic and junction bleeding is a safe method that can be done by appropriately trained personnel at the bedside to improve and maintain blood pressure, in order to transport the patient for their next step in hemorrhage control. With continued training and use of REBOA for NCTH, the AORTA database can continue to mature and greater insight can be made in this population with the advancement of technology and adaptation of the procedure in the treatment algorithm of pelvic and junctional hemorrhage.

CONCLUSIONS

Zone III REBOA for early control of pelvic or junctional hemorrhage in patients in extremis provides hemodynamic stability, with minimal complications, sufficient to achieve definitive control in environments beyond emergency departments. As experience increases and devices change, the AAST AORTA database can better elucidate optimal indications and outcomes for pelvic trauma.

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PhD, Division of Trauma and Surgical Critical Care, Hennepin County Medical Center, Minneapolis, MN; Chad Richardson, MD, FACS, Division of Trauma and Surgical Critical Care, Hennepin County Medical Center, Minneapolis, MN; Matthew Bloom, MD, FACS, Division of Trauma and Surgical Critical Care, Cedars Sinai Hospital, Los Angeles, CA; Nam T Tran, MD, FACS, Division of Trauma and Surgical Critical Care, University of Washington-Harborview, Seattle, WA; Shahram Aarabi, MD, Division of Trauma and Surgical Critical Care, University of Washington-Harborview, Seattle, WA; Eileen Bulger, MD, FACS, Division of Trauma and Surgical Critical Care, University of Washington-Harborview, Seattle, WA; Jeannette G Ward, MS-CR, Division of Trauma and Surgical Critical Care, Chandler Regional Medical Center, Chandler, AZ; John K Bini, MD, FACS, Division of Trauma and Surgical Critical Care, Wright State Research Institute, Miami Valley Hospital, Dayton, OH; John Matsuura, MD, FACS, Division of Trauma and Surgical Critical Care, Wright State Research Institute-Miami Valley Hospital, Dayton, OH; Joshua Pringle, MD, Division of Trauma and Surgical Critical Care, Wright State Research Institute-Miami Valley Hospital, Dayton, OH; Karen Herzing, BSN, RN, Division of Trauma and Surgical Critical Care, Wright State Research Institute-Miami Valley Hospital, Dayton, OH; Kailey Nolan, BS, Division of Trauma and Surgical Critical Care, Wright State Research Institute-Miami Valley Hospital, Dayton, OH; Nathaniel Poulin, MD, FACS, Division of Trauma and Surgical Critical Care, East Carolina Medical Center, Greenville, NC; William Teeter, MD, Division of Trauma and Surgical Critical Care, University of North Carolina at Chapel Hill, Chapel Hill, NC.

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