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Nationwide use of REBOA in adolescent trauma patients: An analysis of the AAST AORTA registry

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Abstract

Background: Trauma is the leading cause of death for children and adolescents. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a minimally invasive method of hemorrhage control used primarily in adults. We aimed to characterize REBOA use in pediatric patients.

Methods: The American Association for the Surgery of Trauma (AAST) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry was queried for patients < 18 years old undergoing REBOA placement (2013–2020). The primary outcome was mortality. Secondary outcomes included injury severity score (ISS), additional interventions, and complications.

Results: Eleven patients with a median age of 17 years old had REBOA placed, with a survival rate of 30%. Inflation of the REBOA balloon resulted in a significant increase in systolic blood pressure (SBP) (median SBP pre-REBOA 53 mmHg vs. post-REBOA 110 mmHg, p = 0.0007). Patients were severely injured with a median ISS of 29 (interquartile range 16–42). There were no access-site complications. All three surviving patients had a discharge Glasgow Coma Scale of 15.

Conclusion: REBOA is used in patients < 18 years old, but all reported patients in this registry were adolescents. No REBOA-related complications were reported. Identifying pediatric patients who may benefit from REBOA and modifying currently existing technology for this group of patients is an area of ongoing research.

Keywords

Pediatric trauma; REBOA; Resuscitative endovascular balloon; occlusion of the aorta

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Introduction

Trauma is the leading cause of death for children and adolescents, primarily due to traumatic brain injury and hemorrhage [1]. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is used to temporarily gain hemorrhage control in exsanguinating patients, but almost all reports have been in adults. The use of REBOA in pediatric trauma patients has been reported in one published retrospective cohort of 54 Japanese patients younger than 18 years old with a survival rate was 42.6% [2]. An additional case series of seven adolescent patients in the United States reported a 29% survival rate [3]. The remaining instances of REBOA in pediatric patients are from case reports, with patients aged 11–12 years old following blunt abdominal trauma [4, 5], and one report of endovascular aortic balloon occlusion in a 9-year-old for an aorto-esophageal fistula following foreign body removal [6].

The literature suggests that REBOA catheters are being used in pediatric patients, particularly adolescents. In pre-clinical studies, REBOA has been shown to decrease blood loss in a pediatric swine model [7], and pediatric swine have been found to tolerate 30 minutes, but not 60 minutes, of complete aortic occlusion [8]. However, there is no consensus on indications for REBOA use in pediatric patients at this time and more data is needed on the outcomes of pediatric patients undergoing REBOA placement to guide future use.

We aimed to characterize the use of REBOA in pediatric patients in the United States by analyzing the American Association for the Surgery of Trauma (AAST) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry for all patients < 18 years old who underwent REBOA placement since its inception.

Patients and methods

Registry information

We performed a retrospective review of the American Association for the Surgery of Trauma (AAST) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry. The AORTA Registry is a multi-institutional registry approved by the AAST Multicenter Trials Committee. The AORTA Registry is a prospectively collected database of trauma patients undergoing aortic occlusion by open and endovascular techniques, including REBOA, and was established in 2013. At the time of this study 52 hospitals had contributed to the registry via a secure online portal. Of these, 25 hospitals are adult trauma centers and 27 hospitals are both adult and pediatric trauma centers. All participating hospitals obtained individual local Institutional Review Board (IRB) approval for waivers of consent prior to submitting de-identified data. This study was approved by our local IRB prior to receiving the data.

Study design and patient selection

All patients < 18 years old who had REBOA placed between September 2013 and April 2020 were included. Patients were excluded if they were 18 years or older, or if they did not undergo REBOA placement. The primary outcome was mortality. Secondary outcomes included patient characteristics, interventions performed, injury severity, and complications.

Data collected included demographic information, mechanism of injury, presenting vital signs and exam, injury severity score, procedures performed, hospital and intensive care unit length of stay, complications, and outcomes. As this is a registry study, some data is incomplete. Any outcome measure with missing data has the number of missing patients reported.

Intervention

Patients underwent REBOA placement, which is done by obtaining retrograde common femoral arterial access and advancing a balloon catheter into either the supraceliac or infrarenal aorta to occlude distal blood flow. During the study period, two different REBOA devices were used. Most commonly, the ER-REBOA catheter (Prytime Medical, Boerne, TX) is used. This device is inserted through a 7 French introducer sheath. Another aortic occlusion device, the CODA balloon catheter (Cook Medical, Bloomington, IN), is inserted through a 12–14 French sheath. Once inserted, the REBOA balloon is positioned in one of two aortic zones. Zone 1, the supraceliac abdominal aorta, is used for presumed intraabdominal hemorrhage. Zone 3, the infrarenal abdominal aorta, is used for presumed pelvic hemorrhage. The aortic balloon is inflated with 0.9% sodium chloride to achieve aortic occlusion. Each participating institution used their own protocol for patient selection for REBOA placement, which was not standardized.

Statistical analysis

Descriptive statistics were performed. Continuous data was reported as median and interquartile ranges (IQR) and categorical data was reported as percentages. Non-parametric continuous data was compared using Mann-Whitney-U tests and categorical data was compared using Fisher’s exact test. Values were considered significant at $p < 0.05$.

Results

Overall results

Eleven patients were identified under the age of 18 years old who had REBOA placed at seven institutions over seven years (Table 1). The majority were 17 years old, with one 16-year-old patient and most were male. Patients were primarily injured by blunt trauma (7/11) with the remaining four patients sustaining gunshot wounds. The median ISS was 29 (IQR 16–41.5). Four patients were under closed chest cardiopulmonary resuscitation before arriving at the hospital. The admission systolic blood pressure was median 73 mmHg (IQR 0–87.5). The median Glasgow Coma Scale (GCS) score on arrival was 3 (IQR 3–10.75). Patients were acidotic, with a median pH of 7.13 (IQR 7.0–7.14) and base deficit of 17 (IQR 16.5–17).

REBOA placement

Ten patients had REBOA as the initial aortic occlusion method; one patient underwent emergency department (ED) resuscitative thoracotomy followed by intraoperative REBOA placement (Patient 11). Details of REBOA placement are presented in Table 2. The remaining REBOA catheters were placed in the ED. Nine patients had data on method of access, with three placed by femoral artery cut-down and six patients undergoing

percutaneous placement. The majority used a 7 French catheter, with one patient using a 14 French catheter. The majority were placed in Zone 1 (8/10 reported), with the remainder in Zone 3 (2/10).

Patients were hypotensive at the start of the REBOA procedure with a median SBP of 53 mmHg (IQR 0–60), with improvement to 110 mmHg (IQR 99–140, p = 0.0007) following balloon inflation (Table 2). Three patents were under CPR during REBOA placement, with return of measurable vitals in two patients following REBOA inflation. The median change in SBP before and after REBOA placement was 56 (IQR 32–85) mmHg. The median duration of aortic occlusion was reported in 7 patients and was 75 minutes (IQR 42–115).

Adjunctive resuscitation and procedures

Patients received a median of 18.5 units of packed red blood cells (IQR 9.25–22), 20 units of fresh frozen plasma (IQR 10–20), and 3 units of platelets (IQR 1–12). Six patients received tranexamic acid. Adjunctive procedures were performed in 9 patients (Table 3), with most undergoing exploratory laparotomy (n = 8). Of these patients, four had splenectomies, three had hepatic packing, and one had a hepatic resection. Pelvic packing was performed in one patient and one patient had pelvic angioembolization done. No patients underwent lung resection, cardiac repair, or craniectomy. Times from admission to start of aortic occlusion procedure, successful aortic occlusion, hemodynamic stability, and definitive hemorrhage control are presented in Table 4.

Outcomes

Complications were reported in three patients, one of whom developed multi-system organ dysfunction, one developed bacteremia, and one developed acute respiratory distress syndrome (Table 5). No patient developed an access-site complication such as hematoma, pseudoaneurysm, lower extremity ischemia, or amputation. Mortality was 70% (7/10, 1 missing), and occurred a median of 7 hours after admission (IQR 3–8 hours). Most patients died in the intensive care unit (5/7 deaths) with one patient each dying in the ED and the operating room. All three surviving patients had a discharge GCS of 15.

Discussion

We identified eleven patients under the age of 18 who underwent REBOA placement in the first analysis of a nationwide database of aortic occlusion in the United States, with the majority undergoing placement in the ED. Aortic occlusion resulted in a drastic improvement in hemodynamics in all patients, and thirty percent of patients survived to hospital discharge. All surviving patients were neurologically intact. There were no access-site complications. All but one patient who died succumbed to their injuries on the first hospital day, and most within several hours of presentation. All patients in the registry were adolescents, with no use reported in children younger than 16 years of age.

The use of REBOA in pediatric trauma patients is rare, with only 63 reported cases in the literature worldwide [2–5] prior to this paper, which brings the total to 74 patients. Of the 73 patients with mortality data, 33 patients survived for an overall survival rate of 45.2%. These patients have mostly been adolescents, with a median age of 17 in the patients from the

AORTA registry and the previously presented series of 7 U.S. patients. The majority (72%) of patients in the Japanese series were between 16–18 years of age, which is similar to our findings. The youngest reported use of REBOA is in an 11-year-old patient who presented under CPR following a motor vehicle collision and had a Zone 1 REBOA placed in the ED, which was subsequently inflated with return of spontaneous circulation and definitive hemorrhage control was performed in the OR [5]. There has been one younger case of aortic balloon occlusion, performed for aorto-esophageal fistula and subsequent hemorrhage following esophageal foreign body removal in a 9-year-old. In this case, a 7 French sheath was used to deploy a 14 mm × 4 cm angioplasty balloon proximal to the fistula to provide temporary hemorrhage control until the patient was able to have an aortic stent placed for definitive repair [6].

Although there are likely younger patients who may benefit from REBOA use, currently available catheters require a 7 French sheath for insertion. A 7 French sheath has an outer diameter of 2.95 mm, and studies from children undergoing femoral access for cardiac catheterization have found there is an increased risk of ipsilateral pulseless extremity when the outer diameter of the catheter exceeds 50% of the vessel lumen [9]. Thus, a common femoral artery diameter of 5.9 mm is the minimum size that would permit use of commercially available REBOA catheters. Based on morphometric analysis of pediatric common femoral artery sizes from computed tomography scans, this corresponds to a 30-kg child [10], which is the 50th percentile for weight of a 9–10 year old child [11, 12]. The aorta is also smaller in children, measuring less than 1.5 cm and 1.3 cm in Zones 1 and 3 respectively, as calculated in a study analyzing measurements from pediatric computed tomography scans [13]. The patients in this study were a median of 66 kg, similar in size to adult patients, which may represent selection bias based on the currently available technology. Further research, and smaller introducer sheaths, are needed before REBOA catheters may be used in children younger than adolescents. Currently several companies are creating and testing balloon catheters compatible with smaller introducer sheaths (< 7Fr). While there is little data to guide the use of REBOA in children and infants, the potential access-site complications of the procedure may be ameliorated with these devices.

Pediatric patients sustain mostly blunt trauma, most commonly falls and motor vehicle collisions, and are for the most part not severely injured, with around 60% of reported injury severity scores less than 8 [14]. Additionally, pediatric trauma patients are known to undergo invasive procedures rarely, with the most notable example being resuscitative thoracotomy with rates as low as 0.17% of pediatric patients at two level 1 trauma centers in Denver, Colorado undergoing resuscitative thoracotomy over a 17-year period [15]. The overall rate of emergency procedural or operative intervention was only 0.6% (47 patients of 8,078) over the same period and was most commonly laparotomy [15]. However, there exists a subgroup of pediatric trauma patients who succumb to their injuries, and most do so within the first 24 hours [1]. Pediatric trauma patients are more likely to die on arrival to the ED than adult patients, and when they survive to admission but die in-hospital, most deaths occur within 24 hours of admission [1]. In a study of 105 pediatric trauma deaths in Texas, 21% were found to be preventable or potentially preventable. Although traumatic brain injury was the most common cause of death overall, hemorrhage was the most common cause of potentially preventable deaths, accounting for nearly half of these deaths (47.4%) [16].

REBOA, a minimally invasive method of temporary hemorrhage control, if more widely available and with a smaller profile, may play a role in reducing this number of potentially preventable pediatric trauma deaths.

Limitations

Our study is limited by nature of being a retrospective database review. We are limited to the variables entered into the database and are unable to report on more detailed information about each patient. Several patients have several missing variables. All patients in this study were 16–17 years old and we were unable to identify any younger patients who underwent REBOA placement in this study. Additionally, our sample size is eleven patients, which precludes meaningful many statistical analyses and this is largely a descriptive study. Thus, further work is needed to characterize pediatric patients who may benefit from REBOA and their hemodynamic response to aortic occlusion. Additionally, the low rate of reported complications is likely a reflection of the high mortality rate, mostly on day of hospital admission, leaving little time for complications to arise or be detected.

Conclusion

REBOA is rarely used in pediatric patients, with all reported cases in adolescent patients. These patients were severely injured and had a high mortality rate. However, they experienced significant hemodynamic improvement following REBOA placement and REBOA may be able to serve as a bridge to definitive hemorrhage control in adolescent trauma patients. Further research is needed to identify pediatric patients who may benefit from REBOA.

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MB: The author is a clinical advisory board member for Prytime Medical Inc and receives stock options, and is a chapter co-author for UptoDate Inc and receives royalties.

JJM: The author is a clinical advisory board member for Prytime Medical Inc and receives stock options.

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Table 1

Demographics and admission vitals and laboratory results.

Patient	Age	Sex	BMI	Mech	Pre-hospital CPR	Arrival SBP (mmHg)	Arrival HR	Arrival GCS	Initial hemoglobin (g/dl)	Initial pH	Initial base deficit	Initial lactate (mmol/L)	ISS
1	16	M	NS	MVC	Yes	0	0	3	7	7.0	−17	NS	59
2	17	M	45.4	GSW	Yes	70	101	3	NS	NS	NS	NS	16
3	17	M	21.9	MCC	No	0	137	14	10.6	NS	NS	NS	NS
4	17	M	NS	MVC	NS	NS	NS	NS	NS	NS	NS	NS	NS
5	17	F	24.9	Auto-ped	Yes	0	0	3	10	NS	NS	5.4	10
6	17	M	NS	GSW	No	90	160	14	10	7.1	−17	11	16
7	17	M	NS	GSW	No	90	160	7	10.6	7.1	−17	10	NS
8	17	M	21.7	Auto-ped	Yes	0	0	3	11.8	7.1	−17	11.6	36
9	17	F	20.1	MVC	No	80	93	3	9.6	7.2	−10	2	41
10	17	M	17.2	GSW	No	76	110	12	8.2	6.9	−16	6.2	43
11	17	F	17.7	MCC	No	142	54	3	8.1	7.0	−19	15.2	22

BMI: Body Mass Index; Mech: Mechanism; CPR: Cardiopulmonary resuscitation; SBP: Systolic blood pressure; HR: Heart rate; GCS: Glasgow Coma Scale; ISS: Injury Severity Score; NS: Not stated; M: Male; F: Female; MVC: motor vehicle collision; Auto-ped: Pedestrian hit by vehicle; GSW: gunshot wound.

Table 2

Details of REBOA placement.

Variable	Result
Hospital location of REBOA placement, n	
ED	9
OR	1
Unknown	1
Method of REBOA access, n	
Percutaneous	6
Cutdown	3
Unknown	2
REBOA catheter size	
7 French	7
14 French	1
Unknown	3
Zone of aortic occlusion, n	
Zone 1	8
Zone 3	2
Unknown	1
CPR during REBOA placement	3/9
SBP at REBOA initiation, mmHg: median (IQR); n	53 (0–60); 9 patients
SBP after balloon inflation, mmHg: median (IQR); n	110 (99–140); 9 patients
Change in SBP before and after REBOA inflation, mmHg: median (IQR); n	56 (32–85); 9 patients
Duration of aortic occlusion, minutes: median (IQR); n	64.5 (29.5–98.3); 8 patients
Time from admission to initiation of REBOA, minutes: median (IQR); n	10 (5–46); 7 patients
Time from admission to aortic occlusion, minutes: median (IQR); n	18 (15–27); 9 patients
Time from admission to hemodynamic stability, minutes: median (IQR); n	20 (18–51.5); 8 patients
Time from admission to definitive hemorrhage control, minutes: median (IQR); n	63 (42–123.5); 8 patients

ED: Emergency Department; OR: Operating Room; CPR: cardiopulmonary resuscitation; SBP: systolic blood pressure; IQR: interquartile range. Continuous variables are presented as median and interquartile range with the number of patients with available data noted.

Table 3

Additional interventions performed.

Patient	Procedures	RBC transfusions	FFP transfusions	Platelet transfusions
1	Laparotomy	18	10	0
	Pelvic packing			
	Hepatic packing, resection			
	Splenectomy			
2	Laparotomy	66	59	54
	Bowel resection			
3	Laparotomy	7	5	0
	Splenectomy			
	Bowel resection			
4	None	NS	NS	NS
5	None	2	NS	NS
6	Laparotomy	22	20	3
	Bowel resection			
7	Laparotomy	22	20	3
	Splenectomy			
8	Laparotomy	19	20	12
	Hepatic packing			
9	Pelvic angioembolization	7	6	1
10	Laparotomy	100	64	13
	Hepatic packing			
	Splenectomy			
11	Laparotomy	16	14	3
	Pelvic packing			
	Pelvic angioembolization			

RBC: Red blood cell; FFP: Fresh frozen plasma; NS: Not stated.

Table 4

Time from admission to various endpoints.

Patient	Admission to start of AO (minutes)	Admission to successful AO (minutes)	Admission to hemodynamic stability (minutes)	Admission to definitive hemorrhage control (minutes)
1	3	17	24	NS
2	7	14	17	210
3	NS	18	18	46
4	NS	NS	NS	NS
5	3	10	NS	NS
6	10	15	18	25
7	NS	20	20	38
8	26	27	31	63
9	118	121	122	180
10	66	70	72	67
11	NS	NS	NS	32

AO: Aortic occlusion; NS: Not stated.

Table 5

Patient outcomes and complications.

Patient	Complications	LOS	Discharge GCS	Disposition	Hours to death	Death Location
1	None	0	3	Died	2	OR
2	None	1	3	Died	8	ICU
3	Bacteremia	10	15	Rehab/Nursing Facility	NA	NA
4	None	NS	NS	NS	NS	NS
5	None	1	3	Died	0	ED
6	ARDS	1	3	Died	8	ICU
7	Multi-organ dysfunction	1	3	Died	6	ICU
8	None	2	NS	Died	NS	ICU
9	None	8	15	Rehab/Nursing Facility	NA	NA
10	None	6	15	Home	NA	NA
11	None	1	3	Died	10	ICU

LOS: Length of stay; GCS: Glasgow Coma Scale; ARDS: Acute Respiratory Distress Syndrome; NS: Not stated; NA: Not applicable; OR: Operating Room; ICU: Intensive Care Unit; ED: Emergency Department.