Original Article

Vol. 8, No. 2; 2024; pp 49–57
DOI: https://doi.org/10.26676/jevtm.25486

The Fog has not Lifted: No Reduction in Complications for Partial REBOA in the AAST AORTA Registry

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Background: Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is a potentially lifesaving but polarizing therapy due to the associated morbidity and uncertainty of who might benefit. Techniques such as partial (p)REBOA that provide hemodynamic support while reducing distal ischemia are now captured in the Aortic Resuscitation in Trauma and Acute Care (AORTA) registry. We hypothesized that pREBOA would be associated with improved mortality and fewer adverse outcomes.

Methods: The AORTA registry was queried for adult patients who received complete (c)REBOA or pREBOA between 2020 and 2022. Patients were excluded if they had a head Abbreviated Injury Scale (AIS) ≥three or an AIS of six in any body region. Outcome measures were complications and mortality. Poisson regression analyses identified the independent effect of the type of approach on outcomes.

Results: 164 patients met the inclusion criteria, with pREBOA used in 36% of cases and no significant difference in patient demographics, injury characteristics, or injury severity between pREBOA and cREBOA. There was no difference in mortality rate (44.1% vs 45.7%). After adjusting for potential confounders, no statistically significant difference in complications was detected between the two approaches [adjusted IRR (95% CI): 1.11 (0.54–2.27), $p = 0.777$]. This association persisted after subgroup analysis of aortic Zone one vs Zone three deployment.

Conclusions: In this registry analysis, pREBOA did not reduce morbidity or mortality compared to cREBOA. Improving the granularity of clinical metrics in the AORTA registry is essential to understanding whether patients will benefit from pREBOA, and how to best implement this controversial resuscitation adjunct.

Keywords: *Resuscitative Endovascular Balloon Occlusion of the AORTA (REBOA); Partial REBOA (pREBOA); Complete REBOA (cREBOA); Hemorrhagic Shock; Resuscitation Adjunct*

Received: 17 June 2024; Accepted: 21 August 2024

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Presentation: This abstract was presented in the poster session at the American Association for the Surgery of Trauma Annual Meeting 2023 in Anaheim, CA.

INTRODUCTION

Severe hemorrhage remains a leading cause of preventable mortality in trauma patients. Approximately 40% of trauma-related deaths are due to hemorrhage or its related consequences [1,2]. Non-compressible truncal hemorrhage (NCTH) represents a unique clinical challenge as it is a condition characterized by severe bleeding from within the trunk of the body that is unable to be managed through traditional compression methods. NCTH has mortality rates as high as 85% in military settings and approaching 50% in civilian patients [3,4].

Multiple studies have shown that complete aortic occlusion with devices such as REBOA is a viable resuscitative adjunct for NCTH as it mitigates hemorrhage and enhances cerebral blood flow, thus acting as an interim measure before achieving definitive hemorrhage control [5–8]. While REBOA is effective in controlling bleeding, it induces ischemia downstream from the site of occlusion resulting in severe ischemia reperfusion injury and/or irreversible organ damage. To lessen the ischemic effects induced by full aortic occlusion, techniques such as partial REBOA have evolved, allowing for partial or variable occlusion of the aorta. Partial REBOA has the potential to maintain perfusion above the level of occlusion while simultaneously establishing a permissive state of regional hypoperfusion to areas of uncontrolled hemorrhage [9–11]. As such, these devices are hypothesized to have a more favorable complication profile but the clinical data has not yet answered this question. Intermittent REBOA (iREBOA) is an additional technique that involves periods of full occlusion and periods of deflation, while partial REBOA aims to maintain hemodynamics with reduced distal flow to help mitigate the supraphysiologic pressures created during times of full occlusion [6,12]. Ultimately, there are still many uncertainties about how to utilize these techniques, including the optimal timing, patient population, and titration strategy for achieving better overall outcomes.

In an effort to understand the relative benefits of alternative methods of balloon management for patients receiving REBOA, we compared the morbidity and mortality of partial REBOA and complete REBOA using the American Association for the Surgery of Trauma (AAST) AORTA Registry. We hypothesized that partial REBOA would be associated with better outcomes than complete REBOA.

METHODS

The study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines and the Declaration of Helsinki [13]. All collected data was retrieved from the Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry from 2020 to 2022. The AORTA Registry is a multi-institutional initiative designed to collect prospective data on adult patients (aged 18 or older) who undergo resuscitative aortic occlusion using both open and endovascular techniques during the acute phases of injury. This data is sourced from hospitals across the United States that are verified by the American College of Surgeons as Level I or Level II trauma centers. Designated registrars at each participating center are responsible for entering the data into the online portal developed by the AAST. This data includes patient demographics, clinical characteristics, intervention characteristics, and outcomes. All adult patients (18 years or older) registered in the database who received a complete or partial REBOA to aid in the management of a traumatic injury were considered for inclusion. Patients were excluded if they suffered a non-traumatic hemorrhage, underwent intermittent REBOA, had a head Abbreviated Injury Scale (AIS) ≥3, as the majority of these patients have a dismal prognosis or complications not related to REBOA, or an AIS of 6 in any region of the body, since these injuries are generally not considered survivable.

The primary outcome of interest was any complication (myocardial infarction, stroke, paraplegia, acute kidney injury requiring dialysis, acute lung injury/acute respiratory distress syndrome, distal embolism, need for amputation, bacteremia, pneumonia, sepsis, and multiorgan dysfunction). Secondary outcome measures included in-hospital mortality, discharge Glasgow Coma Scale (GCS), Glasgow Outcome Scale Extended (GOSE), intensive care unit (ICU) as well as hospital length of stay, and time to death. For the adjusted analyses, discharge GCS was dichotomized as ≤8 and >8 while discharge GOSE was dichotomized as ≤4 and >4. Distal pressure targets and balloon titration strategy were not included in the analysis as this data is not reported in the AAST AORTA Registry.

Statistical Analysis

Patients were divided into two groups based on the type of aortic occlusion: complete or partial. Continuous variables were summarized as medians and interquartile ranges. Categorical variables were presented as counts and percentages. The statistical significance of baseline differences between the cohorts was determined using the Mann–Whitney *U*-test or Fisher's exact test. In order to adjust for potential confounding, Poisson regression models with robust standard errors were employed to calculate the association between the type of aortic occlusion and the binary outcomes (complications, in-hospital mortality, discharge GCS, and discharge GOSE). For the continuous outcomes (ICU length of stay, hospital length of stay, and time to death) quantile regression models

were used instead. All analyses were adjusted for age, sex, type of injury, REBOA location, AIS in all regions, primary source of major hemorrhage, and Cardiopulmonary Resuscitation (CPR) being in progress on arrival. Results are presented as an adjusted incidence rate ratio (IRR) and corresponding 95% confidence interval (CI) for the Poisson regression models. The results of the quantile regression models are instead presented as the change in median length of stay and change in median time to death, along with corresponding 95% CIs.

A two-tailed *p*-value of less than 0.05 was considered statistically significant in all analyses. Missing data was managed using multiple imputation by chained equations. Analyses were performed using the statistical programming language R (R Foundation for Statistical Computing, Vienna, Austria) with the aid of the tidyverse, mice, quantreg, and sandwich packages (R Foundation for Statistical Computing, Vienna, Austria).

Ethical Approval and Informed Consent

Ethical approval was not required. Informed consent was not required.

RESULTS

After applying the inclusion and exclusion criteria, 164 patients were deemed suitable for further analysis (Figure 1). In total, 64% (*N* = 105) were managed using a complete aortic occlusion, while 36% (*N* = 59) were subjected to a partial aortic occlusion. Patients managed using a complete occlusion were older (40 vs 33 years, $p = 0.017$), had a higher presenting GCS (14 [8–15] vs 12 [3–14], $p = 0.025$), and were more likely to be hemorrhaging from the pelvis (18.1% vs 16.9%, $p = 0.030$) as well as less likely to be hemorrhaging from the head or neck (0% vs 8.5%, $p = 0.030$). Those who underwent complete occlusion were also less likely to be undergoing CPR on admission (6.7% vs 18.6%, $p = 0.035$) as well as more likely to be admitted to a level I trauma center (99% vs 91.5%, $p = 0.023$). There were no statistically significant differences in sex, injury severity, or admission vitals (Table 1).

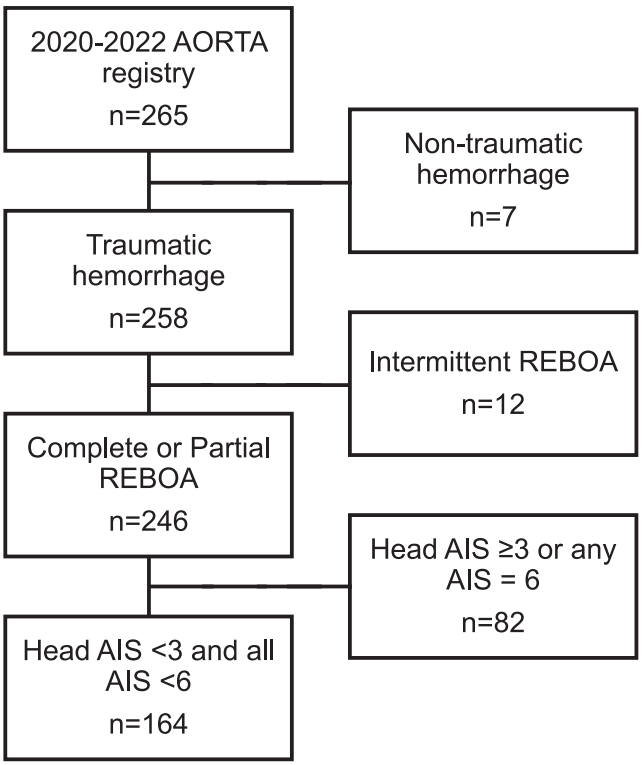

Figure 1 Inclusion and exclusion criteria flowchart.

For patients with Zone 3 placement, a greater percentage of them had complete REBOA (39% vs 18.6%, $p = 0.007$). Additionally, more patients who were treated with complete REBOA later received a pelvic external fixator (14.3% vs 3.4%, $p = 0.032$). There were no significant differences in technique for arterial access, final catheter sheath diameter, rate of successful arterial access, survival to removal of access sheath, hemodynamic stability, time to hemodynamic stability, or other interventions performed (Table 2).

In the univariate analysis, there were no statistically significant differences in the rate of complications, ICU or hospital length of stay, in-hospital mortality, or time to death (Table 3). There was a statistically significant difference in median discharge GCS (5.0 [3.0–15] vs 15 [6.0–15], $p = 0.011$) but no statistically significant difference in discharge GOSE (Table 3). After adjusting for potential confounding in the Poisson regression analysis, no statistically significant difference in complications was detected when comparing partial to complete REBOA [adjusted IRR (95% CI): 1.11 (0.54–2.27), $p = 0.777$]. This was also the case for all secondary outcomes (Table 4).

DISCUSSION

In our registry analysis, we found no statistically significant differences in any complications between patients who received partial REBOA and complete REBOA. This includes complications such as myocardial infarction, stroke, paraplegia, acute kidney injury requiring dialysis, distal embolism, need for amputation, and multi-organ dysfunction. There were also no statistical differences in ICU or hospital length of stay, discharge GCS or GOS, in-hospital mortality, or time to death.

These results were surprising given that several preclinical models have demonstrated that partial REBOA reduces ischemia-reperfusion injury and allows for longer balloon inflation time [14–16]. However, this study is subject to the inherent limitations of a retrospective multicenter registry of time-sensitive, life-saving interventions. One of the main limitations of this study is

Table 1 Demographics and clinical characteristics of REBOA patients.

	Complete Occlusion (N = 105)	*Partial Occlusion (N = 59)*	*p-Value*
Age, median [IQR]	40 [28–54]	33 [26–46]	0.017*
Missing, *n* (%)	1 (1.0)	0 (0.0)	
Sex, *n* (%)			0.544
Female	23 (21.9)	10 (16.9)	
Male	82 (78.1)	49 (83.1)	
Height (cm), median [IQR]	180 [170–180]	180 [170–180]	0.211
Missing, *n* (%)	28 (26.7)	8 (13.6)	
Weight (lbs), median [IQR]	180 [150–220]	180 [150–220]	0.686
Missing, *n* (%)	15 (14.3)	5 (8.5)	
Type of injury, *n* (%)			0.377
Blunt	70 (66.7)	44 (74.6)	
Penetrating	35 (33.3)	15 (25.4)	
Injury Severity Score, median [IQR]	29 [18–36]	26 [17–38]	0.923
Missing, *n* (%)	16 (15.2)	22 (37.3)	
Head AIS, *n* (%)			1.00
0	38 (36.2)	13 (22.0)	
1	4 (3.8)	1 (1.7)	
2	10 (9.5)	4 (6.8)	
Missing	53 (50.5)	41 (69.5)	
Thorax AIS, *n* (%)			0.361
0	20 (19.0)	6 (10.2)	
1	2 (1.9)	0 (0.0)	
2	8 (7.6)	5 (8.5)	
3	24 (22.9)	9 (15.3)	
4	11 (10.5)	8 (13.6)	
5	6 (5.7)	0 (0.0)	
Missing	34 (32.4)	31 (52.5)	
Abdomen AIS, *n* (%)			0.111
0	8 (7.6)	3 (5.1)	
1	2 (1.9)	0 (0.0)	
2	6 (5.7)	9 (15.3)	
3	24 (22.9)	11 (18.6)	
4	23 (21.9)	5 (8.5)	
5	16 (15.2)	8 (13.6)	
Missing	26 (24.8)	23 (39.0)	
Pelvic AIS, *n* (%)			0.414
0	20 (19.0)	5 (8.5)	
2	8 (7.6)	1 (1.7)	
3	7 (6.7)	5 (8.5)	
4	6 (5.7)	4 (6.8)	
5	8 (7.6)	3 (5.1)	
Missing	56 (53.3)	41 (69.5)	
Extremity AIS, *n* (%)			0.373
0	16 (15.2)	5 (8.5)	
1	13 (12.4)	8 (13.6)	
2	10 (9.5)	6 (10.2)	
3	20 (19.0)	8 (13.6)	
4	8 (7.6)	0 (0.0)	
5	7 (6.7)	4 (6.8)	
Missing	31 (29.5)	28 (47.5)	
Primary source of major hemorrhage, *n* (%)			0.030*
Head/neck (above clavicles)	0 (0.0)	5 (8.5)	
Chest (between clavicles and diaphragm)	12 (11.4)	3 (5.1)	
Abdomen	50 (47.6)	28 (47.5)	
Pelvis	19 (18.1)	10 (16.9)	
Extremities	9 (8.6)	5 (8.5)	
Missing	15 (14.3)	8 (13.6)	

(*Continued*)

	Complete Occlusion (N = 105)	*Partial Occlusion (N = 59)*	*p-Value*
First systolic blood pressure, median [IQR]	96 [76–120]	100 [86–130]	0.406
Missing, *n* (%)	25 (23.8)	16 (27.1)	
First heart rate, median [IQR]	110 [85–130]	120 [88–130]	0.773
Missing, *n* (%)	28 (26.7)	12 (20.3)	
First GCS, median [IQR]	14 [8.0–15]	12 [3.0–14]	0.025*
Missing, *n* (%)	32 (30.5)	10 (16.9)	
Prehospital CPR required, *n* (%)	9 (8.6)	10 (16.9)	0.126
Missing	0 (0.0)	1 (1.7)	
Admission systolic blood pressure, median [IQR]	81 [66–110]	90 [70–110]	0.168
Missing, *n* (%)	1 (1.0)	1 (1.7)	
Admission heart rate, median [IQR]	110 [88–130]	110 [81–130]	0.391
Missing, *n* (%)	2 (1.9)	1 (1.7)	
Admission GCS, median [IQR]	13 [3.0–15]	10 [3.0–14]	0.070
CPR in progress on arrival, *n* (%)	7 (6.7)	11 (18.6)	0.035*
Missing	1 (1.0)	0 (0.0)	
Trauma center level, *n* (%)			0.023*
I	104 (99.0)	54 (91.5)	
II	1 (1.0)	5 (8.5)	

The asterisk denotes statistical significance.
REBOA, resuscitative endovascular balloon occlusion of the aorta; IQR, interquartile range; AIS, abbreviated injury scale; GCS, Glasgow Coma Scale; CPR, cardiopulmonary resuscitation.

Table 2 Characteristics of interventions performed on REBOA patients.

	Complete Occlusion (N = 105)	*Partial Occlusion (N = 59)*	*p-Value*
REBOA indication, *n* (%)			0.079
Arrived in arrest/pulseless or arrested during emergency room evaluation	12 (11.4)	15 (25.4)	
Stabilization for transport to CT scan	23 (21.9)	17 (28.8)	
To stabilize the patient for transport to angiography or hybrid room for angiographic intervention	4 (3.8)	4 (6.8)	
To stabilize the patient for transport to the operating room	43 (41.0)	16 (27.1)	
To support bleeding control in planned surgical intervention	1 (1.0)	0 (0.0)	
Intraoperative REBOA placement in operating room for emergent surgery	18 (17.1)	7 (11.9)	
Missing	4 (3.8)	0 (0.0)	
Technique for arterial access, *n* (%)			0.627
Cut-down to facilitate direct visualization and access	8 (7.6)	6 (10.2)	
Fluoroscopic guided	1 (1.0)	0 (0.0)	
Percutaneous using external landmarks and palpation	26 (24.8)	17 (28.8)	
Ultrasound guided	70 (66.7)	32 (54.2)	
Missing	0 (0.0)	4 (6.8)	
REBOA location, *n* (%)			0.007*
Zone 1 (origin of left subclavian artery to the celiac artery)	63 (60.0)	48 (81.4)	
Zone 2 (celiac artery to the lowest renal artery)	1 (1.0)	0 (0.0)	
Zone 3 (lowest renal artery to the aortic bifurcation)	41 (39.0)	11 (18.6)	
Final catheter sheath diameter, *n* (%)			1.00
7 french	98 (93.3)	42 (71.2)	
8 french	2 (1.9)	0 (0.0)	
Missing	5 (4.8)	17 (28.8)	
Successful arterial access, *n* (%)	104 (99.0)	57 (96.6)	1.00
Missing	0 (0.0)	2 (3.4)	
Survival to removal of access sheath, *n* (%)	59 (56.2)	42 (71.2)	0.116
Missing	7 (6.7)	2 (3.4)	
Improved hemodynamics with aortic occlusion, *n* (%)	83 (79.0)	48 (81.4)	0.184
Missing	1 (1.0)	5 (8.5)	

(*Continued*)

Table 2 Characteristics of interventions performed on REBOA patients. (*Continued*)

	Complete Occlusion (N = 105)	*Partial Occlusion (N = 59)*	*p-Value*
Hemodynamic stability with aortic occlusion, *n* (%)	64 (61.0)	36 (61.0)	0.054
Missing	3 (2.9)	14 (23.7)	
Time from admission to hemodynamic stability (minutes), median [IQR]	32 [20–55]	30 [24–48]	0.821
Missing, *n* (%)	40 (38.1)	26 (44.1)	
Time from admission to definitive hemorrhage control (minutes), median [IQR]	74 [49–170]	60 [50–110]	0.222
Missing, *n* (%)	45 (42.9)	26 (44.1)	
Location after aortic occlusion, *n* (%)			0.882
CT scanner	20 (19.0)	14 (23.7)	
Intensive care unit	1 (1.0)	2 (3.4)	
Interventional radiology	3 (2.9)	2 (3.4)	
Operating room	47 (44.8)	27 (45.8)	
Patient did not survive beyond the emergency department	8 (7.6)	5 (8.5)	
Missing	26 (24.8)	9 (15.3)	
Additional interventions, *n* (%)			
Craniectomy or craniotomy	1 (1.0)	0 (0.0)	1.00
Thoracotomy	10 (9.5)	8 (13.6)	0.444
Exploratory laparotomy	67 (63.8)	37 (62.7)	1.00
Hepatic packing	15 (14.3)	12 (20.3)	0.381
Hepatic resection	2 (1.9)	1 (1.7)	1.00
Embolization of liver	3 (2.9)	3 (5.1)	0.668
Splenectomy	16 (15.2)	10 (16.9)	0.825
Bowel resection	23 (21.9)	13 (22.0)	1.00
Pelvic packing	25 (23.8)	9 (15.3)	0.232
Pelvic external fixation	15 (14.3)	2 (3.4)	0.032*

The asterisk denotes statistical significance.
REBOA, resuscitative endovascular balloon occlusion of the aorta; CT, computed tomography; IQR, interquartile range.

Table 3 Crude outcomes in REBOA patients.

	Complete Occlusion (N = 105)	*Partial Occlusion (N = 59)*	*p-Value*
Any complication, *n* (%)	32 (30.5)	13 (22.0)	0.327
Myocardial infarction, *n* (%)	1 (1.0)	1 (1.7)	1.00
Stroke, *n* (%)	0 (0.0)	1 (1.7)	0.360
Paraplegia, *n* (%)	3 (2.9)	0 (0.0)	0.554
Acute kidney injury requiring dialysis	11 (10.5)	7 (11.9)	1.00
Acute lung injury or ARDS	14 (13.3)	5 (8.5)	0.450
Distal embolism, *n* (%)	3 (2.9)	1 (1.7)	1.00
Need for amputation, *n* (%)	2 (1.9)	0 (0.0)	0.537
Bacteremia, *n* (%)	2 (1.9)	3 (5.1)	0.352
Pneumonia, *n* (%)	9 (8.6)	4 (6.8)	0.772
Infection requiring antibiotics only, *n* (%)	2 (1.9)	0 (0.0)	0.537
Infection requiring surgical intervention, *n* (%)	0 (0.0)	1 (1.7)	0.360
Sepsis, *n* (%)	6 (5.7)	2 (3.4)	0.712
Multiorgan dysfunction, *n* (%)	6 (5.7)	4 (6.8)	0.748
ICU length of stay (days), median [IQR]	2.5 [0.00–8.8]	3.0 [1.0–8.0]	0.249
Missing, *n* (%)	3 (2.9)	14 (23.7)	
Hospital length of stay (days), median [IQR]	9.0 [1.0–22]	8.0 [1.0–20]	0.986
Missing, *n* (%)	3 (2.9)	5 (8.5)	
Discharge GCS, median [IQR]	5.0 [3.0–15]	15 [6.0–15]	0.011*
Missing, *n* (%)	25 (23.8)	22 (37.3)	
Discharge GOSE, median [IQR]	1.0 [1.0–5.0]	2.0 [1.0–5.0]	0.430
Missing, *n* (%)	53 (50.5)	42 (71.2)	
In-hospital mortality, *n* (%)	48 (45.7)	26 (44.1)	1.00
Missing	1 (1.0)	4 (6.8)	

(*Continued*)

	Complete Occlusion (N = 105)	*Partial Occlusion (N = 59)*	*p-Value*
Time from admission to death (hours), median [IQR]	2.0 [1.0–4.0]	3.0 [2.0–4.0]	0.337
Mortality location, *n* (%)			0.320
Emergency room	8 (7.6)	6 (10.2)	
Operating room	22 (21.0)	7 (11.9)	
Ward	1 (1.0)	0 (0.0)	
ICU	17 (16.2)	13 (22.0)	
Missing	57 (54.3)	33 (55.9)	

The asterisk denotes statistical significance.
REBOA, resuscitative endovascular balloon occlusion of the aorta; ARDS, Acute Respiratory Distress Syndrome; IQR, interquartile range; ICU, intensive care unit; GCS, Glasgow Coma Scale; GOSE, Glasgow Outcome Scale Extended.

Table 4 Association between type of occlusion (partial vs complete) and adverse outcomes.

Outcome	*IRR (95% CI)*	*p-Value*
Complications	1.11 (0.54–2.27)	0.777
In-hospital mortality	0.86 (0.53–1.39)	0.532
GCS ≤8	0.83 (0.52–1.34)	0.455
GOSE ≤4	0.91 (0.64–1.30)	0.612
	Change in Median (95% CI)	
Hospital length of stay (days)	1.11 (–7.88–10.10)	0.809
ICU length of stay (days)	1.00 (–1.95–3.95)	0.506
Time to death (hours)	0.17 (–1.93–2.27)	0.874

IRRs are calculated using Poisson regression models with robust standard errors. Change in median is calculated using quantile regression models. All analyses are adjusted for age, sex, type of injury, REBOA location, Abbreviated Injury Scale in all regions, primary source of major hemorrhage, and cardiopulmonary resuscitation being in progress on arrival.
REBOA, resuscitative endovascular balloon occlusion of the aorta; IRR, incidence rate ratio; CI, confidence interval; GCS, Glasgow Coma Scale; GOSE, Glasgow Outcome Scale Extended; ICU, Intensive Care Unit.

that important clinical metrics including information on duration and type of partial REBOA were not fully characterized in the AAST AORTA registry. In addition, more than 40% of patient entries were missing time to definitive hemorrhage control data. Taken together, the omission of these key metrics and lack of granularity hinders investigators' ability to fully interpret and draw conclusions from the registry. This missing data is key for understanding clinical efficacy as it is well established that longer periods of occlusion are associated with increased complications [9,16]. The absence of complete and in-depth data poses additional challenges for researchers, as patient data points are missing from various, inconsistent areas, creating a highly heterogeneous database.

Despite several preclinical studies showing improved outcomes with partial REBOA, there is limited clinical data to advocate its use. In an analysis of the Aortic Balloon Occlusion (ABO) trauma registry, Paran et al. found no difference in mortality among patients who underwent partial vs complete occlusion of the aorta [17]. The results of our study support these findings in that there was no significant difference between partial and complete occlusion groups both for complications and mortality. Further clinical evidence is warranted to define the superiority of partial REBOA over complete REBOA.

Most notably, the aortic occlusion strategy was self-reported by the centers along with type of balloon used (i.e. Prytime ER-REBOA or p-REBOA PRO) and it lacks the granularity to determine how clinicians were implementing partial REBOA. This includes no information regarding their balloon volume titration strategy or distal pressure targets. Further, reported balloon placement was confirmed by plain film, albeit inconsistently, or in rare cases with computer tomography (CT) fluoroscopy. Understanding the method of partial REBOA titration is critical because small changes in balloon volume can cause large changes in flow downstream [18]. Depending on how the balloon is titrated, it is possible to induce an intermittent occlusion phenomenon in which downstream flow is either completely arrested or fully restored. This is in contrast to partial occlusion as is intended, with only 10–20% of downstream flow allowed. The differences between partial and intermittent REBOA can be subtle to the provider at the bedside, but can certainly impact hemodynamics and overall hemorrhage control. Without high-fidelity hemodynamic data, such differences are difficult to tease out.

The above referenced 10–20% of downstream flow allowed is based on pre-clinical research involving the use of partial REBOA [18–21]. While there is no universally fixed definition, this range is a widely accepted

target that balances the need for aortic occlusion while preserving some distal perfusion. In preclinical animal models, direct measurement of downstream flow has been achieved using flow probes that are capable of precise flow measurements. In clinical settings, direct measurement of downstream flow is more difficult but can be estimated by distal pressure targets and Doppler ultrasound. There are several preclinical studies that seek to correlate downstream flow to the distal mean arterial pressure (MAP) below the balloon [18,19,22–24]. These studies demonstrate a fairly linear relationship of distal MAP to flow across various states of hypovolemic shock. Given the lack of granularity in the AORTA registry, and the inability to provide direct flow measurements in a clinical context, this data does not exist.

Without a comprehensive understanding of downstream flow and more precise accounting of relevant variables, the conclusions we can draw are limited. This realization should serve as a caution regarding the limitations inherent in this registry, which is particularly relevant given that many REBOA studies utilize the AORTA registry. While some studies may be designed to address the data shortcomings, others may not, especially when describing outcomes directly related to distal ischemia, as in our present paper. Our data sheds light on the need for improving the granularity of the AAST AORTA registry and reaching a consensus on the definition of partial REBOA, which will allow for better analysis and interpretation of REBOA groups.

Finally, while there were no statistically significant differences for indication between the partial REBOA vs the complete REBOA groups, the indication for use is widely varied. These indications include arrival to the emergency department in arrest, hemodynamic stabilization for additional workup with cross-sectional imaging, transport to the operating room or interventional radiology suite, placement of REBOA intraoperatively for emergency surgery, and placement for planned elective surgery. Increasing the sample size in the registry and completeness of the database will allow us to better analyze these vastly different indications to help determine which patient populations might benefit from the use of endovascular hemorrhage control devices.

CONCLUSION

In conclusion, endovascular technologies such as REBOA have emerged as a valuable tool in the management of NCTH; however, its use remains controversial due to associated morbidity and uncertainty about which patient groups will benefit. While some preclinical studies have demonstrated that partial REBOA can reduce ischemia reperfusion injury, in our registry analysis we found no statistically significant difference in complications between patients who received partial or complete REBOA. These findings may suggest that the observed reduction in ischemic injury in preclinical studies may not necessarily translate to a decrease in patient complications. However, the current body of clinical data falls short in providing the nuanced insights required to address these crucial questions. To understand which patient populations will benefit from these devices and how to best implement them, we need to improve the granularity of the data from which we are studying them. Ultimately, this study is a call for increased enrollment in the database, commitment to data integrity, and attention to detail in recording patient variables.

Ethics Statement

(1) All the authors mentioned in the manuscript have agreed to authorship, read and approved the manuscript, and given consent for submission and subsequent publication of the manuscript.
(2) The authors declare that they have read and abided by the JEVTM statement of ethical standards including rules of informed consent and ethical committee approval as stated in the article.

Conflicts of Interest

AJ, LPN, and TKW are co-founders and shareholders of Certus Critical Care, Incorporated. All other authors declare no conflicts of interest.

Funding

No financial support or funding was received for the presented work.

REFERENCES

[1] Krug EG, Sharma GK, Lozano R. The global burden of injuries. Am J Public Health. 2000;90(4):523–6.
[2] Jacob M, Kumar P. The challenge in management of hemorrhagic shock in trauma. Med J Armed Forces India. 2014;70(2):163–9.
[3] Morrison JJ, Stannard A, Rasmussen TE, Jansen JO, Tai NRM, Midwinter MJ. Injury pattern and mortality of noncompressible torso hemorrhage in UK combat casualties. J Trauma Acute Care Surg. 2013;75 (2 Suppl 2):S263–8.
[4] Kisat M, Morrison JJ, Hashmi ZG, Efron DT, Rasmussen TE, Haider AH. Epidemiology and outcomes of non-compressible torso hemorrhage. J Surg Res. 2013;184(1):414–21.
[5] Morrison JJ, Galgon RE, Jansen JO, Cannon JW, Rasmussen TE, Eliason JL. A systematic review of the use of resuscitative endovascular balloon occlusion of the aorta in the management of hemorrhagic shock. J Trauma Acute Care Surg. 2016;80(2):324–34.
[6] Morrison JJ, Ross JD, Houston R, Watson JDB, Sokol KK, Rasmussen TE. Use of resuscitative

endovascular balloon occlusion of the aorta in a highly lethal model of noncompressible torso hemorrhage. Shock. 2014;41(2):130–7.

[7] DuBose JJ, Scalea TM, Brenner M, et al. The AAST prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: Data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). J Trauma Acute Care Surg. 2016;81(3):409–19.

[8] Moore LJ, Martin CD, Harvin JA, Wade CE, Holcomb JB. Resuscitative endovascular balloon occlusion of the aorta for control of noncompressible truncal hemorrhage in the abdomen and pelvis. Am J Surg. 2016;212(6):1222–30.

[9] Heindl SE, Wiltshire DA, Vahora IS, Tsouklidis N, Khan S. Partial versus complete resuscitative endovascular balloon occlusion of the aorta in exsanguinating trauma patients with non-compressible torso hemorrhage. Cureus. 2020;12(7):e8999.

[10] Ribeiro Junior MAF, Feng CYD, Nguyen ATM, et al. The complications associated with Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA). World J Emerg Surg. 2018;13:20.

[11] Madurska MJ, Jansen JO, Reva VA, Mirghani M, Morrison JJ. The compatibility of computed tomography scanning and partial REBOA: A large animal pilot study. J Trauma Acute Care Surg. 2017;83(3):557–61.

[12] Kuckelman JP, Barron M, Moe D, et al. Extending the golden hour for Zone 1 resuscitative endovascular balloon occlusion of the aorta: Improved survival and reperfusion injury with intermittent versus continuous resuscitative endovascular balloon occlusion of the aorta of the aorta in a porcine severe truncal hemorrhage model. J Trauma Acute Care Surg. 2018;85(2):318–26.

[13] World Medical Association. The World Medical Association-WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects [Internet]. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ Accessed 4 January 2024.

[14] Russo RM, Williams TK, Grayson JK, et al. Extending the golden hour: Partial resuscitative endovascular balloon occlusion of the aorta in a highly lethal swine liver injury model. J Trauma Acute Care Surg. 2016;80(3):372–8; discussion 378–80.

[15] Russo RM, Neff LP, Lamb CM, et al. Partial resuscitative endovascular balloon occlusion of the aorta in swine model of hemorrhagic shock. J Am Coll Surg. 2016;223(2):359–68.

[16] Hoareau GL, Tibbits EM, Beyer CA, et al. Resuscitative endovascular balloon occlusion of the aorta: Review of the literature and applications to veterinary emergency and critical care. Front Vet Sci. 2019;6:197.

[17] Paran M, McGreevy D, Hörer TM, et al. International registry on aortic balloon occlusion in major trauma: Partial inflation does not improve outcomes in abdominal trauma. Surgeon. 2024;22(1):37–42.

[18] Johnson MA, Davidson AJ, Russo RM, et al. Small changes, big effects: The hemodynamics of partial and complete aortic occlusion to inform next generation resuscitation techniques and technologies. J Trauma Acute Surg. 2017;82(6):1106–11.

[19] Forte DM, Do WS, Weiss JB, et al. Titrate to equilibrate and not exsanguinate! Characterization and validation of a novel partial resuscitative endovascular balloon occlusion of the aorta catheter in normal and hemorrhagic shock conditions. J Trauma Acute Care Surg. 2019;87(5):1015–25.

[20] Sadeghi M, Hörer TM, Forsman D, et al. Blood pressure targeting by partial REBOA is possible in severe hemorrhagic shock in pigs and produces less circulatory, metabolic and inflammatory sequelae than total REBOA. Injury. 1, 2018;49(12):2132–41.

[21] Williams TK, Neff LP, Johnson MA, et al. Extending REBOA: Endovascular Variable Aortic Control (EVAC) in a lethal model of hemorrhagic shock. J Trauma Acute Care Surg. 2016;81(2):294–301.

[22] White JM, Ronaldi AE, Polcz JE, et al. A new pressure-regulated, partial resuscitative endovascular balloon occlusion of the aorta device achieves targeted distal perfusion. J Surg Res. 2020;256:171–9.

[23] Russo RM, White JM, Baer DG. Partial resuscitative endovascular balloon occlusion of the aorta: A systematic review of the preclinical and clinical literature. J Surg Res. 2021;262:101–14.

[24] Marble J, Patel NTP, Lane MR, Williams TK, Neff LP, Johnson MA. The physiology of aortic flow and pressures during partial resuscitative endovascular balloon occlusion of the aorta in a swine model of hemorrhagic shock. J Trauma Acute Care Surg. 2022; 93 (2S Suppl 1):S94–101.