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)

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INTRODUCTION: Aortic occlusion (AO) for resuscitation in traumatic shock remains controversial. Resuscitative endovascular balloon occlusion of the aorta (REBOA) offers an emerging alternative.

METHODS: The American Association for the Surgery of Trauma Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery registry prospectively identified trauma patients requiring AO from eight ACS Level 1 centers. Presentation, intervention, and outcome variables were collected and analyzed to compare REBOA and open AO.

RESULTS: From November 2013 to February 2015, 114 AO patients were captured (REBOA, 46; open AO, 68); 80.7% were male, and 62.3% were blunt injured. Aortic occlusion occurred in the emergency department (73.7%) or the operating room (26.3%). Hemodynamic improvement after AO was observed in 62.3% [REBOA, 67.4%; open OA, 61.8%); 36.0% achieving stability (systolic blood pressure consistently >90 mm Hg, >5 minutes); REBOA, 22 of 46 (47.8%); open OA, 19 of 68 (27.9%); p =0.014]. Resuscitative endovascular balloon occlusion of the aorta (REBOA) access was femoral cut-down (50%); US guided (10.9%) and percutaneous without imaging (28.3%). Deployment was achieved in Zones I (78.6%), II (2.4%), and III (19.0%). A second AO attempt was required in 9.6% [REBOA, 2 of 46 (4.3%); open OA, 9 of 68 (13.2%)]. Complications of REBOA were uncommon (pseudoaneurysm, 2.1%; embolism, 4.3%; limb ischemia, 0%). There was no difference in time to successful AO between REBOA and open procedures (REBOA, 6.6 ± 5.6 minutes; open OA, 7.2 ± 15.1; p = 0.842). Overall survival was 21.1% (24 of 114), with no significant difference between REBOA and open AO with regard to mortality [REBOA, 28.2% (13 of 46); open OA, 16.1% (11 of 68); p = 0.120].

CONCLUSION: Resuscitative endovascular balloon occlusion of the aorta has emerged as a viable alternative to open AO in centers that have developed this capability. Further maturation of the American Association for the Surgery of Trauma Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery database is required to better elucidate optimal indications and outcomes. (*J Trauma Acute Care Surg.* 2016;81: 409–419. Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic/care management study, level IV.

KEY WORDS: Aortic occlusion; trauma; REBOA; mortality; resuscitation.

Aortic occlusion (AO) to facilitate the acute resuscitation of trauma and acute care surgery patients in shock remains a controversial topic.[1–11] It is believed that early use of AO preserves cerebral perfusion and coronary filling in the setting of life-threatening hypotension and hypovolemia due to hemorrhage. Basic science data suggest that use of AO in the setting of physiologic depletion due to hemorrhage may result in increased central aortic pressure, carotid flow, and brain oxygenation.[12,13] Most data on the clinical use of AO has, however, been retrospective and limited in nature.[6,7] The largest collected description of this experience[6] was a landmark study but was limited by the absence of consistent definitions and the variability of employed practices between published series. To date, no large multicenter prospective study of the clinical use of AO in trauma and acute care surgery has been attempted.

Aortic occlusion for trauma has traditionally been accomplished by supradiaphragmatic clamping of the descending thoracic aorta via emergent thoracotomy or as an initial step during laparotomy. This approach has been used in a variety of settings, with variable results due to unclear indications and alterations in practice.[6–11] An evolution in endovascular technologies, however, has provided additional means by which to achieve AO. Expanding experience with the use of balloon occlusion in the setting of abdominal aortic rupture due to chronic vascular disease has demonstrated the potential of these new technologies.[14,15] Discussion of the use of endovascular aortic occlusion in the realm of trauma has led to the description of this approach[16] and the demonstration of its effectiveness in both animal models of severe hemorrhage[17] and early human clinical experience.[18] To date, however, no comparison of the clinical use of endovascular AO to traditional open means has been published.

The purpose of the American Association for the Surgery of Trauma (AAST) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry is to record in a prospective observational fashion the modern use of AO in the acute resuscitation of trauma and acute care surgery patients in shock. It is our objective to provide some meaningful data on the effectiveness of AO via both open and endovascular means. These data can then be used to develop and refine protocols that will optimize resource use and patient outcomes for patients with shock.

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This study was presented at the 74th annual meeting of American Association for the Surgery of Trauma, September 9–12, 2015, in Las Vegas, Nevada.

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MATERIALS AND METHODS

The prospective observational AORTA study was approved by the AAST Multicenter Trials Committee. All presently reported data were obtained from centers within the continental United States that are verified by the American College of Surgeons as Level I trauma centers. All collaborating centers have obtained individual local institutional board review approval before participation. Data are collected prospectively and entered by registrars designated by individual centers into the online data collection portal resource developed by the AAST.

Adult trauma and acute care surgery patients (age 18 or older) undergoing AO in the acute phases after injury are enrolled. Captured data include patients' demographics, admission physiology/laboratory examination results, and injury severity scores. Required procedures are noted, as are resuscitation requirements. The timing, type, and conduct of AO are recorded, as are resulting physiologic response, changes in post-AO laboratory results, and subsequent outcomes.

Values are reported as means ± standard deviation (SD) for continuous variables with normal distributions as determined by assessment of skewness calculation. Continuous variables not possessing normal distribution median and interquartile range are used. 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

Overall AO Findings

From November 2013 to February 2015, 114 AO patients were entered into the AORTA registry by eight American College of Surgeons (ACS) Level I trauma centers. Most patients enrolled were male (80.7%), and the mean age was 40.8 years (Table 1). Blunt mechanisms of injury were more common [71 of 114 (62.3%)] than penetrating mechanisms [42 of 114 (36.8%)], but gunshot wounds were the most frequently recorded discrete injury pattern [33 of 114 (28.9%)]. Median Injury Severity Score was 31.5 [interquartile range (IQR), 26]. Prehospital cardiopulmonary resuscitation (CPR) was required in 42.1% (48 of 114). Ten patients were transfers who decompensated during transport. Among patients presenting directly from the scene of injury, time from injury to arrival was known in 72 patients, with a median value of 36.5 minutes (IQR, 22) and a range extending from 5 to 100 minutes. On arrival to the treating facility, 59.6% were confirmed as hypotensive [systolic blood pressure (SBP) < 90 mm Hg] and 65.8% (75 of 114) were intubated. Signs of life documented upon arrival included pupillary response in 38.6% (44 of 114), organized cardiac rhythm [50 of 114 (43.9%)] and spontaneous movement [28 of 114 (24.6%)].

Cardiopulmonary resuscitation was in progress in the resuscitation area after arrival in 44.7% (51 of 114). Total CPR duration (including both prehospital and hospital) was accurately recorded in 64 patients for a median time of 27.5 minutes (IQR, 27) of CPR required, ranging from less than a minute to 50 minutes, with 35.9% overall documented with combined CPR requirement times in excess of 15 minutes. Ultimately, active CPR was required and ongoing for 61.4% of the patients during initial AO attempt (Table 2). For the overall cohort, at the time of initial AO median SBP was 0 (IQR, 60) and median Glasgow Coma Score (GCS) was 3 (IQR, 0).

Most AO attempts overall were conducted by a trauma/acute care surgery attending physician [69.3% (79 of 114); Table 2]. Aortic occlusion was most commonly performed in the (ED) [73.7% (84 of 114)], with 26.3% (30 of 114) conducted in the operating room (OR). Overall mean time from successful AO from initiation of the procedures was 7.0 ± 12.6 minutes.

Improvement in subsequent hemodynamics following AO was noted in 62.3% (71 of 114), with a mean ± SD initial post-AO SBP of 74.4 ± 58.8 mm Hg achieved. Only 36.0% (41 of 114), however, achieved initial hemodynamic stability (defined for the purposes of our registry as SBP consistently >90 mm Hg for at least 5 minutes following AO). The median period of AO used was 25.0 minutes (IQR, 27; Table 2).

Patients surviving AO required a variety of subsequent procedures (Table 2), most commonly exploratory laparotomy [65 of 114 (57.0%)]. Hepatic packing was required in 19.3% (22 of 114) and pelvic packing in 11.4% (13 of 114). Median packed red blood cell requirements were a median of 15.0 units (IQR, 18), with continuous vasopressors required in 76.3% (87 of 114) and 24.6% (28 of 114) receiving tranexamic acid in the context of resuscitative attempts.

Laboratory values recorded in the first 24 hours revealed a median hemoglobin nadir of 8.2 g/dL (IQR, 3.0 mg/dL), a median international normalized ratio peak of 1.65 (IQR, 0.82), median lowest pH of 7.05 (IQR, 0.21), and a median lactate peak of 12.3 mg/dL (IQR, 7.4 mg/dL; Table 3).

Resulting complications noted among survivors of AO included acute kidney injury requiring dialysis (3.5%), acute lung injury or acute respiratory distress syndrome (2.6%), pneumonia (6.1%), and multiorgan dysfunction (6.1%). Overall in-hospital mortality was 78.9% (90 of 114), with most deaths occurring in the ED after AO attempt [50% (57 of 1140); Table 3]. Among survivors overall, neurologic outcomes were good, with median discharge GCS of 15.0 (IQR, 0) and median Glasgow Coma Outcomes Score (GOS) of 4.0 (IQR, 2; Table 3); a GCS of 15 on discharge was appreciated in 79.2% of survivors.

Comparison of Aortic Occlusion Techniques

Aortic occlusion techniques used included open [59.6% (68 of 114)] and resuscitative endovascular balloon occlusion of the aorta [REBOA; 40.4% *46/114)]. Open operative exposure approaches included anterolateral thoracotomy (43), clamshell thoracotomy (18), and via laparotomy (7) (Table 4). Five of the eight contributing centers performed both open and REBOA approaches, with the remaining three using only open techniques.

Open and endovascular AO patients differed in various ways (Tables 1, 2, 3). Open patients were more likely to be male (88.2% vs. 69.6%; p = 0.013) and have sustained penetrating mechanisms of injury (47.1% vs. 23.9%; p = 0.013). They were also less likely to have been intubated in the prehospital environment (11.8% vs. 37.0%; p = 0.002) than REBOA counterparts.

Open patients were more likely to have documented hypotension (SBP ≤90 mm Hg) on admission to the ED (69.1% vs. 47.7%; p = 0.024) than REBOA patients; and the median admission SBP for patients undergoing open AO was lower (median, 0 mm Hg; IQR, 80 vs. 23 mm Hg; IQR, 105; p = 0.017) (Table 1). Similarly, patients undergoing open AO attempts were

TABLE 1. Demographics and Prehospital and Admission Variables for Patients Undergoing AO After Trauma

	Total (n = 114)	Endovascular (n = 46)	Open (n = 68)	*P* Value
Age, mean ± SD, years	40.8 ± 17.9	43.2 ± 19.6	39.2 ± 16.7	0.244
Male sex, n (%)	92/114 (80.7%)	32/46 (69.6%)	60/68 (88.2%)	0.013
Known history of peripheral vascular disease, n (%)	1/114 (0.9%)	1/46 (2.2%)	0/68 (0%)	0.222
Transfer from outside facility, n (%)	10/114 (8.8%)	7/46 (15.2%)	3/68 (4.4%)	0.045
Penetrating mechanism, n (%)	42/114 (36.8%)	11/46 (23.9%)	32/68 (47.1%)	0.013
Gunshot wound, n (%)	33/42 (78.6%)	9/46 (19.6%)	24/68 (35.3%)	
Stab wound, n (%)	9/42 (21.4%)	1/46 (2.2%)	8/68 (11.8%)	
Blunt mechanism, n (%)	71/114 (62.3%)	35/46 (76.1%)	36/68 (53.9%)	0.013
Motor vehicle accident, n (%)	24/71 (33.8%)	9/46 (19.6%)	15/68 (22.1%)	
Motorcycle accident, n (%)	16/71 (22.5%)	10/46 (21.7%)	6/68 (8.8%)	
Auto vs. pedestrian, n (%)	25/71 (35.2%)	6/46 (8.8%)	12/68 (17.6%)	
Fall, n (%)	4/71 (5.6%)	2/46 (4.3%)	2 (29%)	
Injury Severity Score, median/IQR	31.5/26	31.0/30	31.5/22	0.871
Head AIS, mean ± SD	2.7 ± 2.3	2.0/5	1.5/4	0.592
Chest AIS, mean ± SD	3.1 ± 1.7	1.0/4	3.0/4	0.002
Abdomen AIS, mean ± SD	2.7 ± 1.7	2.5/3	2.0/5	0.023
Field SBP, median/IQR	91.0/82	91.0/68	91.5/125	0.472
Field heart rate, median/IQR	88.0/51	73.5/68	99.0/42	0.075
Field Glasgow Coma Score, median/IQR	3.0/11	3.0/12	10.5/11	0.995
Field intubation, n (%)	75/114 (65.8%)	17/46 (37.0%)	8/68 (11.8%)	0.006
Prehospital CPR required, n (%)	48/114 (42.1%)	16/46 (34.7%)	32/68 (47.1%)	0.129
Time from injury to arrival at facility, median/IQR, min	36.5/25	32.5/25	36.0/20	0.247
Admission SBP, median/IQR	86.0/129	23/105	0/80	0.017
Admission SBP <90 mm Hg, n (%)	68/114 (59.6%)	21/46 (45.6%)	47/68 (69.1%)	0.024
Admission heart rate, median/IQR	109.5/101	45.0/102	0/121	0.110
Admission GCS, median/IQR	3.0/10	3.0/9	3.0/4	0.509
Intubated on arrival, n (%)	75/114 (65.8%)	31/46 (67.4%)	44/68 (64.7%)	0.551
Temperature, mean ± SD, °C	35.6 ± 1.3	36.1 ± 1.2	35.3 ± 1.2	0.018
Pupillary response present on arrival, n (%)	44/114 (38.6%)	19/46 (41.3%)	25/68 (36.8%)	0.625
Organized cardiac rhythm present on arrival, n (%)	50/114 (43.9%)	21/46 (45.7%)	29/68 (42.6%)	0.751
Spontaneous movement present on arrival, n (%)	28/114 (24.6%)	13/46 (28.3%)	15/68 (22.1%)	0.450
CPR in progress on arrival, n (%)	51/114 (44.7%)	16/46 (34.8%)	35/68 (51.5%)	0.067
Total duration of CPR required, median/IQR, min	27.5/27	25.5/29	27.0/20	0.568
Admission hemoglobin, mean ± SD	10.5 ± 2.3	10.2 ± 2.1	10.6 ± 2.5	0.406
Admission hematocrit, mean ± SD	30.7 ± 7.2	29.9 ± 6.3	31.1 ± 7.8	0.466
Admission INR, mean ± SD	2.04 ± 1.18	1.72 ± 0.65	2.22 ± 1.38	0.111
Admission pH, mean ± SD	7.09 ± 0.21	7.14 ± 0.21	7.05 ± 0.21	0.081
Admission base deficit [−], mean ± SD	13.8 ± 8.2	13.4 ± 5.6	14.1 ± 9.6	0.760
Admission lactate, mean ± SD	10.0 ± 5.4	8.8 ± 4.2	10.9 ± 6.1	0.101

AIS, Abbreviated Injury Score; ISS, Injury Severity Score; INR, international normalized ratio.

more likely to have active CPR ongoing during initial AO attempt (72.1% vs. 45.7%; $p = 0.008$; Table 2).

Regarding the conduct of AO, the procedure was more likely to have been initiated by a fellow (30.9% vs. 4.3%; $p < 0.001$) or resident (11.8% vs. 0%; $p < 0.001$) when open AO was attempted. In contrast, REBOA was more commonly performed by a trauma/acute care surgery attending physician (87.0% vs. 57.4%; $p < 0.001$) or a vascular surgery attending physician (6.5% vs. 0%; $p < 0.001$) (Table 2). A second AO attempt was more likely to be required following open attempts than REBOA (13.2% vs. 4.3%; $p = 0.012$). There was no difference between open and REBOA modalities with regard to time from either admission or initiation of procedure to successful AO.

After occlusion, REBOA patients were noted to have a higher mean SBP (90.0 ± 52.9 mm Hg vs. 64.6 ± 61.1 mm Hg; $p = 0.029$), but were also less likely to have an uncontrolled bleeding source identified above the level of AO (10.9% vs. 26.5%; $p < 0.001$; Table 2). The only significant difference noted between REBOA and open AO patients with regard to associated procedures was the finding that REBOA patients were more likely to undergo subsequent pelvic external fixator placement (6.5% vs. 0%; $p = 0.033$) than open counterparts.

No significant differences were noted between REBOA and open AO with regard to resuscitation requirements, laboratory values at 24 hours, or organ system complications (Table 3). There was no significant difference between the 2groups with

TABLE 2. Detail of AO and Associated Required Procedures

	Total (n = 114)	Endovascular (n = 46)	Open (n = 68)	*p* Value
Location of initial AO attempt				
Emergency department, n (%)	84/114 (73.7%)	33/46 (71.7%)	51/68 (75.0%)	0.698
Operating room, n (%)	30/114 (26.3%)	13/46 (28.3%)	17/68 (25.0%)	0.698
Active CPR ongoing during initial AO attempt, n (%)	70/114 (61.4%)	21/46 (45.7%)	49/68 (72.1%)	0.008
Aortic occlusion initiation physiology				
Systolic blood pressure, median/IQR, mm Hg	0/60	50.0/77	0/0	<0.001
Heart rate, median/IQR, beats per minute	0/87	85/123	0/40	0.001
Glasgow Coma Score, median/IQR	3/0	3/0	3/0	0.461
Training level of primary aortic occlusion individual known, n (%)				
Surgery resident, n (%)	8/114 (7.0%)	0 (0%)	8/68 (11.8%)	<0.001
Trauma/Acute care surgery fellow, n (%)	23/114 (20.2%)	2/46 (4.3%)	21/68 (30.9%)	<0.001
Trauma/Acute care surgery attending physician, n (%)	79/114 (69.3%)	40/46 (87.0%)	39/68 (57.4%)	<0.001
Vascular surgery attending physician, n (%)	3/114 (2.6%)	3/46 (6.5%)	0/68 (0%)	<0.001
Improvement in hemodynamics with aortic occlusion, n (%)	71/114 (62.3%)	29/46 (67.4%)	42/68 (61.8%)	0.544
Hemodynamic stability (SBP consistently >90 mm Hg) achieved with AO, n (%)	41/114 (36.0%)	22/46 (51.2%)	19/68 (27.9%)	0.014
Aortic occlusion physiologic response				
Postocclusion SBP, mean ± SD, mm Hg	74.4 ± 58.8	90.0 ± 52.9	64.9 ± 61.1	0.029
Postocclusion HR, mean ± SD	70.4 ± 53.7	81.2 ± 54.8	65.0 ± 52.7	0.166
Postocclusion GCS, median/IQR	3.0/0	3.0/0	3.0/0	0.478
Duration of AO, median/IQR, min	25.0/27	20.0/39	25.0/27	0.249
Second AO required, n (%)	11/114 (9.6%)	2/46 (4.3%)	9/68 (13.2%)	0.012
Location of second AO attempt, ED, n (%)	4/11 (36.4%)	2/2 (100%)	2/9 (22.2%)	0.770
Location of second AO attempt, OR, n (%)	7/11 (63.6%)	2/2 (100%))	7/9 (77.8%)	0.770
Type of second attempt, endovascular, n (%)	5/11 (45.5%)	1/2 (50.0%)	4/9 (44.4%)	0.287
Type of second attempt, open, n (%)	6/11 (54.4%)	1/2 (50.0%)	5/9 (55.5%)	0.287
Hemodynamics improved with second AO, n (%)	9/11 (81.8%)	2/2 (100%)	7/9 (77.8%)	0.244
Hemodynamic stability (SBP consistently >90 mm Hg) achieved with second AO, n (%)	8/11 (72.7%)	2/2 (100%)	6/9 (66.7%)	0.217
Time from admission to start of initial AO procedure, median/IQR, min	20.0/41	28.0/34	12.0/65	0.179
Time from admission to successful AO, median/IQR, min	25.0/41	30.5/36	15.0/70	0.091
Time from initiation of AO to successful AO, mean ± SD, min	7.0 ± 12.6	6.6 ± 5.6	7.2 ± 15.1	0.842
Time from admission to hemodynamic stability, median/IQR, min	35.0/40	34.0/37	35/65	0.755
Time of admission to definitive hemorrhage control , median/IQR, min	63.0/73	61.5/65	80.0/85	0.878
Uncontrolled bleeding source above AO ultimately identified, n (%)	23/114 (20.2%)	5/46 (10.9%)	18/68 (26.5%)	<0.001
Source of predominant hemorrhage, arterial source, n (%)	19/114 (16.7%)	6/46 (13.0%)	13/68 (19.1%)	<0.001
Source of predominant hemorrhage, venous source, n (%)	15/114 (13.2%)	4/46 (8.7%)	11/68 (16.2%)	<0.001
Source of predominant hemorrhage, unclear/mixed, n (%)	48/114 (42.1%)	11/46 (23.9%)	37/68 (77.1%)	<0.001
Adjunctive procedures required				
Pelvic binder, n (%)	8/114 (7.0%)	4/46 (8.7%)	4/68 (5.9%)	0.564
Exploratory laparotomy, n (%)	65/114 (57.0%)	25/46 (54.3%)	40/68 (58.8%)	0.636
Hepatic packing, n (%)	22/114 (19.3%)	6/46 (13.0%)	16/68 (23.5%)	0.164
Pelvic packing, n (%)	13/114 (11.4%)	3/46 (6.5%)	10/68 (14.7%)	0.177
Hepatic resection, n (%)	1/114 (0.9%)	1/46 (2.2%)	0/68 (0%)	0.222
Splenectomy, n (%)	11/114 (9.6%)	4/46 (8.7%)	7/68 (10.3%)	0.777
Bowel resection, n (%)	12/114 (10.5%)	4/46 (8.7%)	8/68 (11.8%)	0.600
Craniectomy/Craniotomy, n (%)	1/114 (0.9%)	1/46 (2.2%)	0/68 (0.0%)	0.222
Pelvic external fixation, n (%)	3/114 (2.6%)	3/46 (6.5%)	0/68 (0%)	0.033
Embolization of liver, n (%)	3/114 (2.6%)	1/46 (2.2%)	2/68 (2.9%)	0.802
Embolization of spleen, n (%)	0/114 (0%)	0/46 (0%)	0/68 (0.0%)	N/A
Embolization of pelvis, n (%)	3/114 (2.6%)	2/46 (4.3%)	1/68 (1.5%)	0.346
Thoracotomy, n (%)	9/114 (7.9%)	4/46 (8.7%)	5/68 (7.4%)	0.794
Lung resection, n (%)	4/114 (3.5%)	0/46 (0%)	4/68 (5.9%)	0.094

TABLE 2. *(Continued)*

	Total (n = 114)	Endovascular (n = 46)	Open (n = 68)	*p* Value
Cardiac repair, n (%)	5/114 (4.4%)	1/46 (2.2%)	4/68 (5.9%)	0.343
Cardiac repair, left ventricle, n (%)	0/114 (0%)	0/46 (0%)	0/68 (0.0%)	N/A
Cardiac repair, left atrium, n (%)	0/114 (0%)	0/46 (0%)	0/68 (0.0%)	N/A
Cardiac repair, right ventricle, n (%)	1/114 (0.9%)	0/46 (0%)	1/68 (1.5%)	0.409
Cardiac repair, right atrium, n (%)	4/114 (3.5%)	0/46 (0%)	4/68 (5.9%)	0.094

HR, heart rate; min, minutes.

regard to mortality overall (REBOA, 71.7% vs. open, 83.8%; $p = 0.120$) or in survival after AO initiation in the ED [overall, 9.5% (8 of 84); REBOA, 15.2% (5 of 28); open, 5.9% (3 of 49); $p = 0.16$]. There was also no statistically significant difference in adjusted mortality between patients who underwent REBOA versus open AO (OR, 0.263; 95% CI, 0.043–1.609;

TABLE 3. Resuscitation Requirements, General Complications, and Outcomes for AO Patients

	Total (n = 114)	Endovascular (n = 46)	Open (n = 68)	*p* Value
Resuscitation requirements, first 24 hours				
Units packed red blood cells, median/IQR	15.0/18	20.5/18	13.5/18	0.654
Units fresh frozen plasma, median/IQR	10.0/16	14.5/18	6.0/18	0.343
Units platelets, median/IQR	2.0/12	5.5/12	1.5/11	0.872
Units cryoprecipitate, median/IQR	3.5/5	1.0/11	0.0/1	0.149
Total crystalloids, median/IQR, L	3.5/12	4.0/5	3.0/5	0.697
Vasopressors required, n (%)	87/114 (76.3%)	33/46 (71.7%)	54/68 (79.4%)	0.132
Factor VIIa, n (%)	6/114 (5.3%)	2/46 (4.3%)	4/68 (5.9%)	0.840
Tranexamic acid, n (%)	28/114 (24.6%)	14/46 (30.4%)	14/68 (20.6%)	0.038
Laboratory values, first 24 hours				
Lowest hemoglobin, median/IQR	8.2/3.0	8.8/2.9	8.0/3.0	0.410
Highest INR, median/IQR	1.65/0.82	1.70/0.7	1.60/1.0	0.150
Lowest base deficit (−), median/IQR	17/10	15.0/9.0	18.0/11	0.081
Lowest pH, median/IQR	7.05/0.21	7.06/0.24	7.04/0.22	0.400
Highest lactate, median/IQR, mg/dL	12.3/7.4	13.1/5.4	10.8/8.3	0.108
Acute kidney injury with dialysis required, n (%)	4/114 (3.5%)	2/46 (4.3%)	2/68 (2.9%)	0.660
Acute lung injury or adult respiratory distress syndrome, n (%)	3/114 (2.6%)	0/46 (0%)	3/68 (4.4%)	0.149
Bacteremia, n (%)	3/114 (2.6%)	1/46 (2.2%)	2/68 (2.9%)	0.802
Pneumonia, n (%)	7/114 (6.1%)	2/46 (4.3%)	5/68 (7.4%)	0.512
Sepsis or septic shock, n (%)	7/114 (6.1%)	2/46 (4.3%)	5/68 (7.4%)	0.512
Stroke/Cerebrovascular accident, n (%)	0/114 (0%)	0/46 (0%)	0/68 (0.0%)	N/A
Paraplegia, n (%)	0/114 (0%)	0/46 (0%)	0/68 (0.0%)	N/A
Myocardial infarction, n (%)	2/114 (1.8%)	0/46 (0%)	2/68 (2.9%)	0.241
Multiorgan dysfunction, n (%)	7/114 (6.1%)	2/46 (4.3%)	5/68 (7.4%)	0.512
Neurodeficit secondary to spinal cord ischemia, n (%)	0/114 (0%)	0/46 (0%)	0/68 (0.0%)	N/A
Ventilator days, median/IQR	1.0/1	1.0/1	1.0/0	0.499
Intensive care unit length of stay, median/IQR	0/1	1.0/1	0/1	0.855
Hospital length of stay, median/IQR, days	1.0/5	1.0/1	1.0/1	0.083
In hospital mortality, n (%)	90/114 (78.9%)	33/46 (71.7%)	57/68 (83.8%)	0.120
Mortality, hours after admission, median/IQR	1.0/1.0	2.0/3.0	1.0/1.0	0.481
Mortality hospital day, median/IQR	1.0/0	1.0/2	1.0/0	0.757
Mortality location, ED, n (%)	57/114 (50.0%)	25/46 (54.3%)	31/68 (45.6%)	0.043
Mortality location, OR, n (%)	23/114 (20.2%)	12/46 (26.1%)	11/68 (16.2%)	0.043
Mortality location, intensive care unit, n (%)	34/114 (29.8%)	9/46 (19.6%)	25/68 (36.8%)	0.043
Discharge GCS among survivors, median/IQR	15.0/0	15.0/0	15.0/0	0.766
Discharge Glasgow Coma Outcome Score among survivors, median/IQR	4.0/2	4.0/1	4.5/1	0.196
Discharge to home, n (%)	12/114 (10.5%)	4/46 (8.7%)	8/68 (11.8%)	0.015
Discharge to rehab, nursing facility, n (%)	11/114 (9.6%)	9/46 (19.6%)	2/68 (2.9%)	0.015

Rehab, rehabilitation.

TABLE 4. Type of Initial AO Attempted

Endovascular/REBOA, n (%)	46/114 (40.4%)
Open, n (%)	68/114 (59.6%)
Anterolateral thoracotomy	43/114 (37.7%)
Clamshell thoracotomy	18/114 (15.8%)
Laparotomy	7/114 (6.1%)

p = 0.148). The location of mortality did differ, however, with post-REBOA deaths more commonly occurring in the ED or OR (54.3% and 26.1% vs. 45.6% and 16.2%, respectively; p = 0.043). In contrast, a significantly larger portion of post-open AO mortalities occurred in the intensive care unit (36.8% vs. 19.6%, p = 0.043). There was no difference in neurologic outcomes (discharge GCS or GOS) between REBOA and open AO techniques among survivors (Table 3).

Approach-specific complications were unique to the type of AO used (Table 5). One REBOA patient developed an arterial pseudoaneurysm at the access site [2.2% (1/46)], and two patients experienced distal embolic events [4.3% (2/46)]. No infection or need for amputation was reported for any REBOA patients. Among the open AO patients, one [1.4% (1/68)] developed a retained hemothorax requiring operative evacuation and two [2.9% (2/68)] developed local wound infections requiring additional surgical intervention.

Additional details specific to the conduct of REBOA were also captured (Table 6), including the type of femoral access, which was conducted through open cut-down in 50% of cases. Imaging used to facilitate positioning of the wire and balloon in the aorta for conduct of REBOA included plain film (52.2%) and C-arm fluoroscopy (13.0%). In 26.1% of patients, initial REBOA placement was conducted without any imaging, using only external landmarks to facilitate balloon positioning. Most REBOA balloon deployments were undertaken in Zone 1 (descending aorta extending from the origin of the left subclavian to the celiac artery; 78.6%), with 19.0% deployed in Zone 3 (abdominal aorta from the lowest renal artery to the aortic bifurcation) and one Zone 2 (abdominal aorta from the celiac artery to the lowest renal artery) deployment recorded. Balloon migration after deployment was observed in two patients.

TABLE 5. Approach-Specific Complications of AO

Complication	Values
Endovascular specific complications (n = 46)	
Hematoma, n (%)	0/46 (0%)
Pseudoaneurysm, n (%)	1/46 (2.2%)
Arteriovenous fistula, n (%)	0/46 (0%)
Extremity ischemia, n (%)	0/46 (0%)
Stenosis, n (%)	0/46 (0%)
Distal embolism, n (%)	2/46 (4.3%)
Infection requiring antibiotics only, n (%)	0/46 (0%)
Need for patch angioplasty, n (%)	0/46 (0%)
Need for arterial bypass, n (%)	0/46 (0%)
Need for amputation, n (%)	0/46 (0%)
Open access complications (n = 68)	
Retained hemothorax requiring operative evacuation via VATS or thoracotomy, n (%)	1/68 (1.4%)
Empyema, n (%)	0/68 (0%)
Local wound infection requiring surgery, n (%)	2/68 (2.9%)

DISCUSSION

Our present report describes the findings from the first contemporary multicenter prospective registry of AO for trauma and acute care surgery. The described modern experience demonstrates that the mortality among patients requiring AO after injury remains high, but that survivors demonstrate an appreciable rate of good neurologic outcome. Our 21.1% survival rate is an improvement upon the historical standard established by the landmark publication of Rhee et al.[6] These investigators noted a 7.4% overall survival among a heterogeneous series of retrospective reports from trauma patients subjected to ED thoracotomy over a 25-year period ending in 2000. A more recent updated review of the literature conducted by Seamon et al.[7] of the Eastern Association for the Surgery of Trauma revealed that among 72 studies including 10,238 patients, overall survival after ED thoracotomy was 8.5%. Both of these works, while extensive

TABLE 6. Details of REBOA Technique Captured

Detail	(N = 46)
Endovascular elements of access	
Access site, femoral, n (%)	46/46 (100%)
Access side, left, n (%)	15/46 (32.6%)
Access side, right, n %)	31/46 (67.4%)
Cut-down used, n (%)	23/46 (50%)
Ultrasound-guided percutaneous, n (%)	5/46 (10.9%)
Percutaneous using external landmarks and palpation, n (%)	13/46 (28.3%)
Fluoroscopy guided, n (%)	1/46 (2.2%)
Initial catheter size, 4 Fr, n (%)	5/46 (10.9%)
Initial catheter size, 5 Fr, n (%)	13/46 (28.3%)
Initial catheter size, 8 Fr, n (%)	5/46 (10.9%)
Initial catheter size, 10 Fr, n (%)	1/46 (2.2%)
Initial catheter size, 12 Fr, n (%)	2/46 (4.4%)
Initial catheter size, 14 Fr, n (%)	1/46 (2.2%)
Initial catheter size, 18 Fr, n (%)	4/46 (8.7%)
Initial catheter upsized, n (%)	36/46 (78.2%)
Upsized final catheter, 10 Fr, n (%)	1/46 (2.2%)
Upsized final catheter, 11 Fr, n (%)	1/46 (2.2%)
Upsized final catheter, 12 Fr, n (%)	24/46 (52.2%)
Upsized final catheter, 14 Fr, n (%)	10/46 (21.7%)
Imaging used to facilitate positioning of balloon for AO	
Plain film, n (%)	24/46 (52.2%)
C-arm fluoroscopy, n (%)	6/46 (13.0%)
None, blind insertion using external landmarks only, n (%)	12/46 (26.1%)
Successful AO achieved, n (%)	42/46 (91.3%)
Zone of deployment	
Zone 1, n (%)	33/42 (78.6%)
Zone 2, n (%)	1/42 (2.4%)
Zone 3, n (%)	8/42 (19.0%)
Balloon migration observed, n (%)	2/46 (4.4%)
Conversion to open AO required, n (%)	4/46 (8.7%)

in their review of the literature, included historical series and reports dating back decades. Our present series reflects contemporary practice at eight ACS Level I trauma centers. The higher survival demonstrated in our series is likely the result of expanded understanding regarding appropriate selection for AO after trauma. It is important to note, however, that there remain an appreciable number of patients in our present series who underwent AO after blunt mechanisms, prolonged CPR, and in the absence of many of the signs of life (pupillary response, organized cardiac rhythm, and spontaneous movement) shown to be ideal for optimal outcome following open resuscitative thoracotomy.[6,7] With continued maturation of the AORTA registry, we hope to be able to use contemporary practice analysis to provide greater insight into the correlation between selection for AO and optimized outcomes.

Our present report of AO after injury is also among the first to include patients with both open and endovascular AO interventions. Over the past several years, REBOA has increasingly been discussed as a potential adjunct to trauma resuscitation.[12–18] Brenner et al.[18] published the first clinical series of the use of REBOA following trauma in 2013, demonstrating successful use following both blunt and penetrating mechanisms of injury. A subsequent series published by Saito et al.[19] reported on REBOA use in 24 blunt injury patients treated at a single center. This report demonstrated that AO could effectively increase mean SBP in patients with hemoperitoneum and pelvic ring fracture, but the authors also highlighted that 12.5% (3 of 14) of patients in their series required amputations owing to ischemic limb complications after access. Among these three, two amputations were directly associated with severe extremity or pelvic injury, and one was the result of an iatrogenic vascular injury complication occurring following multiple percutaneous access attempts in an obese patient. In our present larger series, we noted one pseudoaneurysm at the REBOA access site and two distal embolizations, but no patients experienced extremity ischemia or required either arterial bypass or amputation.

In addition to the potential for limb complications following femoral access, concerns regarding REBOA have also included the time required for vascular access and balloon positioning versus open AO. In our present series, five of eight ACS-verified centers used REBOA following trauma. The mean time from initiation of procedure to successfully achieved AO did not vary between the endovascular and open techniques (6.6 vs. 7.2 minutes; $p = 0.842$). It should be noted, however, that most REBOA procedures were conducted by either a trauma/acute care surgery attending physician (87.0%) or a vascular surgery attending physician (6.5%) (Table 2). By way of comparison, fellows in training and surgical residents were the primary providers conducting AO in a combined 42.7% of open procedures. This difference in training level of the primary operator may also, in part, explain why the need for a second AO attempt was significantly higher among open approaches than REBOA (13.2% vs. 4.3%).

It should also be recognized that REBOA does represent a unique skill set that may not be commonly acquired in traditional general surgery training or even trauma/acute care surgical fellowship. The emergence of unique training platforms to provide this skill set has emerged[20,21] in the past several years. While the specific number of providers contributing to our present data who have taken these courses is not precisely certain, it is known that several of them have taken either the Endovascular Skills for Trauma and Resuscitative Surgery course or the Basic Endovascular Skills for Trauma course, or are instructors themselves.

Our present data also suggest that contemporary REBOA use as a whole may vary from open AO use in specific ways. We noted that open techniques were significantly more likely to be used following penetrating mechanisms (47.1% vs. 23.9%; $p = 0.013$; Table 1). Open AO patients were also more likely to present as hypotensive on admission (69.1% vs. 47.7%; $p = 0.24$) and had significantly lower median blood pressures on arrival (Table 1). These findings may represent a practice emphasizing a lower physiologic threshold for initiation of REBOA among centers that actively use the modality. As opposed to the last ditch nature of AO via ED thoracotomy, REBOA offers a less dramatic and less invasive alternative for AO. Among select patients with evidence of ongoing noncompressible hemorrhage and hypotension, but not frank hemodynamic collapse, REBOA via femoral access may be better tolerated than an abruptly created thoracic incision requiring either sedation (and potential further hemodynamic compromise) or an obtunded patient. Resuscitative endovascular balloon occlusion of the aorta may also offer a better option at a graded response to significant noncompressible hemorrhage. The placement of a wire and sheath does not obligate one to deploy a balloon and, even when balloon occlusion is required, the balloon inflation and deflation has the potential to be better titrated than the all-or-none application of an aortic clamp used during open AO. In addition, REBOA affords the access to AO without the expense of the additional poorly controlled bleeding source and loss of domain associated with an emergent thoracic incision and an open chest.

These potential benefits are, however, challenging to examine with present data. The optimal indications for AO use, either endovascular or open, continue to require better elucidation. Open AO has traditionally been used for patients either without signs of life or very near death. Life-threatening hemorrhage can present a spectrum of patient physiology across which one technique may prove more ideal, with a shared range within that spectrum in which emerging endovascular AO approaches may ultimately be found to be superior to traditional open approaches. At present, however, the delineation between a patient best suited to open or endovascular AO requires additional study. With maturation, it is our hope that the AAST AORTA registry will contribute to that understanding.

This report has important limitations. The data collected reflect that from individual ACS Level I trauma centers with their own unique capabilities and practice patterns. It is important to note as well that with regard to REBOA use, only five of the eight contributing centers used this modality. Extrapolation to other care environments should be exercised with caution. Additionally, while we used mortality as our primary outcome end point in the present report, functional outcome among survivors is also an important element of successful AO use after trauma. The presented preliminary data do, however, demonstrate that there is no significant difference in discharge GCS or GOS between REBOA or open AO patients (Table 3). Additional data and database maturity are required to better examine this specific end point following AO. Finally, it must be recognized that this preliminary population from the AORTA registry represents a heterogeneous population, as it pertains to the application of AO techniques. There are also likely additional factors not captured in registry data, including physician perspective/preference and institutional policies among early REBOA adopters that may influence AO conduct and outcomes for patients in the AORTA registry. There remains a significant need for further accumulation of data on AO patients and their outcomes. Only through the accumulation of this additional data will better matched cohorts of open and endovascular AO be available for comparison.

Our experience suggests that AO use in the setting of trauma/acute care surgery continues to evolve. Resuscitative endovascular balloon occlusion of the aorta capabilities seem to have been successfully integrated into care at several leading trauma centers. While data suggest there may be selection preferences for REBOA use in this early experience, REBOA outcomes seem comparable to AO conducted by open techniques. Further study is needed to define the optimal use of AO and, specifically, the optimal role and conduct of REBOA in the early phases after injury.

CONCLUSION

Aortic occlusion for resuscitation after trauma remains a dramatic but crucial tool in the care of profoundly hypotensive patients after injury. Contemporary survival rates seem to have improved compared to historical controls, and good neurologic outcomes among survivors can be achieved. Resuscitative endovascular balloon occlusion of the aorta has emerged as a viable alternative to open AO in centers that have developed this capability, with similar outcomes to open AO techniques based on limited early data. Ongoing maturation of the AAST AORTA database is required to determine the impact of REBOA use.

AUTHORSHIP

This work represents the original efforts of the investigators. All listed authors contributed to study design, data collection, data interpretation, and manuscript development.

DISCLOSURE

The authors declare no conflicts of interest.

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DISCUSSION

Dr. Timothy Fabian (Memphis, Tennessee): At last year's meeting in discussion of a multi-center experience of REBOA from Japan, Matt Wall stated: "In the lifecycle of new techniques it is important to follow initial enthusiasm with careful introspection to identify advantages as well as pitfalls and complications of new techniques." In the past year, there have been a couple of papers that have added further pause and called for more reflection.

I congratulate Dr. DuBose and coauthors for contributing new data from the AAST multi-center study from the Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery

Registry for consideration. I will make a few comments and ask a couple of questions to Dr. DuBose.

The overall survival was 21%, not bad for this group of very severely-injured patients. In order to better define selection process and outcomes for aortic occlusion have you compared and stratified survivors versus non-survivors, regardless of occlusion technique, a simple registry analysis?

This was an observational study, so it is not terribly surprising that the occlusion cohorts were not well matched, but I would like to reflect on some important differences that may help in our evaluation of where we are with REBOA at this point in time.

The open group had a higher percentage of penetrating wounds and they appear more physiologically compromised on admission. They were significantly more hypotensive and more hypothermic. While not reaching statistical significance, they also had lower pH and higher lactate and INR values.

Those data would suggest they were positioned for inferior outcomes yet there was no difference in mortality or organ dysfunction rates.

Furthermore, a significantly higher percentage of the open group had control performed by a resident or a fellow while the REBOA group was performed almost entirely by attending physicians.

Those considerations certainly make it difficult to assess REBOA as a superior approach. In fact, one must question whether REBOA was inferior to open control in this study. Could you comment, please?

I will confess to being an enthusiastic early proponent of this endovascular approach. I have had a fairly strong bias that it would prove to be a superior approach to proximal aortic control, even in the face of skepticism from some of my own colleagues. However, at this point it is probably fair to ask, “Where is the beef?”

I realize REBOA remains at a relatively early stage of development and this was not a large study or a randomized, controlled trial—although there will never be one—so we definitely need to keep going. Perhaps increasing experience and advancing technology will move the ball forward. What is your perspective on the future?

I look for the AAST aortic study group to continue pushing the horizon and anticipate they will provide important future direction for improving outcomes with severe, non-compressible hemorrhage.

I thank the Association for the privilege of the floor.

Dr. David Blake (Norfolk, Virginia): That was an outstanding presentation. I would like to ask is two questions.

First of all, do you have any data based on stratification of the type of injury, that is major arterial in isolation versus a combined injury or an isolated venous injury that gets discovered upon subsequent laparotomy?

Secondly, do you have any data for the subgroup of pelvic injury patients that this particular procedure might show some benefit or not?

Thank you very much.

Dr. Juan Asensio (Omaha, Nebraska): I rise to congratulate Dr. Brenner, for the well-organized REBOA course that she directs. I have some comments to make about this old/new technique.

A long time ago Owen Wangensteen said: “The stages of a new idea are multiple. Many are stillborn. But every new suggestion deserves at least a trial of being blown upon in the hope that there may be sparks in the ashes."

Bob Buckman and used the aortic percluder way back when at Temple University, and it went away, we simply did not find it useful for the large volume of penetrating injuries that we dealt with. I think REBOA as a technique is a good addition to the trauma surgeon’s armamentarium and thus must be studied. That’s just the editorial comment. I do strongly believe that eventually we will find its niche.

My questions are: of the patients that you included in your series, how many of these patients were admitted with penetrating injuries, for instance, a thoraco-abdominal injury, how many of these patients had cardiac injuries? How many of these patients had abdominal/vascular injuries?

I think the technique and indications need to be developed and refined and I congratulate you on your thorough study.

Dr. Ernest E. Moore (Denver, Colorado): This is clearly an opportunity for the AAST to define the role of REBOA in postinjury resuscitation.

As you know, there have been concerns. Recently a report from Japan suggested increased mortality when the balloon is inflated for suprarenal injuries.

There is no question that REBOA is ideal for pelvic fracture and bleeding, once the skill has been acquired. But the debate for hemorrhage control in upper abdomen and chest remains vigorous.

Unfortunately, the numbers in each subgroup in the current registry do not permit a multivariate analysis at this point. I don’t believe REBOA will replace resuscitation thoracotomy for injuries in Zone I where relief of pericardial tamponade, hilar clamping to prevent air embolism, or immediate mechanical control of bleeding are life-saving. However, the use of REBOA for injuries in Zone II may require a randomized trial to clarify its role.

Dr. Joseph J. DuBose (Davis, California): Wonderful questions. Thank you from the audience. Dr. Fabian, thank you for your kind review. Your point about stratification of survival of the overall population is well taken.

This is 114 patients and it proved a surprisingly heterogeneous group. Despite attempts to weed through the data significantly and adjust for differences, that fact cannot be ignored in the interpretation of our data.

In our utilization of multivariate logistic regression , overall CPR utilization proved to be one of the most important independent predictors; but it is hard to comment on the significance of this definitively when the total CPR time was only definitively known in 64 patients.

With regard to your second and third questions, the open group clearly had more going against them in our present study population. We attempted to adjust for that, but this fact cannot be ignored. It is important to note, however, that there is a trend towards improved survival with REBOA after adjustment. While this is not significant at present, as the database matures we will continue to follow this closely.

Your point about “where is the beef?” is forefront in everybody’s mind involved with this study and I think I have to say that – at this point - the beef is still on the hoof and needs to graze some more.

It is our hope that this dataset will continue to mature, providing for a better opportunity to examine the contemporary use of aortic occlusion for trauma. I am hoping that people in this audience will look in their hearts and at their schedules and say I can contribute patients to this study to improve the understanding so that we can really get to that prime cut of beef that everybody is salivating for, especially as new technology comes online and techniques change.

Dr. Blake, to your point, I think all of our commenters commented on the heterogeneity of this population and really want to look at stratification. I think as this database matures we will be able to do that, to differentiate out between Zone 2 and Zone 3 deployments and look at other specific patient subsets.

And, really, this is the foundation for the kinds of data that will help guide, we hope, the prospective randomized, controlled studies that Dr. Moore suggested. Thank you.