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Zone 1 Endovascular Balloon Occlusion of the Aorta vs Resuscitative Thoracotomy for Patient Resuscitation After Severe Hemorrhagic Shock

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IMPORTANCE Aortic occlusion (AO) is a lifesaving therapy for the treatment of severe traumatic hemorrhagic shock; however, there remains controversy whether AO should be accomplished via resuscitative thoracotomy (RT) or via endovascular balloon occlusion of the aorta (REBOA) in zone 1.

OBJECTIVE To compare outcomes of AO via RT vs REBOA zone 1.

DESIGN, SETTING, AND PARTICIPANTS This was a comparative effectiveness research study using a multicenter registry of postinjury AO from October 2013 to September 2021. AO via REBOA zone 1 (above celiac artery) was compared with RT performed in the emergency department of facilities experienced in both procedures and documented in the prospective multicenter Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry. Propensity score matching (PSM) with exact institution matching was used, in addition to subgroup multivariate analysis to control for confounders. The study setting included the ED, where AO via RT or REBOA was performed, and participants were adult trauma patients 16 years or older.

EXPOSURES AO via REBOA zone 1 vs RT.

MAIN OUTCOMES AND MEASURES The primary outcome was survival. Secondary outcomes were ventilation-free days (VFDs), intensive care unit (ICU)–free days, discharge Glasgow Coma Scale score, and Glasgow Outcome Score (GOS).

RESULTS A total of 991 patients (median [IQR] age, 32 [25-48] years; 808 male individuals [81.9%]) with a median (IQR) Injury Severity Score of 29 (18-50) were included. Of the total participants, 306 (30.9%) had AO via REBOA zone 1, and 685 (69.1%) had AO via RT. PSM selected 112 comparable patients (56 pairs). REBOA zone 1 was associated with a statistically significant lower mortality compared with RT (78.6% [44] vs 92.9% [52]; $P = .03$). There were no significant differences in VFD greater than 0 (REBOA, 18.5% [10] vs RT, 7.1% [4]; $P = .07$), ICU-free days greater than 0 (REBOA, 18.2% [10] vs RT, 7.1% [4]; $P = .08$), or discharge GOS of 5 or more (REBOA, 7.5% [4] vs RT, 3.6% [2]; $P = .38$). Multivariate analysis confirmed the survival benefit of REBOA zone 1 after adjustment for significant confounders (relative risk [RR], 1.25; 95% CI, 1.15-1.36). In all subgroup analyses (cardiopulmonary resuscitation on arrival, traumatic brain injury, chest injury, pelvic injury, blunt/penetrating mechanism, systolic blood pressure ≤60 mm Hg on AO initiation), REBOA zone 1 offered an either similar or superior survival.

CONCLUSIONS AND RELEVANCE Results of this comparative effectiveness research suggest that REBOA zone 1 provided better or similar survival than RT for patients requiring AO postinjury. These findings provide the ethically necessary equipoise between these therapeutic approaches to allow the planning of a randomized controlled trial to establish the safety and effectiveness of REBOA zone 1 for AO in trauma resuscitation.

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Supplemental content

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Group Information: A complete list of the members of the AAST AORTA Study Group appears in Supplement 2.

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Aortic occlusion (AO) is an integral part of the armamentarium for treating exsanguinating hemorrhage in the emergency department (ED). Its goal is to redistribute the limited circulating blood to cerebral and coronary perfusion and attenuate ongoing blood loss from subdiaphragmatic bleeding.[1] Traditionally, it was performed via a resuscitative thoracotomy (RT) for penetrating cardiac wounds[2] and later for massive hemoperitoneum to prevent cardiac decompensation prior to laparotomy.[3] However, this aggressive procedure is associated with morbidity not only to the patient but also to the health care team.[4] Blood-borne illnesses (HIV, hepatitis C) have historically been the primary concern; however, the COVID-19 pandemic added further risk.[5-7]

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an intraaortic balloon occlusion device placed percutaneously and advanced into the descending aorta to achieve AO. Both REBOA and RT aim at achieving temporary AO in patients in extremis due to hemorrhagic shock. Contemporary investigations on their comparative effectiveness and safety lack appropriate control groups or provide disparate results. Harfouche et al[8] found a survival benefit of REBOA in a single-center study matching patients requiring REBOA to non-REBOA. However, the study excluded patients who arrived in cardiac arrest, when AO can be lifesaving, and the non-REBOA group was not necessarily treated with RT. Studies using the multicenter Japan Trauma Data Bank (2004-2011[9] and 2004-2016[10]) found opposing results regarding the survival benefit from REBOA compared with non-REBOA using propensity score matching. Again, both studies used controls not necessarily treated with RT. A 2019 study comparing the outcomes of REBOA with non-REBOA in propensity score-matched patients in the 2015 to 2016 American College of Surgeons Trauma Quality Improvement Program US national data set,[11] reported increased mortality with REBOA. However, the study specifically excluded patients treated with RT from their control group. Finally, a meta-analysis[12-15] comparing AO via RT and via REBOA reported a survival benefit from REBOA; however, the analytic approach required a number of questionable assumptions.

In addition to unsuitable control groups, most studies lacked granular data on the physiologic status at AO and the injury patterns, 2 essential elements to determine the indication of open vs endovascular AO. Furthermore, recent data suggest that there are sizable differences in indications and outcomes of REBOA AO at zone 1 (above the celiac artery) vs zone 3 (below the renal arteries),[16] which most prior investigations did not distinguish. The prospective multicenter (28 trauma centers) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry, sponsored by the American Association for the Surgery of Trauma, was designed to supply granular physiologic and injury data, as well AO zone, allowing for more accurate assessments of the effectiveness of AO via RT vs REBOA.[15] The preliminary report from the AORTA registry[17] reviewed the first 285 patients and concluded that REBOA zone 1 was superior to RT, particularly in patients not requiring cardiopulmonary resuscitation (CPR). A more recent report of the AORTA registry focusing on traumatic brain injury (TBI) confirmed a survival benefit of REBOA zone 1 vs RT.[18]

Key Points

Question Is zone 1 endovascular balloon occlusion of the aorta (REBOA) a safe and effective alternative to resuscitative thoracotomy (RT) in the resuscitation of patients with severe traumatic hemorrhagic shock?

Findings After controlling for confounders through propensity score matching, this comparative effectiveness research study including 991 patients from 28 trauma centers in the 2013 to 2021 Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery registry found that patients subjected to a REBOA zone 1 aortic occlusion were significantly more likely to survive their hospitalization than similar patients undergoing AO via RT.

Meaning Results suggest that REBOA zone 1 aortic occlusion is a safe and effective alternative to RT.

We produced a contemporaneous report of the AORTA registry comparing AO via REBOA zone 1 vs RT in the overall group of patients undergoing either procedure and in predetermined subgroups. We also identified the prognostic indicators of each procedure. We hypothesized that AO via REBOA zone 1 would result in better outcomes than RT among patients who underwent AO in the ED for severe hemorrhagic shock.

Methods

Study Design

This was a multicenter, observational, comparative effectiveness research study using the prospective AORTA registry. All participating centers were required to have institutional review board approval prior to enrollment of patients into the AORTA registry. The study was conducted with a waiver of consent due to minimal risk. Patients admitted between October 2013 and September 2021 were eligible for this study. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.

Study Population

Included in this study were adult trauma patients 16 years and older undergoing AO during resuscitation in the ED. We excluded patients transferred from other hospitals. Race and ethnicity data were not collected during this time period in the AORTA registry. Future data collection will incorporate this important descriptor. The study was limited to facilities with 10 or more cases of RT and 10 or more cases of REBOA zone 1 in the AORTA registry during the study period to capture hospitals with experience in both procedures.

Outcomes and Subgroups

The primary outcome was in-hospital survival. Secondary outcomes included ventilation-free days and intensive care unit (ICU)–free days (both out of 28 days), calculated as proposed by Schoenfeld et al,[19] as well as Glasgow Coma Scale (GCS) and Glasgow Outcome Score (GOS) on discharge.

Several subgroups were defined to refine the indication of REBOA vs RT: TBI Head Abbreviated Injury Score (AIS; score ≥3),

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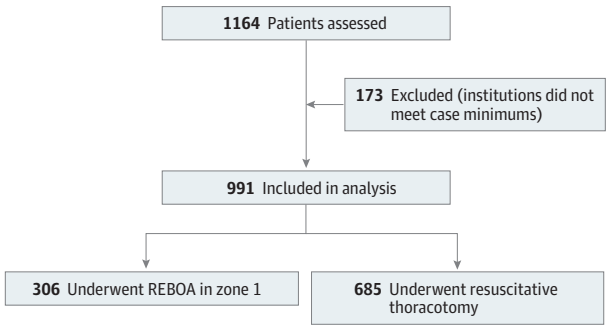
Figure 1. Flow Diagram for Patient Inclusion



REBOA indicates resuscitative endovascular balloon occlusion of the aorta.

severe chest injury (AIS chest ≥3), severe isolated chest injury (AIS chest ≥3 and AIS of all other regions ≤2), penetrating severe chest injury (AIS chest ≥3), severe pelvic injury (AIS pelvis ≥3), blunt and penetrating mechanisms, and arrival CPR requirement.

Statistical Analysis

We conducted propensity score matching (PSM) on all variables deemed clinically relevant and/or significantly associated univariately with the procedures (greedy matching, maximum caliper 0.15), with exact matching on institution. The latter has been often neglected in previous PSM studies, yet it is essential to avoid comparing hospitals rather than AO types. When variables were highly collinear ($|r|>0.35$), one of them was chosen based on availability and reliability to be included in the model. Survival between matched groups was compared with Kaplan-Meier curves and tested with the log-rank and Wilcoxon tests, whereas comparisons of continuous outcomes were done via the Wilcoxon rank sum test, and comparisons of categorical outcomes were done via the χ^2 test. To adjust for any confounding remaining after matching, a Cox proportional hazards model was used.

In addition, we performed a multivariate analysis using generalized estimating equations with robust SEs (to account for clustered data by hospital) to adjust the correlation of AO type (RT vs REBOA) with hospital mortality for potential confounders. Only statistically significant confounders were kept in these models. The significant independent predictors of death in each one of the AO modes were detected by a stepwise selection procedure in generalized estimating equation models with robust SEs.

All analyses were conducted in SAS, version 9.4 (SAS Institute). Stratification variables and outcomes had negligible missingness (<5%); for other variables, listwise deletion was applied, and tables report the proportion of the actual denominator. Continuous data are presented as median (IQR). All tests were 2-tailed with significance declared at $P < .05$.

Results

Figure 1 shows the flow diagram for study inclusion. Overall, of 1164 patients meeting inclusion criteria, 173 were removed due to the institution low procedure volume, leaving 991 patients (median [IQR] age, 32 [25-48] years; 808 male individuals [81.9%]; 183 female individuals [18.5%]) in the analytic data set, of whom 306 (30.9%) underwent RT, and 685 (69.1%) underwent REBOA zone 1. In the analytic data set, patients had a median (IQR) Injury Severity Score (ISS) of 29 (18-50). **Table 1** depicts the patients characteristics and outcomes of the 2 groups. Overall, patients who underwent RT were more severely injured, had more physiologic derangement, and experienced worse outcomes than their REBOA zone 1 counterparts.

PSM Analysis in the Overall Group

PSM controlled for the following variables: institution (exact matching) and age, sex, ISS, injury mechanism, TBI, severe chest injury, severe abdominal injury, severe pelvic injury, severe extremities injury, prehospital CPR, admission systolic blood pressure (SBP), admission GCS, CPR on arrival, CPR during AO, initial AO SBP of 60 mm Hg or less, AO initial GCS, and procedure performer (trauma surgeon vs others). PSM selected 112 patients (56 pairs) and substantially reduced the differences between groups (**Table 2**). Balance diagnostics included the standardized mean difference (SMD), which was below 20.0 for all variables, except for injury mechanism, which remained relatively unbalanced with an SMD of 0.23. Other balance diagnostics are available in supplemental digital content (eFigure in the Supplement).

All matched patients were treated in level I trauma centers. REBOA zone 1 was associated with significantly lower mortality than RT (78.6% [44] vs 92.9% [52]; log-rank $P = .02$; Wilcoxon tests, $P = .01$; Cox proportional hazards model, $P = .03$) (**Figure 2**). A Cox proportional hazards model adjusting for blunt/penetrating mechanism was performed because mechanism of injury remained relatively unbalanced between matched groups. The significant survival benefit for REBOA zone 1 remained. Most deaths in the REBOA zone 1 group occurred in the ED, followed by the ICU, whereas patients who underwent RT were equally likely to die in the ED or in the operating room, with a minority (17.3% [9 of 56]) dying in the ICU. There were no significant differences in ventilator-free days greater than 0 (REBOA, 18.5% [10] vs RT, 7.1% [4]; $P = .07$), ICU-free days greater than 0 (REBOA, 18.2% [10] vs RT, 7.1% [4]; $P = .08$), or discharge GOS of 5 or more (REBOA, 7.5% [4] vs RT, 3.6% [2]; $P = .38$). REBOA zone 1 resulted in more ventilator-free days and ICU-free days, although these differences were not significant. There were no statistically significant differences in discharge GOS or GCS (the latter only in survivors). Complications following AO for both procedures are shown in Table 2. It should be noted that all complications are subject to survivor bias, thus they were more likely in the group with the longest survival.

Matched and unmatched patients had similar demographic characteristics (albeit matched patients were slightly older), ISS, and SBP at AO initiation as well as acid-base and coagulation status on hospital arrival (eTable in the Supplement). However, compared with unmatched patients, the matched group was more likely to be treated in high-volume centers, to have had blunt injuries resulting in less physiologic derangement and requirement for CPR, and survived

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Table 1. Characteristics of the Population Studied

Characteristic	Median (IQR) or No. (%)			*P* value
	Total (n = 991 [100%])	REBOA zone 1 (n = 306 [30.9%])	Resuscitative thoracotomy (n = 685 [69.1%])	
Facility's annual patient volume, No. (%)				
1000-2000	202 (20.4)	11 (3.6)	191 (27.9)	<.001
>2000-3000	188 (19.0)	21 (6.9)	167 (24.4)	
>3000	601 (60.6)	274 (89.5)	327 (47.7)	
Age, y	32.0 (25.0 to 48.0)	40.0 (27.0 to 57.0)	30.0 (24.0 to 42.0)	<.001
Sex				
Male	808 (81.5)	238 (77.8)	570 (83.2)	.03
Female	183 (18.5)	68 (22.2)	115 (16.8)	
BMI[a]	25.8 (23.5 to 30.5)	26.0 (23.7 to 30.4)	25.8 (23.2 to 30.6)	.67
Injury characteristics, No. (%)				
Blunt mechanism	565 (57.1)	64 (21.1)	501 (73.1)	<.001
Injury Severity Score	29.0 (18.0 to 50.0)	33.0 (21.0 to 43.0)	26.0 (17.0 to 50.0)	.73
Head/neck AIS	0 (0 to 2.0)	1.0 (0 to 4.0)	0 (0 to 0)	<.001
Traumatic brain injury	211 (21.3)	118 (38.6)	93 (13.6)	<.001
Chest AIS	3.0 (0 to 4.0)	3.0 (0 to 4.0)	3.0 (0 to 5.0)	.001
Severe chest injury	577 (58.2)	174 (56.9)	403 (58.8)	.56
Abdomen AIS	0 (0 to 3.0)	2.0 (0 to 4.0)	0 (0 to 2.0)	<.001
Severe abdomen injury	315 (31.8)	149 (48.7)	166 (24.2)	<.001
Pelvic AIS	0	0	0	.97
Severe pelvic injury	14 (1.4)	5 (1.6)	9 (1.3)	.69
Extremity AIS	0	0 (0 to 0)	0 (0 to 0)	<.001
Severe extremity injury	56 (5.7)	8 (2.6)	48 (7.0)	.01
Prehospital				
SBP, mm Hg	76.0 (0 to 111.5)	96.0 (62.0 to 129.0)	40.0 (0 to 92.0)	<.001
Heart rate, beats/min	86.0 (22.0 to 120.0)	100.0 (69.0 to 128.0)	68.0 (0 to 110.0)	<.001
Shock index	0.8 (0 to 1.4)	0.9 (0.6 to 1.3)	0.8 (0 to 1.5)	.06
GCS	3.0 (3.0 to 10.0)	3.0 (3.0 to 12.0)	3.0 (3.0 to 8.0)	<.001
CPR, No. (%)	443 (45.4)	97 (31.8)	346 (51.6)	<.001
Minutes from injury to hospital	30.0 (20.0 to 53.0)	43.0 (28.0 to 65.0)	24.0 (16.0 to 40.0)	<.001
Hospital admission				
SBP, mm Hg	0 (0 to 83.5)	77.0 (0 to 107.0)	0 (0 to 56.0)	<.001
Heart rate, beats/min	0 (0 to 106.0)	99.0 (24.0 to 129.0)	0 (0 to 69.5)	<.001
Shock index	0 (0 to 1.2)	1.0 (0.2 to 1.6)	0 (0 to 0.7)	<.001
GCS	3.0 (3.0 to 3.0)	3.0 (3.0 to 7.0)	3.0 (3.0 to 3.0)	<.001
CPR, No. (%)	449 (45.4)	94 (30.7)	355 (51.9)	<.001
CPR duration, No. (%)				
60 min or more	16 (1.7)	6 (2.0)	10 (1.5)	<.001
<60 min	387 (41.0)	79 (26.6)	308 (47.6)	
Not applicable	541 (57.3)	212 (71.4)	329 (50.9)	
Laboratory tests				
Hemoglobin, g/dL	11.0 (9.2 to 12.5)	11.0 (9.4 to 12.3)	11.0 (8.9 to 12.6)	.82
Prothrombin INR	1.6 (1.3 to 2.2)	1.6 (1.2 to 2.0)	1.7 (1.3 to 2.4)	.04
Base excess, mEq/L	−14.0 (−20.0 to −8.0)	−11.5 (−16.0 to −8.0)	−16.0 (−23.0 to −9.5)	<.001
Lactate, mmol/L	9.3 (6.0 to 14.3)	8.3 (4.9 to 12.1)	11.3 (7.2 to 15.2)	<.001

(continued)

longer transportation times from injury to ED (eTable in the Supplement). The outcomes were very similar between the matched and unmatched groups.

Multivariate Analysis

After adjustment for statistically significant confounders (TBI, severe chest injury, severe pelvic injury, admission GCS, CPR on arrival, AO initial GCS), RT was associated with significantly higher mortality than REBOA zone 1 (adjusted relative risk [aRR], 1.25; 95% CI, 95% CI, 1.15-1.36) in the overall study sample (**Table 3**). Subgroup confounder-adjusted analyses (Table 3) showed higher mortality associated with RT compared with REBOA zone 1 in all stratified analyses, reaching statistical significance in both blunt and penetrating injuries, as well as in other subgroups, including patients not requiring CPR on arrival and without severe TBI, as well as in those with severe chest injury (isolated or in combination with other injuries, regardless of blunt or penetrating mechanism). There were

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Table 1. Characteristics of the Population Studied (continued)

Characteristic	Median (IQR) or No. (%)			*P* value
	Total (n = 991 [100%])	REBOA zone 1 (n = 306 [30.9%])	Resuscitative thoracotomy (n = 685 [69.1%])	
AO characteristics, No. (%)				
CPR during AO	507 (51.7)	114 (37.5)	393 (58.1)	<.001
AO initial SBP, mm Hg	0 (0 to 40.0)	53.0 (0 to 70.0)	0	<.001
AO initial SBP ≤60 mm Hg	154 (17.3)	116 (41.0)	38 (6.3)	<.001
AO initial GCS	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	<.001
AO performer = trauma surgeon	706 (72.5)	239 (81.3)	467 (68.7)	<.001
Hemodynamic improvement	440 (45.1)	220 (72.6)	220 (32.7)	<.001
Hemodynamic stability[b]	256 (26.4)	108 (16.1)	148 (49.2)	<.001
SBP after first AO, mm Hg	0 (0 to 107.0)	105.0 (71.5 to 126.0)	0 (0 to 51.5)	<.001
GCS after first AO	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	<.001
First AO duration, min	20.0 (9.0 to 48.0)	30.0 (12.0 to 70.0)	15.0 (8.0 to 36.0)	<.001
Second AO needed	51 (6.0)	17 (6.0)	34 (6.1)	.99
Second AO type				
Endovascular	28 (54.9)	9 (52.9)	19 (55.9)	.84
Open	23 (45.1)	8 (47.1)	15 (44.1)	
Minutes to start first AO	5.0 (2.0 to 13.0)	14.0 (7.0 to 23.0)	3.0 (2.0 to 7.0)	<.001
Minutes to first successful AO	11.0 (6.0 to 20.0)	20.0 (13.0 to 31.0)	7.0 (5.0 to 12.0)	<.001
Transfusions, fluids, inotropes, and TXA in first 24 h				
Red blood cell units	6.0 (3.0 to 17.0)	12.0 (4.0 to 26.0)	5.0 (2.0 to 12.0)	<.001
Plasma units	4.0 (2.0 to 13.0)	8.0 (3.0 to 21.0)	3.0 (1.0 to 8.0)	<.001
Platelets units	1.0 (0 to 3.0)	2.0 (0 to 5.0)	0 (0 to 3.0)	<.001
Cryoprecipitate units	0 (0)	0 (0 to 1.0)	0 (0 to 0.0)	.001
TXA, No. (%)	221 (28.5)	93 (34.3)	128 (25.4)	.01
Complications and outcomes, No. (%)				
Acute kidney injury	70 (7.1)	48 (15.7)	22 (3.2)	<.001
Acute lung injury	50 (5.0)	24 (7.8)	26 (3.8)	.01
Multiple organ failure	28 (2.8)	18 (5.9)	10 (1.5)	<.001
Pneumonia	40 (4.0)	22 (7.2)	18 (2.6)	<.001
Sepsis	37 (3.7)	31 (10.1)	6 (0.9)	<.001
Stroke	7 (0.7)	3 (1.0)	4 (0.6)	.49
Spinal ischemia with neurodeficit	3 (0.3)	2 (0.7)	1 (0.1)	.18
Vascular reconstruction	27 (8.8)	27 (10.1)	0	.03
Extremity ischemia	11 (1.1)	10 (3.3)	1 (0.1)	<.001
Amputation	4 (0.4)	4 (1.3)	0	.01
Ventilation days	1.0 (0 to 1.0)	1.0 (1.0 to 4.0)	1.0 (0 to 1.0)	<.001
VFD	0 (0)	0 (0 to 0.5)	0 (0 to 0.0)	<.001
VFD >0	100 (10.2)	76 (25.0)	24 (3.5)	<.001
ICU days	0 (0 to 1.0)	1.0 (0 to 5.0)	0 (0)	<.001
ICU-free days	0 (0 to 0.0)	0 (0 to 0.0)	0 (0)	<.001
ICU-free days >0	99 (10.0)	74 (24.3)	25 (3.7)	<.001
Discharge GCS (survivors only)	15.0 (15.0 to 15.0)	15.0 (15.0 to 15.0)	15.0 (15.0 to 15.0)	.16
Discharge GCS = 15 (survivors only)	87 (84.5)	68 (87.2)	19 (76.0)	.18
Discharge GOS	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	<.001
Discharge GOS ≥5	29 (3.1)	22 (8.3)	7 (1.0)	<.001
Discharge disposition				
Home	55 (5.5)	36 (11.8)	19 (2.8)	<.001
Mortality	869 (87.7)	218 (71.2)	651 (95.0)	
Rehabilitation/nursing facility	67 (6.8)	52 (17.0)	15 (2.2)	
Death	870 (87.8)	218 (71.2)	652 (95.2)	<.001

(continued)

very few patients with pelvic injuries thus precluding a meaningful analysis, but a statistically significant survival benefit was detected among patients without severe pelvic trauma. Patients with SBP of 60 mm Hg or less benefited significantly from REBOA zone 1 compared with those subjected to RT.

Prognostic Indicators in REBOA Zone 1 and RT AO

Significant independent predictors of death in REBOA zone 1 AO were as follows: TBI (aRR, 1.20; 95% CI, 1.01-1.43), admission GCS (aRR, 0.95; 95% CI, 0.91-0.98), CPR on arrival (aRR, 1.16; 95% CI, 1.04-1.30), CPR during AO (aRR, 1.23; 95% CI,

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Table 1. Characteristics of the Population Studied (continued)

Characteristic	Median (IQR) or No. (%)			*P* value
	Total (n = 991 [100%])	REBOA zone 1 (n = 306 [30.9%])	Resuscitative thoracotomy (n = 685 [69.1%])	
Death location				
ED	504 (57.9)	83 (38.1)	421 (64.6)	<.001
ICU	161 (18.5)	86 (39.4)	75 (11.5)	
Interventional radiology	3 (0.3)	2 (0.9)	1 (0.2)	
Operating room	201 (23.1)	47 (21.6)	154 (23.6)	

Abbreviations: AIS, abbreviated injury score; AO, aortic occlusion; AORTA, Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery; BMI, body mass index; CPR, cardiopulmonary resuscitation; ED, emergency department; GCS, Glasgow Coma Scale; GOS, Glasgow Outcome Score; ICU, intensive care unit; INR, international normalized ratio; SBP, systolic blood pressure; TXA, tranexamic acid; VFD, ventilation-free days.

SI conversion factor: To convert hemoglobin from gram per deciliter to gram per liter, multiply by 10; to convert base excess from milliequivalent per liter to millimole per liter, multiply by 1; to convert lactate from millimole per liter to milligram per deciliter, divide by 0.111.

[a] Calculated as weight in kilograms divided by height in meters squared.

[b] Defined for the purposes of the AORTA registry systolic blood pressure consistently greater than 90 mm Hg for at least 5 minutes after AO.

1.13-1.33), and AO initial GCS (aRR, 0.89; 95% CI, 0.83-0.96). The only significant predictor of death in RT AO was prehospital CPR (aRR, 1.07; 95% CI, 1.05-1.09).

Discussion

Results of this contemporaneous comparative effectiveness research study of the multicenter AORTA registry suggest that AO with REBOA zone 1 resulted in overall better survival compared with RT. This survival benefit was observed in all subgroups, reaching significance in several of them. More importantly, in none of the stratified analyses was REBOA zone 1 AO significantly inferior to RT. This included the subgroup with penetrating chest injuries, traditionally considered a REBOA contraindication.

The current study is in line with other recent studies reporting a survival benefit of ED REBOA over ED RT in the US as well as in other countries.[8-10,12,14,17,18,20,21] A recent meta-analysis[22] observed a similar benefit. These are in contrast with the US study by Joseph at al[11] and 2 studies using the Japan Trauma Data Bank,[9,23] which found REBOA to be associated with higher mortality. However, the former specifically excluded patients undergoing RT, which would be the alternative therapeutic approach for these patients. The latter did not specify what were the therapies used in the comparison group, and Inoue et al[23] excluded patients requiring CPR on arrival, among whom AO can be a lifesaving procedure. We believe these choices of comparison groups and sampling strategies have hindered the assessment of the effectiveness of AO by REBOA. Our study advances the knowledge brought by these latter studies for several reasons: (1) it used a more contemporary data set; (2) the AORTA registry was developed specifically to assess the outcomes of AO modalities and contains the required data granularity to do so, as opposed to data sets/registries developed for nonspecific quality improvement purposes; (3) our comparison group was the current alternative AO approach (as opposed to the patients who did not require AO); (4) our study specifically compared REBOA zone 1 AO (ie, excluding zones 2 and 3), an information that is missing in most data sets; and (5) our sample included patients requiring CPR on arrival, for whom AO can be lifesaving. In addition, our study is, to our knowledge, the only one to require exact matching on institution, an essential step to avoid comparing different institutions as opposed to different procedures, especially when the indication of either treatment varies widely by institution.

There are several potential benefits that may explain the improved survival with REBOA over RT. After traumatic circulatory arrest, CPR is critical to the return of spontaneous circulation. Teeter et al[24] demonstrated that the total duration of interruptions of cardiac compressions was shorter for REBOA vs RT, before and during resuscitation with AO. The same group showed that REBOA patients who underwent closed chest compression had a higher rate of return of spontaneous circulation and higher end-tidal carbon dioxide than patients who underwent RT with open cardiac massage.[25] The availability of partial REBOA inflation may mitigate the detrimental effects of complete aortic occlusion such as supraphysiologic proximal pressure, increased cardiac afterload, and distal visceral ischemia.[26,27] In patients who attain return of spontaneous circulation, the ability to incrementally decrease balloon volume in REBOA may also allow for safer and more controlled restoration of aortic blood flow.

REBOA has complications with arterial access (eg, pseudoaneurysm) and ischemia-reperfusion complications (eg, arterial thromboses, lower extremity amputation, and kidney failure).[28,29] The assessment of post-AO complications are subject to survivor bias, and although competing risk analytic methods can minimize this effect, they do not eliminate it. Only through randomized clinical trials (RCTs) would a more definitive assessment of the complications of REBOA compared with RT be possible.

From a health care professional standpoint, RT is a high-risk procedure. Use of scalpels and studded Finochietto retractors in an emergency setting, can result in percutaneous injury to the performer.[30] A prospective multiinstitutional study found a 7.2% exposure rate per RT and 1.6% per RT participant.[4] Given the elevated rates of HIV (4.3%) and HCV (14%) in trauma patients,[4] the exposure from RT may have significant health consequences to the health care team.

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Table 2. Characteristics of Propensity Score–Matched Patients

Characteristic	Median (IQR)			*P* value	SMD[a]
	Total (n = 112)	REBOA zone 1 (n = 56)	Resuscitative thoracotomy (n = 56)		
Facility annual patient volume, No. (%)					
1000-2000	8 (7.1)	4 (7.1)	4 (7.1)	<.99	0
>2000-3000	12 (10.7)	6 (10.7)	6 (10.7)		0
>3000	92 (82.1)	46 (82.1)	46 (82.1)		0
Age, y	37.5 (27.0 to 52.5)	40.0 (27.0 to 57.0)	35.5 (26.5 to 51.5)	.42	2.0
Male sex	87 (77.7)	44 (78.6)	43 (76.8)	.82	4.3
BMI[b]	26.0 (24.2 to 30.0)	26.1 (24.3 to 30.4)	25.9 (24.1 to 29.3)	.65	−0.4
Injury characteristics, No. (%)					
Blunt mechanism	76 (67.9)	41 (73.2)	35 (62.5)	.22	23.1
Injury Severity Score	29.0 (17.5 to 41.0)	28.0 (19.5 to 39.5)	30.0 (17.5 to 41.0)	<.99	0
Head AIS	0 (0 to 3.0)	0 (0 to 3.0)	0 (0 to 3.0)	.91	0
Traumatic brain injury	37 (33.0)	18 (32.1)	19 (33.9)	.84	3.8
Chest AIS	3.0 (0 to 4.0)	3.0 (0 to 4.0)	3.0 (0 to 4.0)	.90	0
Severe chest injury	65 (58.0)	34 (60.7)	31 (55.4)	.57	10.8
Abdomen AIS	2.5 (0 to 4.0)	2.0 (0 to 4.0)	3.0 (0 to 4.0)	.67	0
Severe abdomen injury	56 (50.0)	27 (48.2)	29 (51.8)	.71	7.2
Pelvis AIS	0	0	0	.70	0
Severe pelvic injury	2 (1.8)	1 (1.8)	1 (1.8)	<.99	0
Extremity AIS	0	0	0	.78	0
Severe extremity injury	7 (6.3)	3 (5.4)	4 (7.1)	.70	7.0
Prehospital					
SBP, mm Hg	82.0 (0 to 128.0)	86.0 (27.0 to 132.0)	80.0 (0 to 110.0)	.35	−7.0
Heart rate, beats/min	96.5 (70.0 to 130.0)	95.0 (68.0 to 137.0)	96.5 (72.0 to 121.0)	.66	−3.0
GCS	3.0 (3.0 to 10.0)	3.5 (3.0 to 10.5)	3.0 (3.0 to 9.0)	.24	0
CPR, No. (%)	37 (33.0)	18 (32.1)	19 (33.9)	.84	3.8
Minutes from injury to ED	48.0 (28.0 to 70.0)	50.0 (28.0 to 75.0)	46.0 (27.0 to 65.0)	.52	−3.0
Hospital admission					
SBP, mm Hg	66.5 (0 to 105.0)	61.0 (0 to 105.5)	69.0 (0 to 101.5)	.98	0
Heart rate, beats/min	88.0 (0 to 114.0)	95.0 (0 to 123.5)	82.0 (0 to 105.0)	.19	−7.0
GCS	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	.75	0
CPR, No. (%)	38 (33.9)	19 (33.9)	19 (33.9)	<.99	0
CPR duration <60 min, No. (%)	29 (27.9)	16 (30.2)	13 (25.5)	.53	10.5
Hospital admission laboratory tests					
Hemoglobin, g/dL	11.2 (8.9 to 12.8)	11.8 (9.0 to 13.1)	10.7 (8.4 to 12.6)	.26	−0.8
Prothrombin INR	1.6 (1.4 to 2.2)	1.6 (1.4 to 2.2)	1.6 (1.4 to 2.1)	.78	0
Base deficit, mEq/L	−12.0 (−20.0 to −9.0)	−12.0 (−16.0 to −8.0)	−12.5 (−24.0 to −10.0)	.20	−3.0
AO characteristics, No. (%)					
CPR during AO	62 (55.4)	31 (55.4)	31 (55.4)	<.99	0
AO initial SBP, mm Hg	0 (0 to 51.0)	0 (0 to 53.5)	0	.05	0
AO initial SBP <60 mm Hg	19 (17.0)	8 (14.3)	11 (19.6)	.45	14.2
AO initial GCS	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	<.99	0
AO performer = trauma surgeon	84 (75.0)	40 (71.4)	44 (78.6)	.38	16.7
Hemodynamic improvement	67 (59.8)	38 (67.9)	29 (51.8)	.08	33.3
Hemodynamic stability[c]	37 (33.0)	22 (39.3)	15 (26.8)	.16	26.8
SBP post first AO, mm Hg	64.0 (0 to 110.0)	90.0 (0.0 to 115.0)	0 (0 to 98.0)	.02	−20.0
GCS post first AO	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	3.0 (3.0 to 3.0)	.34	0
First AO duration, min	26.0 (11.0 to 45.0)	28.0 (11.0 to 41.0)	20.0 (11.0 to 45.0)	.68	−1.5
Second AO needed	8 (7.7)	4 (7.7)	4 (7.7)	<.99	0
Second AO type					
Endovascular	5 (62.5)	2 (50.0)	3 (75.0)	.47	53.5
Open	3 (37.5)	2 (50.0)	1 (25.0)		53.5
Minutes to start first AO	11.0 (4.0 to 21.0)	14.0 (6.0 to 24.0)	8.0 (4.0 to 16.0)	.01	5.0
Minutes to successful first AO	17.0 (11.0 to 26.0)	21.0 (13.5 to 30.0)	12.0 (8.0 to 19.0)	<.001	−8.0

(continued)

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Table 2. Characteristics of Propensity Score–Matched Patients (continued)

Characteristic	Median (IQR)			*P* value	SMD[a]
	Total (n = 112)	REBOA zone 1 (n = 56)	Resuscitative thoracotomy (n = 56)		
Transfusions, fluids, inotropes, and TXA in the first 24 h					
Red blood cell units	9.0 (4.0 to 22.5)	9.5 (4.0 to 23.0)	8.5 (4.0 to 22.0)	.89	0
Plasma units	6.0 (2.0 to 18.0)	5.0 (3.0 to 19.0)	6.0 (2.0 to 17.5)	.99	0
Platelets units	1.0 (0 to 5.0)	1.0 (0.0 to 3.5)	1.0 (0 to 6.0)	.31	0
Cryoprecipitate units	0	0	0	.42	0
TXA, No. (%)	25 (24.0)	13 (25.5)	12 (22.6)	.73	6.8
Complications and outcomes, No. (%)					
Acute kidney injury	11 (9.8)	6 (10.7)	5 (8.9)	.75	6.1
Acute lung injury	7 (6.3)	3 (5.4)	4 (7.1)	.70	7.0
Pneumonia	6 (5.4)	3 (5.4)	3 (5.4)	<.99	0
Sepsis	4 (3.6)	3 (5.4)	1 (1.8)	.31	19.4
Stroke	2 (1.8)	0	2 (3.6)	.15	346.0
Multiple organ failure	2 (1.8)	1 (1.8)	1 (1.8)	<.99	0
Spinal ischemia with neurodeficit	0	0	0	NA	0
Extremity ischemia	1 (0.9)	1 (1.8)	0	.32	380.1
Amputation	0	0	0	NA	0
Ventilation days	1.0 (0 to 1.0)	1.0 (1.0 to 2.0)	1.0 (0 to 1.0)	.14	0
VFD	0 (0 to 0.0)	0	0	.07	0
VFD >0	14 (12.7)	10 (18.5)	4 (7.1)	.07	34.6
ICU days	0 (0 to 1.5)	1.0 (0 to 3.0)	0 (0 to 1.0)	.01	0
ICU-free days	0	0	0	.07	0
ICU-free days >0	14 (12.6)	10 (18.2)	4 (7.1)	.08	33.9
Discharge GCS (survivors only)	15.0 (15.0 to 15.0)	15.0 (15.0 to 15.0)	15.0 (13.0 to 15.0)	.92	0
Discharge GCS = 15 (survivors only)	3 (21.4)	2 (20.0)	1 (25.0)	.84	12.0
Discharge GOS	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	.29	0
Discharge GOS ≥5	6 (5.6)	4 (7.5)	2 (3.6)	.38	17.1
Discharge disposition					
Home	9 (8.0)	7 (12.5)	2 (3.6)	.09	33.2
Mortality	96 (85.7)	44 (78.6)	52 (92.9)		41.8
Rehab/nursing facility	7 (6.3)	5 (8.9)	2 (3.6)		22.0
Death	96 (85.7)	44 (78.6)	52 (92.9)	.03	41.8
Survival hours	2.0 (1.0 to 48.0)	6.0 (1.0 to 288.0)	1.8 (1.0 to 4.0)	.02	1.0
Death location					
NA	16 (14.3)	12 (21.4)	4 (7.1)	.05	41.8
Emergency department	42 (43.8)	21 (47.7)	21 (40.4)		14.7
ICU	24 (25.0)	15 (34.1)	9 (17.3)		39.2
Operating room	29 (30.2)	8 (18.2)	21 (40.4)		50.3

Abbreviations: AIS, abbreviated injury score; AO, aortic occlusion; AORTA, Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery; BMI, body mass index; CPR, cardiopulmonary resuscitation; ED, emergency department; GCS, Glasgow Coma Scale; GOS, Glasgow Outcome Score; ICU, intensive care unit; INR, international normalized ratio; SBP, systolic blood pressure; SMD, standardized mean difference; TXA, tranexamic acid; VFD, ventilation-free days.

SI conversion factor: To convert hemoglobin from gram per deciliter to gram per liter, multiply by 10; to convert base excess from milliequivalent per liter to millimole per liter, multiply by 1; to convert lactate from millimole per liter to milligram per deciliter, divide by 0.111.

[a] SMD ideal less than 0.20 for confounders.

[b] Calculated as weight in kilograms divided by height in meters squared.

[c] Defined for the purposes of the AORTA registry as systolic blood pressure consistently greater than 90 mm Hg for at least 5 minutes after AO.

Although our findings pertain primarily to civilian trauma, they support recommendations for the use of REBOA in military settings, especially in austere environments where RT is not a viable alternative. Several studies assessed REBOA in combat settings, albeit with limited sample sizes (<20).[31] The 2020 Joint Trauma System REBOA practice guideline acknowledges the successful use of REBOA in austere military locations, especially for triage of multiple casualties.[32-34]

Limitations

Our study has limitations. The propensity score matching excluded a large proportion of the individuals, indicating the 2 procedures are indicated for substantially different types of injury patterns and limiting the conclusions about the comparative effectiveness and safety of the 2 AO procedures. Overall matched patients presented with less severe physiologic derangement than unmatched patients, thus suggesting that

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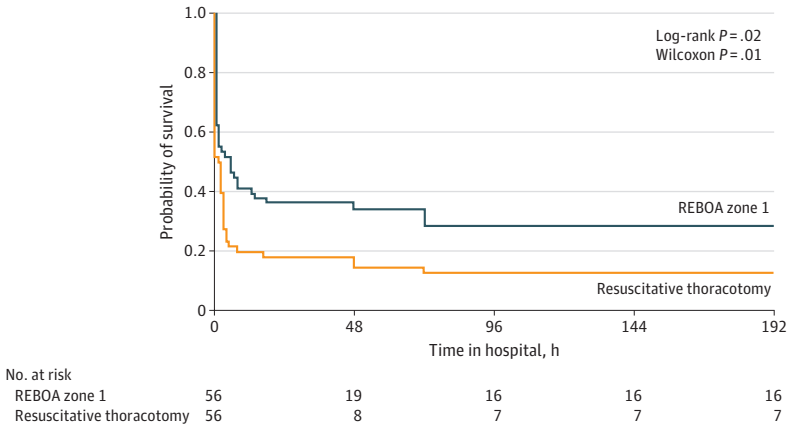
Figure 2. Survival Curves for Propensity Score–Matched Patients (n = 112)



No. at risk

REBOA zone 1	56	19	16	16	16
Resuscitative thoracotomy	56	8	7	7	7

Resuscitative endovascular balloon occlusion of the aorta (REBOA) aortic occlusion had a significantly higher patient survival than aortic occlusion via resuscitative thoracotomy.

Table 3. Multivariate Analysis for Outcome Death for the Overall Study Sample and for Prespecified Subgroups[a]

Outcome	No. RT	No. REBOA zone 1	Adjusted relative risk (95% CI)	*P* value
Overall sample	685	306	1.25 (1.15-1.36)	<.001
Required CPR on arrival				
Yes	355	94	1.05 (0.80-1.37)	.72
No	329	212	1.43 (1.22-1.68)	<.001
Traumatic brain injury				
Yes	93	118	1.04 (0.98-1.10)	.19
No	592	188	1.35 (1.11-1.64)	.003
Chest injury				
Severe	403	174	1.30 (1.16-1.45)	<.001
Penetrating	289	19	1.49 (1.16-1.91)	.002
Isolated severe	234	38	1.34 (1.01-1.77)	.04
No severe	282	132	1.14 (0.86-1.52)	.37
Pelvic injury				
Severe	5	9	NA	
No severe	676	301	1.24 (1.11-1.38)	<.001
Mechanism				
Blunt	184	240	1.22 (1.11-1.34)	<.001
Penetrating	501	64	1.36 (1.25-1.47)	<.001
AO initial SBP, mm Hg				
>60	38	116	1.44 (0.92-2.27)	.11
≤60	570	167	1.18 (1.07-1.31)	.001

Abbreviations: CPR, cardiopulmonary resuscitation; NA, not applicable; REBOA, resuscitative endovascular balloon occlusion of the aorta; RT, resuscitative thoracotomy.

[a] All multivariate models adjusted for significant confounders unless confounder was the stratification variable (traumatic brain injury, severe chest injury, severe pelvic injury, admission Glasgow Coma Scale, CPR on arrival, aortic occlusion initial Glasgow Coma Scale).

matching did not select a representative sample. Multivariate analyses in the overall sample and in each analyzed subgroup, however, confirmed the results of the matched group. Moreover, the subgroup analyses showed that REBOA zone 1 consistently resulted in similar or superior outcomes than RT. We were limited in the assessment of post-AO complications as they were subject to survivor bias. Because the AORTA registry (as most of the current trauma data sets) does not yet include the date of the complication, the appropriate analytic approach (competing risk analysis) was not possible. Although this is a prospective registry, we anticipate that at least some of the data may not be obtained in real time, thus potentially subject to recall bias. Finally, our findings were generated in US institutions with ample experience with both REBOA placement and RT; thus, their generalizability is limited to centers with similar skills set and trauma care systems. For example, in US level I trauma centers, trauma surgeons take call in-house, whereas in other health care systems, trauma surgeons may not be immediately available.

Overall, these limitations do not preclude the conclusion that equipoise was sufficiently established, thus permitting an RCT. Such an RCT will require the coordination of multiple trauma centers, appropriate training of all REBOA operators, and standardization of several processes and procedures (both within and between institutions). Given the severity of the eligible cases, this will need to be conducted as emergency re-

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search with a waiver of consent. Randomization may require alternative methods, such as the system used by the Denver group in testing the effectiveness of goal-directed hemostatic resuscitation (ie, alternate weeks for each study group).[35] Such a trial would be labor intensive, costly, and long lasting to accrue the sample size necessary to allow stratifications by injury pattern with adequate statistical power. We recognize, therefore, that the likelihood of such a trial is not high, given its magnitude and current competing interests and conditions (eg, COVID-19 pandemic, monkeypox public health emergency, climatic changes). Thus, we believe our study, given its rigor in data collection, sampling strategy and statistical analysis, contributes to what has been labeled focused empiricism, ie, using the best data available to make incremental changes until more powerful study designs can be conducted.[36,37]

Conclusions

Results of this comparative effectiveness research study suggest that overall and in all subgroups of injury and physiologic patterns, REBOA was associated with a similar or better survival benefit compared with RT. These findings suggest that in critically injured patients requiring AO due to severe hemorrhagic shock who are admitted to trauma systems with immediate availability of skilled, experienced trauma surgeons, REBOA may be an effective alternative to RT. In addition, the collective body of evidence justifies the ethical requirement of equipoise for the planning of an RCT to provide more definitive answers, while contributing to the current body of knowledge regarding emergency aortic occlusion for severe traumatic hemorrhage.

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Invited Commentary

Focused Empiricism and the Efficacy of Resuscitative Endovascular Balloon Occlusion of the Aorta

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Nearly half of patients who arrive at US trauma centers with hemoperitoneum and hypotension and one-quarter of service members killed in combat die just from blood loss and hemorrhagic shock.[1-3] The age-old, surgeon-centric approach of quickly getting to the operating room works for most but not all patients. These stubborn statistics, along with the evolution of less invasive endovascular techniques used for other conditions, have resulted in a reappraisal of resuscitative endovascular balloon occlusion of the aorta (REBOA).[4]

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The emergence of REBOA has disrupted practice paradigms and been accompanied by calls for "high-quality" data to prove its merit.[4] Despite the known or empirical benefit of aortic occlusion to increase proximal pressure, decrease distal bleeding, and delay onset of a fatal dysrhythmia, skeptics and those unaccustomed to endovascular procedures have used the paucity of high-quality data to refute REBOA. Although the search for therapeutic evidence should remain a guiding principle, such high-quality data support very few of the lifesaving interventions performed during trauma resuscitations and emergent operations today.

In a 2016 report, the National Academy of Medicine (NAM) highlighted the military's use of focused empiricism as a method to advance care in settings for which there is no national funding or in which it is impractical to perform randomized controlled trials.[5,6] Acknowledging that innovation must still occur, even in such difficult clinical settings, the NAM lauded the military's use of practical observations and the best information available to make changes within a system of per-

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