High resuscitative endovascular balloon occlusion of the aorta procedural volume is associated with improved outcomes: An analysis of the AORTA registry

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| BACKGROUND: | The use of resuscitative endovascular balloon occlusion of the aorta (REBOA) is controversial. We hypothesize that REBOA out- |
|---|---|
| METHODS: | comes are improved in centers with high REBOA utilization. We examined the Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery registry over a 5-year period (2014–2018). Resuscitative endowscular balloon occlusion of the aorta outcomes were analyzed by stratifying institutions into low-volume |
| RESULTS: | (<10), average-volume (11–30), and high-volume (>30) deployment centers. A multivariable model adjusting for volume group, mechanism of injury, signs of life, systolic blood pressure at initiation, operator level, device type, zone of placement, and hemo- dynamic response to aortic occlusion was created to analyze REBOA mortality and REBOA-related complications. Four hundred ninety-five REBOA placements were included. High-volume centers accounted for 63%, while low accounted for 13%. High-volume institutions were more likely to place a REBOA in the emergency department (81% vs. 63% low volume, $p = 0.003$), had a lower mean systolic blood pressure at insertion (53 ± 38 vs. 64 ± 40, $p = 0.001$), and more Zone I deployments (64% vs. 55%, $p = 0.002$). Median time from admission to REBOA placement was significantly less in patients treated at high-volume centers (15 [7–30] minutes vs. 35 [20–65] minutes, $p = 0.001$). Resuscitative endovascular balloon occlusion of the aorta mortality was significantly higher at low-volume centers (67% vs. 57%; adjusted odds ratio, 1 29; adj. $n = 0.040$), while average- |
| CONCLUSION: LEVEL OF EVIDENCE: KEY WORDS: | high-volume centers were similar. Resuscitative endovascular balloon occlusion of the aorta complications were less frequent at high-/average-volume centers, but did not reach statistical significance (adj $p = 0.784$). Resuscitative endovascular balloon occlusion of the aorta survival is increased at high versus low utilization centers. Increased ex- perience with REBOA may be associated with earlier deployment and subsequently improved patient outcomes. (<i>J Trauma Acute</i> <i>Care Surg.</i> 2021;91: 781–789. Copyright © 2021 Wolters Kluwer Health, Inc. All rights reserved.) Therapeutic/Care Management, level IV. REBOA; volume; mortality. |

N oncompressible torso hemorrhage (NCTH) remains a common cause of early mortality after traumatic injury.^{1–3} Resuscitative endovascular balloon occlusion of the aorta (REBOA) was first described as a means of hemorrhage control during the Korean War, but due to high complication rates and lack of sophisticated device technology, it did not become widespread until several decades later.⁴ Improvements in both trauma systems which deliver increasing numbers of patients with NCTH in extremis and REBOA instrumentation have resulted in an increased use of this modality across trauma centers in the United States.⁵

The reasons for increased REBOA use are likely multifactorial and include increased device simplicity, presentations at national meetings, industry-driven marketing, increased societyendorsed training, and the recognition that NCTH remains a

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perplexing and lethal issue.⁶ However, inconsistent survival benefit and concern over complications related to arterial access and the REBOA catheter itself have led to concern over its widespread adoption.^{7–9} Resuscitative endovascular balloon occlusion of the aorta placement is a high-acuity, low-volume procedure that requires initial training and maintenance of skills to sustain con-sistent proficiency.^{10,11} Relationships between volume and outcomes have been demonstrated with other high-risk surgical procedures, but the impact of institutional REBOA volume and patient outcomes is unknown.^{12–14} We hypothesized that REBOA outcomes are improved in centers with high REBOA utilization. By analyzing the American Association for the Surgery of Trauma Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery (AORTA) multi-institutional database,¹⁵ we sought to examine outcomes in high- versus low-volume REBOA centers. Our primary outcome was to compare the mortality rate between high- and low-volume REBOA centers. Our secondary outcome was to compare REBOA-related complication rates.

METHODS

This was a 5-year retrospective analysis (January 1, 2014 to November 6, 2018) of the prospective observational American Association for the Surgery of Trauma Multicenter Trials Committee AORTA registry. The methodology of this registry has been reported previously.⁹ Briefly, all patients 18 years and older undergoing aortic occlusion (AO) in the acute phases after injury were eligible for inclusion. Data captured in the registry included study center, demographics, admission physiology/injury characteristics, as well as procedural related data and subsequent outcomes.

The primary endpoint of investigation was in-hospital mortality stratified by the volume of REBOA deployments. Secondary outcomes included complications stratified by volume group and type of device over the duration of the study period. Because of the skewness of the data, REBOA volume cutpoints were chosen so as to include at least 50 patients in each cohort and to avoid clustering of cases at a small number of trauma centers. The mean overall number of insertions in the study was 15 (median, 3; interquartile range [IQR], 2–12) with a range of 2 to 110. For this analysis, centers submitting less than 10 REBOA cases were considered low volume, centers with 11 to 30 REBOA deployments were considered average, and centers reporting more than 30 cases of REBOA were considered high-volume. Resuscitative endovascular balloon occlusion of the aorta case cutoffs were chosen to ensure that there would be at least 50 patients from at least five centers in each group for comparison. Youden's index was calculated to define an optimal cutpoint for the number of REBOA insertions done per center, with in-hospital mortality as primary outcome.

Values are reported as means \pm standard deviation (SD) for continuous variables with normal distributions and were compared using either Student's *t* test or analysis of variance. Nonparametric data were presented as the median and interquartile range and analyzed using either the Mann-Whitney *U* test or Kruskal-Wallis test. Categorical variables were expressed as percentages and were compared using the χ^2 test. All variables with a *p* value less than 0.2 (and less than 10% of missing data) on univariate analysis were entered into a multivariable logistic regression model to assess risk factors for mortality, with volume group as an independent variable. Receiver operator curve plots were then constructed to assess the area under the curve (AUC) and the

discriminatory ability of the multivariate models. The Hosmer-Lemeshow goodness of fit was also calculated for the model.

Separate models based on volume group and type of REBOA device utilized were also created to examine specific factors associated with procedural complications. A subanalysis was also performed for outcomes associated with the 7-French REBOA catheter only (Supplementary Digital Tables, http://links.lww.com/TA/B971). Risk factors associated with respective outcomes are presented as adjusted odds ratios (AOR), 95% confidence intervals (CIs) and adjusted p values. A two-tailed p value less than 0.05 was considered statistically significant. All analyses were performed using the Statistical Package for Social Sciences (SPSS) version 25.0 (SPSS Inc, Chicago, IL).

RESULTS

Overall Demographic and Physiological Trends in REBOA Patients

Over the 5-year study period, there were 495 patients that underwent REBOA placement. The mean age of patients undergoing REBOA was 43 ± 18 years and was not significantly different across center volume groups, p = 0.561 (Table 1).

Blunt trauma was common across all groups (80%, p = 0.357), with motor vehicle accidents being the most common cause of blunt injury. The median Injury Severity Scores

| TABLE 1. Demographic and Physiologic Characteristics Stratified by Volume Group | | | | | | | |
|---|---------------------|--------------------------|-----------------------|-------------------|-------|--|--|
| Variable (n) | Low Volume (n = 66) | Average Volume (n = 119) | High Volume (n = 310) | Overall (N = 495) | р | | |
| Age: mean \pm SD (492), y | 44 ± 189 | 42 ± 18 | 412 ± 18 | 43 ± 18 | 0.561 | | |
| Males (495), % | 72 | 75 | 77 | 76 | 0.754 | | |
| Penetrating (495), % | 17 | 24 | 19 | 20 | 0.357 | | |
| Gunshot | 82 | 100 | 88 | 91 | 0.273 | | |
| Stab wound | 9 | 0 | 9 | 6 | | | |
| Other | 9 | 0 | 3 | 3 | | | |
| Blunt (495), % | 83 | 76 | 81 | 80 | 0.357 | | |
| Motor vehicle accident | 38 | 50 | 36 | 40 | 0.008 | | |
| Motor cycle accident | 15 | 19 | 20 | 19 | | | |
| Auto vs. Pedestrian | 29 | 20 | 30 | 28 | | | |
| Falls | 18 | 11 | 7 | 9 | | | |
| Other | 0 | 0 | 8 | 5 | | | |
| ISS: median [IQR] (434) | 34 [25-45] | 29 [22-41] | 34 [25-43] | 34 [24-43] | 0.972 | | |
| AIS | | | | | | | |
| Head AIS score: median [IQR] (360) | 2 [0-4] | 2 [0-4] | 3 [0-4] | 2 [0-4] | 0.305 | | |
| Chest AIS score: median [IQR] (388) | 3 [2-4] | 3 [2–4] | 3 [2-4] | 3 [2-4] | 0.910 | | |
| Abdominal AIS score: median [IQR] (406) | 3 [1-5] | 4 [2–5] | 3 [2-4] | 3 [2-4] | 0.009 | | |
| Prehospital CPR: median [IQR] (467), % | 20 | 20 | 27 | 24 | 0.053 | | |
| Admission vitals | | | | | | | |
| SBP: mean \pm SD (476) | 93 ± 49 | 88 ± 49 | 76 ± 48 | 81 ± 49 | 0.009 | | |
| SBP < 90 mm Hg (476), % | 44 | 43 | 58 | 53 | 0.007 | | |
| HR: mean \pm SD (469), bpm | 101 ± 43 | 111 ± 37 | 95 ± 52 | 99 ± 48 | 0.003 | | |
| GCS score: median [IQR] (480) | 3 [3–12] | 3 [3–14] | 3 [3–13] | 3 [3–13] | 0.177 | | |
| Pupillary response (495), % | 64 | 47 | 51 | 52 | 0.090 | | |
| Organized cardiac activity (495), % | 73 | 66 | 65 | 67 | 0.497 | | |
| Spontaneous movement (495), % | 41 | 39 | 38 | 39 | 0.929 | | |
| CPR (483), % | 12 | 18 | 22 | 20 | 0.019 | | |

HR, heart rate; GCS, Glasgow Coma Scale; INR, international normalized ratio.

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(ISS) were high overall, reflecting the critical nature of injury seen (ISS, 34; IQR, 24–43; p = 0.972). Prehospital cardiopulmonary resuscitation (CPR) was more frequently seen in patients presenting to high-volume centers (24% vs. low volume 20%), although this did not reach statistical significance (p = 0.053).

Upon arrival to the emergency department (ED), patients at high-volume REBOA centers had a greater incidence of hypotension (systolic blood pressure [SBP] < 90 mm Hg) (high, 53% vs. average, 43% vs. low, 44%, p = 0.007) and lower mean SBP (high, 76 ± 48 mm Hg vs. average, 88 ± 49 mm Hg vs. low, $93 \pm$ 49 mm Hg, p = 0.009). There were no significant differences in the presence of signs of life, but more patients at high-volume REBOA centers were undergoing CPR upon arrival.

AO Procedural Details and Analysis

Resuscitative endovascular balloon occlusion of the aorta placement was more likely to be done in the ED (Table 2) at high-/average-volume centers (high, 82% vs. average, 69% vs. low, 64%, p = 0.003), while low-volume centers had the greatest proportion of REBOA placements in the operating room (33%).

Cardiopulmonary resuscitation during initiation of the REBOA procedure was more commonly seen in high-volume group (high, 29% vs. average, 20 vs. low, 29%, p = 0.023). The mean SBP when initiating REBOA was significantly lower in the high-volume group of patients (high, 53 ± 38 mm Hg vs. average, 71 ± 43 mm Hg vs. low, 64 ± 41 mm Hg, p < 0.001). Excluding patients with CPR in progress, there was no difference in the mean SBP between the groups (low, 79 mm Hg vs. average, 76 mm Hg vs. low, 70 mm Hg; p = 0.124). The primary operator performing the REBOA differed across volume groups, with trauma attendings performing the procedure more frequently at high-/low-volume centers (high, 91% vs. average, 63 vs. low, 83%; p < 0.001).

There were notable differences in the methods utilized to obtain access to the common femoral artery across volume groups (Fig. 1A). Open cutdowns and ultrasounds for REBOA access were performed more frequently at high-/average-volume centers, while landmarks were more commonly used at lowvolume centers. The 7-French sheath was the most common access device placed at all centers (high, 44% vs. average, 62% vs. low, 58%, p < 0.001), though upsizing was done more

TABLE 2. REBOA Procedural Details Stratified by Volume Group

| | Variable (n) | Low Volume (n = 66) | Average Volume (n = 119) | High Volume (n = 310) | Overall (N = 495) | р |
|---|---|------------------------|-----------------------------|--------------------------|----------------------|---------|
| ED, %646982760.003Operating room, %33261621Other, %3533Primary REBOA operator (495)Surgical resident, %1.550.31.6Trauma fellow, %62939Trauma fellow, %6.10.00.31.0Other, %0.33.45.54.7REBOA initiation physiology (432)83639183SBP: mean ± SD, mm Hg64 ± 4171 ± 4353 ± 3859 ± 40SBP 0-60 mm Hg, %28344943<0.001 | Location of REBOA (495) | | | | | |
| $\begin{array}{c c c c c c c c c c c c c c c c c c c $ | ED, % | 64 | 69 | 82 | 76 | 0.003 |
| $\begin{array}{c c c c c c c c c c c c c c c c c c c $ | Operating room, % | 33 | 26 | 16 | 21 | |
| Primary REBOA operator (495) Surgical resident, % 1.5 5 0.3 1.6 <0.001 | Other, % | 3 | 5 | 3 | 3 | |
| $\begin{array}{cccccccccccccccccccccccccccccccccccc$ | Primary REBOA operator (495) | | | | | |
| $\begin{array}{cccccccccccccccccccccccccccccccccccc$ | Surgical resident, % | 1.5 | 5 | 0.3 | 1.6 | < 0.001 |
| $\begin{array}{cccccccccccccccccccccccccccccccccccc$ | Trauma fellow, % | 6 | 29 | 3 | 9 | |
| $\begin{array}{c c c c c c c c c c c c c c c c c c c $ | Trauma attending, % | 83 | 63 | 91 | 83 | |
| Other, %3.03.45.54.7REBOA initiation physiology (432)SBP: mean \pm SD, mm Hg64 \pm 4171 \pm 4353 \pm 3859 \pm 40<0.001 | Vascular attending, % | 6.1 | 0.0 | 0.3 | 1.0 | |
| REBOA initiation physiology (432)SBP: mean \pm SD, mm Hg 64 ± 41 71 ± 43 53 ± 38 59 ± 40 <0.001 SBP 0-60 mm Hg, % 28 34 49 43 <0.001 SBP 60-90 mm Hg, % 27 35 40 40 0.321 SBP >90 mm Hg, % 26 32 11 18 <0.001 REBOA response (421) 35 66 56 58 0.165 Postocclusion SBP: mean \pm SD, mm Hg 96 ± 48 110 ± 47 98 ± 48 101 ± 48 0.087 Improvement in post-REBOA hemodynamics (477) 70 77 76 76 0.004 Ves, % 00 0 5.8 3.6 3.6 REBOA timing 35 $[20-65]$ 27 [14-56.5] 15 [7-30] 20 [10-42] <0.001 Duration of AO: median [IQR], min 35 [20-65] 27 [14-56.5] 15 [7-30] 20 [10-42] <0.001 Duration of AO: median [IQR], min 35 [20-65] 27 [14-56.5] 15 [7-30] 20 [10-42] <0.001 Duration of AO: median [IQR], min 35 [20-65] 27 [14-56.5] 15 [7-30] 20 [10-42] <0.001 Duration of AO: median [IQR], min 35 [20-65] 27 [14-56.5] 15 [7-30] 20 [10-42] <0.001 Duration of AO: median [IQR], min 59 [29-151] 41 [26-108] 39 [24-68] 40 [25-86] 0.026 Time from admission to hemodynamic stability: median [IQR], min 59 [29-151] 41 [26-108] 39 [24-68] 40 [25- | Other, % | 3.0 | 3.4 | 5.5 | 4.7 | |
| $\begin{array}{cccccccccccccccccccccccccccccccccccc$ | REBOA initiation physiology (432) | | | | | |
| $\begin{array}{cccccccccccccccccccccccccccccccccccc$ | SBP: mean \pm SD, mm Hg | 64 ± 41 | 71 ± 43 | 53 ± 38 | 59 ± 40 | < 0.001 |
| $\begin{array}{cccccccccccccccccccccccccccccccccccc$ | SBP 0–60 mm Hg, % | 28 | 34 | 49 | 43 | < 0.001 |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | SBP 60–90 mm Hg, % | 47 | 35 | 40 | 40 | 0.321 |
| $\begin{array}{c c c c c c c c c c c c c c c c c c c $ | SBP > 90 mm Hg, % | 26 | 32 | 11 | 18 | < 0.001 |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | REBOA response (421) | | | | | |
| $\begin{array}{c c c c c c c c c c c c c c c c c c c $ | SBP >90 mm Hg post-REBOA, % | 59 | 66 | 56 | 58 | 0.165 |
| $ \begin{array}{llllllllllllllllllllllllllllllllllll$ | Postocclusion SBP: mean \pm SD, mm Hg | 96 ± 48 | 110 ± 47 | 98 ± 48 | 101 ± 48 | 0.087 |
| Yes, %707776760.004Unknown, %005.83.6REBOA timingAdmission to start of AO: median [IQR], min35 [20–65]27 [14–56.5]15 [7–30]20 [10–42]<0.001 | Improvement in post-REBOA hemodynamics (477) | | | | | |
| Unknown, %005.83.6REBOA timingAdmission to start of AO: median [IQR], min35 [20–65]27 [14–56.5]15 [7–30]20 [10–42]<0.001 | Yes, % | 70 | 77 | 76 | 76 | 0.004 |
| REBOA timing 35 [20–65] 27 [14–56.5] 15 [7–30] 20 [10–42] <0.001 | Unknown, % | 0 | 0 | 5.8 | 3.6 | |
| Admission to start of AO: median [IQR], min $35 [20-65]$ $27 [14-56.5]$ $15 [7-30]$ $20 [10-42]$ <0.001 Duration of AO: median [IQR], min $30 [10.8-45]$ $30 [20-60]$ $40 [15-75]$ $35 [15-66]$ 0.040 Time from admission to successful AO: median [IQR], min $40 [23-74]$ $37 [20-77]$ $25 [15-46]$ $30 [17-56]$ <0.001 Time from admission to hemodynamic stability: median [IQR], min $59 [29-151]$ $41 [26-108]$ $39 [24-68]$ $40 [25-86]$ 0.026 Time from admission to hemorrhage control: median [IQR], min $97 [65-223]$ $81 [52-129]$ $96 [54-161]$ $95 [55-159]$ 0.151 Transfusion requirements $7 [65-223]$ $81 [52-129]$ $96 [54-161]$ $95 [55-159]$ 0.151 Transfusion requirements $7 [65-223]$ $81 [52-129]$ $96 [54-161]$ $95 [55-159]$ 0.151 PRBC (472): median [IQR] $12 [6-19]$ $14 [7-24]$ $12 [6-25]$ $12 [6-25]$ 0.773 FFP (460): median [IQR] $10 [6-18]$ $9 [4-20]$ $10 [5-20]$ $10 [4-20]$ 0.900 Platelets (436): median [IQR] $2 [1,8]$ $3 [1,7]$ $3 [1-11]$ $3 [1-9]$ 0.475 Cryo (371): median [IQR] $0.5 [0-2]$ $0 [0-1]$ $0 [0-1]$ $0 [0-1]$ $0 [0-1]$ | REBOA timing | | | | | |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | Admission to start of AO: median [IQR], min | 35 [20-65] | 27 [14-56.5] | 15 [7-30] | 20 [10-42] | < 0.001 |
| Time from admission to successful AO: median [IQR], min40 $[23-74]$ 37 $[20-77]$ 25 $[15-46]$ 30 $[17-56]$ <0.001Time from admission to hemodynamic stability: median [IQR], min59 $[29-151]$ 41 $[26-108]$ 39 $[24-68]$ 40 $[25-86]$ 0.026Time from admission to hemorrhage control: median [IQR], min97 $[65-223]$ 81 $[52-129]$ 96 $[54-161]$ 95 $[55-159]$ 0.151Transfusion requirementspRBC (472): median [IQR]12 $[6-19]$ 14 $[7-24]$ 12 $[6-25]$ 12 $[6-25]$ 0.773FFP (460): median [IQR]10 $[6-18]$ 9 $[4-20]$ 10 $[5-20]$ 10 $[4-20]$ 0.900Platelets (436): median [IQR]2 $[1,8]$ 3 $[1,7]$ 3 $[1-11]$ 3 $[1-9]$ 0.475Cryo (371): median [IQR]0.5 $[0-2]$ 0 $[0-1]$ 0 $[0-1]$ 0 $[0-1]$ 0.056 | Duration of AO: median [IQR], min | 30 [10.8-45] | 30 [20-60] | 40 [15-75] | 35 [15-66] | 0.040 |
| Time from admission to hemodynamic stability: median [IQR], min59 [29–151]41 [26–108]39 [24–68]40 [25–86]0.026Time from admission to hemorrhage control: median [IQR], min97 [65–223]81 [52–129]96 [54–161]95 [55–159]0.151Transfusion requirementspRBC (472): median [IQR]12 [6–19]14 [7–24]12 [6–25]12 [6–25]0.773FFP (460): median [IQR]10 [6–18]9 [4–20]10 [5–20]10 [4–20]0.900Platelets (436): median [IQR]2 [1,8]3 [1,7]3 [1–11]3 [1–9]0.475Cryo (371): median [IQR]0.5 [0–2]0 [0–1]0 [0–1]0 [0–1]0.056 | Time from admission to successful AO: median [IQR], min | 40 [23-74] | 37 [20–77] | 25 [15-46] | 30 [17-56] | < 0.001 |
| Time from admission to hemorrhage control: median [IQR], min 97 [65–223] 81 [52–129] 96 [54–161] 95 [55–159] 0.151 Transfusion requirements pRBC (472): median [IQR] 12 [6–19] 14 [7–24] 12 [6–25] 12 [6–25] 0.773 FFP (460): median [IQR] 10 [6–18] 9 [4–20] 10 [5–20] 10 [4–20] 0.900 Platelets (436): median [IQR] 2 [1,8] 3 [1,7] 3 [1–11] 3 [1–9] 0.475 Cryo (371): median [IQR] 0.5 [0–2] 0 [0–1] 0 [0–1] 0 [0–1] 0.056 | Time from admission to hemodynamic stability: median [IQR], min | 59 [29–151] | 41 [26–108] | 39 [24-68] | 40 [25-86] | 0.026 |
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| | Cryo (371): median [IQR] | 0.5 [0-2] | 0 [0–1] | 0 [0-1] | 0 [0-1] | 0.056 |

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Initial REBOA Zone of Occlusion



Low Volume Average Volume High Volume

Figure 1. *A*, Methods of REBOA access stratified by center volume. *B*, Initial REBOA sheath selection stratified by type of REBOA sheath. *C*, Initial REBOA zone of occlusion stratified by REBOA zone. *p* Value represents significance for overall trends.

at high-/average-volume centers (Fig. 1*B*). Zone of REBOA deployment also varied across volume groups (Fig. 1*C*) with initial Zone I deployments occurring with greater frequency at high/average institutions (high, 64% vs. average, 72% vs. low, 55%, p < 0.001). Zone II placements occurred most commonly in the low-volume group (6%).

Improvement in postocclusion hemodynamics was more likely to occur in patients undergoing REBOA at high-/average-volume institutions (high, 76% vs. average, 77% vs. low, 70%, p = 0.004, Table 2). In those patients with available data, the median time from admission to start of REBOA (high volume, 15 minutes; IQR, 7–30 minutes vs. average, 27 minutes; IQR, 14–57 minutes vs. low, 35 minutes; IQR, 20–65 minutes; p < 0.001) was shorter in patients treated at high-volume

facilities, as was the time to successful AO (high volume, 25 minutes; IQR, 15–46 minutes vs. average, 37 minutes; IQR, 20–77 minutes vs. low, 40 minutes; IQR, 23–74 minutes; p = 0.040), respectively.

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REBOA Hemorrhage Control and Level of REBOA placement

Patients who underwent REBOA placement in Zone II or III frequently had significant bleeding above the level of the balloon that required surgical intervention. Forty-eight percent of patients who underwent Zone III REBOA also required an intraperitoneal procedure versus 63% of Zone II REBOA placements and 71% of Zone I placements (p = 0.001) (Table 3).

REBOA Survival and Complications

Unadjusted mortality was greatest in the low REBOA volume group (low, 67% vs. average, 60% vs. high, 57%, p = 0.352, Fig. 2) although this did not reach statistical significance. The mortality for patients undergoing CPR was 90% with no differences between the groups.

A multivariate model was created to assess factors associated with mortality. Covariates included age, sex, mechanism of injury, SBP at time of REBOA initiation, signs of life at time of REBOA (pupillary response, organized electrical activity, or spontaneous movement), location of REBOA (location of placement and zone of deployment), level of operator performing REBOA, hemodynamic response after REBOA, type of hemorrhage control intervention, need for any transfusion, Abbreviated Injury Scale (AIS), level of trauma center, source of hemorrhage, and REBOA volume group. Significant factors associated with reduced mortality included the presence of signs of life (AOR, 0.33; 95% CI, 0.16–0.69; adjusted p = 0.003), presence of hemodynamic stability after REBOA (AOR, 0.36; 95% CI, 0.21-0.61; adjusted p = 0.001), Zone III placement (AOR, 0.30; 95% CI, 0.18–0.51; adjusted p = 0.001), and high REBOA volume centers (AOR, 0.77; 95% CI, 0.60–0.98; adjusted p = 0.040). Having a REBOA placed in the ED and CPR during the time of REBOA placement was associated with increased mortality. The Hosmer Lemeshow (p = 0.676) and AUC for the model was 0.83 (95% CI, 0.8–0.87). A separate model comparing only high and average REBOA volume centers was also created to assess any potential difference in mortality between these groups, but this parameter was not significantly different (AOR, 0.38; 95% CI, 0.58–1.23; adjusted p = 0.379). The mortality for the respective groups with the CPR patients removed was low, 57%; average, 53%; and high, 44% with an AOR (high vs. low volume) of 84 (95% CI, 0.70–0.99) and an adjusted p value of 0.04. To account for clustering in the mortality model, a multilevel linear model with mortality as outcome and number of

TABLE 3. Hemorrhage Control Procedures Stratified by Level of REBOA Placement

| | Zone of REBOA Occlusion | | | | |
|---------------------------|-------------------------|---------|----------|-------|-------|
| | Zone I | Zone II | Zone III | Total | р |
| Intrathoracic procedure | 12% | 0% | 4% | 9% | 0.001 |
| Intraperitoneal procedure | 71% | 63% | 48% | 62% | 0.001 |
| Pelvic procedure | 23% | 38% | 61% | 35% | 0.001 |



REBOA Specific Complications and In-Hospital Mortality Stratified by Center Volume

Figure 2. REBOA-specific complications and in-hospital mortality stratified by center volume.

procedures as predictor with varying intercept by center (high, average, low) was created. In this model, the number of REBOA procedures was a predictor of mortality, with a fixed effect regression coefficient of -0.080, an 8% lower risk of death with increasing number of insertions, with a *p* value of 0.04. The mixed linear model results returned an intraclass correlation coefficient of about 6.7%. Thus, the proportion of variance in the data accounted for by the center volume variable indicated that center status or variation by center did not contribute appreciably to the mortality effect seen for number of REBOA insertions.

Youden's index was calculated to define an optimal cutpoint for the number of REBOA insertions done per center; using this calculation, the optimal cutpoint was defined as 26 cases per center. This had sensitivity of 82% and specificity of 27% for mortality. The calculated index was 0.09. This cutpoint was next used to perform a sensitivity analysis on our previous regression model. The cutpoint of greater than/equal to 26 REBOA cases was entered into the model as a high-volume center. Patients that underwent REBOA placement at a high-volume center (as per the new definition) had 44% lower mortality (AOR, 0.56; 95%



Figure 3. *A*, REBOA-specific complications stratified by center volume. *B*, REBOA-specific complications stratified by final catheter size. AOR of any endovascular complication with 7-Fr versus other catheter size.

CI, 0.32–0.98) adjusted p = 0.043). The AUC for this model was 0.83 (95% CI, 0.79–0.87).

The overall REBOA complication rate was 12% and was not significantly different across the volume groups (low, 17% vs. average, 11% vs. high, 12%; p = 0.469, Fig. 2). The most common complication was distal embolism in 4.2% of cases, followed by extremity ischemia in 4.0% (Fig. 3). A multivariate logistic regression model was created to examine the adjusted risk of any complication during the course of the study period. Covariates included age, sex, mechanism of injury, sheath diameter, method of arterial access, SBP at time of REBOA initiation, signs of life at time of REBOA, location of REBOA (location of placement and zone of deployment), level of operator performing REBOA, hemodynamic response after REBOA, source of hemorrhage, and REBOA volume group. The variables that were associated with decreased complications were 7-French sheaths (AOR, 0.35; 95% CI, 0.19–0.65; adjusted p = 0.001) and CPR at the time of REBOA (AOR, 0.35; 95% CI, 0.13-0.92; adjusted p = 0.032). The REBOA volume group was not significantly associated with a decreased rate of complications (AOR, 0.97; 95% CI, 0.78–1.21; adjusted p = 0.784). The Hosmer Lemeshow (p = 0.509) and AUC for the model was 0.75 (95% CI, 0.69–0.82; p = 0.001).

DISCUSSION

Our results demonstrate that survival was significantly increased at high compared with low REBOA utilization centers. There were no significant differences in mortality in high-versus average-volume centers (57% at high-volume centers vs. 59% at average-volume centers). The REBOA-related complications were not different across centers. Level I trauma centers with high-volume trauma have been shown to have better outcomes than lower-level centers in patients who present with injuries associated with high mortality.^{12,16,17} Busy Level I trauma centers are more likely to see patients with higher injury burden and physiologic derangement that require life-sustaining treatments such as REBOA. The survival benefit occurred despite high utilization center patients having a higher percentage of cardiac arrests, lower mean blood pressure at insertion, and more Zone 1 deployments.

There are several potential reasons for this finding. First, high-volume centers initially deployed zone I REBOA catheters more often than lower volume centers. This may have contributed to the increased survival by facilitating earlier temporary hemorrhage control. Patients who underwent Zone II or Zone III REBOA placements frequently needed additional surgical procedures above the level of the inflated balloon in order to achieve hemostasis. Second, in high-volume centers, the median time from admission to REBOA placement was significantly less. Time from "door to hemorrhage control" has been demonstrated to correlate with improved survival.^{18,19} We demonstrated a median time from admission to REBOA placement of 15 minutes in high-volume centers versus 35 minutes in low-volume centers. The time to successful AO was also significantly faster at high REBOA volume institutions. It is also important to note that high-volume centers were more likely to place REBOA in the ED, whereas low-volume centers were more likely to place REBOA in the OR. This could have

contributed to the delay in hemostasis seen at low-volume centers. It is possible that at high-volume centers, increased experience with REBOA and its indications for use is associated with earlier time to deployment. Lastly, internal systems for improved resuscitation and hemorrhage control could exist within high-volume trauma centers and REBOA deployment was acting as a surrogate for those factors.

Multiple studies have demonstrated that the major ratelimiting step to successful REBOA placement is the ability to safely cannulate the common femoral artery (CFA).²⁰⁻²³ It may be difficult to use percutaneous methods to cannulate the artery of a patient in hemorrhagic shock; in this case, open cutdown can be performed. Patients at high-volume centers had more open cutdowns and increased used of ultrasound compared with patients evaluated at low-volume centers. Greater than 50% of overall REBOA procedural time was attributed to obtaining CFA access, with no difference noted between percutaneous or open cutdown methods.²³ Catheter placement requires anatomic knowledge and can be challenging, especially for the inexperienced provider. In addition, providers in high-volume centers may have more experience with resuscitating patients after deploying Zone 1 REBOA or with repositioning catheters after initial placement. Data from several Japanese studies have demonstrated that prolonged time to REBOA placement and hemorrhage control are associated with increased mortality. Inoue et al.²⁴ analyzed patients with severe torso trauma and found a door to surgery time of 97 minutes with REBOA. This increased time resulted in an in-hospital mortality of 62% in REBOA patients versus 45% in matched cohorts who did not receive REBOA. In a similar study, Norii et al.²² demonstrated a prolonged time to definitive care in survivors treated with REBOA (213 minutes). When matched with similar patients who did not receive REBOA, subsequent survival was lower in the REBOA group (crude conditional odds ratio of survival by REBOA treatment, 0.30; 95% CI, 23–0.40).

Decreased experience to maintain proficiency with REBOA in low-volume centers may be another reason for increased mortality. As REBOA is a high-acuity, low-frequency procedure, maintenance of competency and understanding the pitfalls is vital; this may not occur in low-volume centers. This issue may have attributed to decreased Zone I REBOA placements and erroneous inflation at Zone II observed in low-volume centers. We also noted a higher frequency of bleeding occurring above the level of balloon inflation in low-volume centers.

Training courses have been put forward to train clinicians how to perform REBOA catheter placement, including Basic Endovascular Skills for Trauma course¹¹ and the Endovascular Skills for Trauma Management workshop.²⁵ Experience with a training course has been demonstrated to significantly improve clinician knowledge and procedural task time.^{11,20} However, benefits from a single training course likely decreases over time, and an ongoing competency program is necessary.^{5,10,20} Based on our data, it seems reasonable to advocate that clinicians at low-volume trauma centers should not only receive initial formal training but also continued refresher courses or simulation training to maintain competency, even in the absence of clinical cases.

It is important to assess not only the mortality but also the morbidity associated with REBOA, as serious potential complications may occur from problems with vascular access, balloon inflation, and distal ischemia.^{7,8} Major complications, including arterial dissections and limb ischemia requiring amputation, have been reported.⁸ In this study, we found that REBOA complications were less frequent at high-volume (12%) and average-volume (11%) versus low-volume (17%) centers, although this did not reach statistical significance. A recently published study by Theodorou et al.²⁶ compared patients who underwent REBOA at high-volume hospitals versus low-volume hospitals. While patients seen at high-volume hospitals were more likely to undergo successful REBOA placement, overall complication rates were similar; these complication rates, however, may have been skewed because of the survival advantage seen at high-volume centers. This highlights the fact that despite having the potential to decrease mortality, REBOA is not a benign procedure and is associated with significant complications, even in centers that perform it frequently.

Lastly, it is important to note that we found a decrease in overall endovascular complication rate in patients who underwent REBOA with a smaller (7 French) catheter size versus larger catheters (10% vs. 17%, p = 0.02). This has been reported previously. Matsumura et al.²⁷ found that smaller (under 8 French) REBOA devices were associated with fewer complications and could be removed using only manual compression in 96% of cases, vs. 45% of cases using larger (>9 French) sheaths. Ordoñez et al.²⁸ also found a decreased rate of complications in patients who underwent REBOA with smaller 7-French sheaths compared with larger caliber sheaths. Our findings reinforce the increased safety of lower profile devices and call into question why larger diameters sheaths and endovascular devices are still being used.

Our data demonstrate that REBOA may be an important tool in the hands of skilled providers with well-developed REBOA programs. High-volume trauma centers are likely to be centers with established indications for REBOA, with well-trained surgeons who have the skills necessary to place the device expeditiously. Given that average-volume centers had similar outcomes to the high-volume centers in our study, acceptable REBOA outcomes are possible even in centers that do not perform REBOA as frequently. It is also clear that REBOA is nothing more than an adjunctive, temporizing measure, and expedient definitive hemorrhage control is paramount to ensure optimal survival.

There are several limitations to this study. This is a retrospective review of patients from a voluntarily submitted national database. As such, associations between REBOA volume and outcome can only be inferred and not definitively proven. Several key variables were also not available in this data set including background operator training and experience, cause of death, indications for AO or rationale for REBOA zone placement, and usage of any partial or intermittent inflation techniques. Several REBOA-specific complications, such as compartment syndrome, are not available. Abbreviated Injury Scale is also not well documented in the registry, because head, chest, and abdominal AIS are the only body regions available. Also, because this was a retrospective study, we cannot attribute differences in outcomes to the REBOA procedure alone, as practices may vary across institutions. Proficiency in REBOA may simply be a proxy for better overall processes of care at higher- or average-volume institutions. In addition, the AORTA registry only has data available for patients who underwent successful REBOA placement, and does not report data on patients who underwent failed REBOA placements; this selection bias may have affected our results. While the number of centers contributing to the AORTA registry has increased dramatically, these are largely the experience of academic Level I trauma institutions, which limits the generalization of our conclusions. In addition, our study does not have a control group (patients who did not undergo AO or REBOA); thus, this study cannot determine whether REBOA at any volume center is better than no REBOA. Lastly, while there appears to be a volume and outcome relationship with REBOA deployment, the exact number of deployments needed per surgeon/institution is unknown and will likely vary from center to center. The cutoffs chosen for low, average, and high REBOA volume centers were somewhat arbitrary, because the distribution of data were nonparametric. Thus, designation of groups based on mean and SD alone would result in clustering, because only the top REBOA utilization centers would be overrepresented. Cutoffs were chosen as to provide a sufficient number of cases in each group, with at least five centers in each group for comparison.

In conclusion, we have demonstrated that in centers utilizing REBOA, survival appears to be improved in high versus low utilization centers. Increased experience with REBOA may be associated with earlier deployment and subsequently improved patient outcomes. Evaluating the effect of institutional REBOA experience and continuous assessment of REBOA competency and its impact on outcomes should be assessed prospectively.

AUTHORSHIP

All authors participated in article preparation. E.G. participated in the literature search, data analysis, and writing. B.N. participated in the data analysis and writing. M.K participated in the data interpretation and critical revision. C.D.M. assisted with study design, data analysis and interpretation. D.H.L. assisted with data interpretation and critical analysis. M.B. was involved with study design, data analysis, data interpretation, and critical revision. The remaining authors were involved with data acquisition and data analysis.

DISCLOSURE

The authors declare no funding or conflicts of interest.

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