Original Article

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Comparison of 7 and 11–12 French Access for REBOA: Results from the AAST Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry

Joseph J DuBose MD[1], Jonathan Morrison MD[2], Megan Brenner MD[2], Laura Moore MD[3], John B Holcomb MD[3], Kenji Inaba MD[4], Jeremy Cannon MD[5], Mark Seamon MD[5], David Skarupa MD[6], Ernest Moore MD[7], Charles J Fox MD[7], Joseph Ibrahim MD[8], Thomas M Scalea MD[2]; and the AAST AORTA Study Group

[1]Uniformed Services University of the Health Sciences, Washington, DC, USA
[2]University of Maryland Medical R Adams Cowley Shock Trauma Center, Baltimore, MD, USA
[3]University of Texas Health Sciences Center, Houston, TX, USA
[4]Los Angeles County + University of Southern California, Los Angeles, CA, USA
[5]University of Pennsylvania, Philadelphia, PA, USA
[6]University of Florida – Jacksonville, Jacksonville, FL, USA
[7]Denver Health & University of Colorado, Denver, CO, USA
[8]Orlando Regional Medical Center, Orlando, FL, USA

Background: The introduction of low-profile devices designed for resuscitative endovascular balloon occlusion of the aorta (REBOA) after trauma has the potential to change practice, outcomes, and complication profiles.
Methods: The AAST Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry was used to identify REBOA patients from 16 centers. Presentation, intervention, and outcome variables were compared via traditional 11–12 French access platforms and trauma-specific devices requiring only 7 French access.
Results: From November 2013 to December 2017, 242 patients with complete data were identified, constituting 124 7 French and 118 11–12 French uses. Demographics of presentation were not different between the two groups, except that patients using the 7 French had a higher mean Injury Severity Score (39.2 vs. 34.1, $p = 0.028$). The 7 French was associated with a lower cut-down requirement for access (22.6% vs. 37.3%, $p = 0.049$) and increased ultrasound guidance utilization (29.0% vs. 23.7%, $p = 0.049$). The 7 French afforded earlier aortic occlusion in the course of resuscitation (median 25.0 mins vs. 30 mins, $p = 0.010$) and a lower median requirement of packed red blood cells (10.0 vs. 15.5 units, $p = 0.006$) and fresh frozen plasma (7.5 vs. 14.0 units, $p = 0.005$). The 7 French patients were more likely to survive 24 h (58.1% vs. 42.4%, $p = 0.015$) and less likely to suffer in-hospital mortality (57.3% vs. 75.4%, $p = 0.003$). Finally, the 7 French device was associated with a four times lower rate of distal extremity embolism (20.0% vs. 5.6%, $p = 0.014$; OR 95% CI 4.25 [1.25–14.45]) compared to the 11–12 French.

Corresponding author:
Joe DuBose, MD, FACS, FCCM, 22 South Greene Street, Baltimore, MD 21201, USA.
Email: jjd3c@yahoo.com

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Conclusions: The introduction of trauma-specific 7 French REBOA devices appears to have influenced REBOA practices, with earlier use in severely injured hypotensive patients via less invasive means that are associated with lower transfusion requirements, fewer thrombotic complications, and improved survival. Additional study is required to determine optimal REBOA use.

Keywords: *REBOA; Trauma; Aortic Occlusion; Injury; Hemorrhage*

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INTRODUCTION

Endovascular technologies continue to evolve as modalities that can be effectively employed in the treatment of the severely injured. Resuscitative endovascular balloon occlusion of the aorta (REBOA), in particular, has emerged as a potentially important temporizing tool for select patients who exhibit significant hemorrhage from non-compressible sites and do not respond adequately to initial resuscitation [1–9]. Continued research remains vital to better understand the optimal utilization of this modality. There remains a need to better identify optimal training requirements and elucidate both ideal patient selection for use and define optimal practices related to patient management after associated aortic occlusion.

The American Association for the Surgery of Trauma (AAST) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry is one important effort devised to contribute to ongoing research in this area [2,4]. This prospective, multicenter registry is designed to capture details regarding patient demographics, physiology, and outcomes following aortic occlusion in the setting of trauma. In addition, the data collection from this source captures key data elements specific to aortic occlusion procedures that cannot be collected from traditional trauma registry sources.

As part of the data collection for the AORTA registry, specific data is captured on the types of access employed and devices utilized. Since the initiation of the registry in 2013, there have been several changes in the availability of devices that may be employed for the purpose of REBOA. In particular, the FDA approval of a wire-free, trauma-specific device in 2015 has resulted in a dynamic shift in practice patterns at most centers employing REBOA as a resuscitative tool. The introduction of 7 French wire-free devices, theoretically, represents a major improvement over the utilization of older devices – which involve additional steps for sheath and wire exchange and also require 11–12 French access at a minimum for use.

The purpose of our present study was to utilize the AORTA registry to compare results with REBOA use between older 11–12 French devices and newer 7 French access systems. It was our hypothesis that the newer, smaller diameter systems would improve time to aortic occlusion and potentially mitigate the risk for distal thromboembolic events of the lower extremities relative to their larger profile predecessors [10–13].

MATERIALS AND METHODS

The Prospective Observational Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) study was approved by the American Association for the Surgery of Trauma (AAST) Multicenter Trials Committee. All presently reported data were obtained from centers within North America that are either American College of Surgeons verified Level I/Level II Trauma centers or are active Canadian trauma centers. All collaborating centers have obtained individual local Institutional Board Review approval prior to participation. Data are collected prospectively and entered by registrars designated by individual centers into the online data collection portal resource developed by the AAST.

For the purposes of our present examination, the AORTA registry was queried to capture all adult (age >17) patients undergoing documented REBOA following trauma from November 2013 to December 2017. The final access size required for the conduct of REBOA was utilized to divide patients into either 7 French or 11–12 French categories. These groups were then compared relative to demographics, procedural elements of REBOA and outcomes – including complications.

Values are reported as means ± standard deviation (SD) for continuous variables with normal distributions as determined by the assessment of skewness calculation. For those continuous variables not possessing a normal distribution median values and interquartile range were utilized. Categorical variables are expressed as percentages. Groups were compared using chi-squared analysis and Student's *t* tests. Statistical significance was set at greater than $p < 0.05$. All analyses were performed using the Statistical Package for Social Sciences (SPSS Mac©), version 22.0 (SPSS Inc, Chicago, IL, USA).

RESULTS

From November 2013 to December 2017, 242 patients with complete data were identified, constituting 124 7 French and 118 11–12 French uses. The mean was 42.3 years and 75.2% were male. Blunt mechanisms of injury predominated, at 77.7% (Table 1). Demographics of presentation were not different between the two groups, except that the 7 French patients had a higher mean Injury Severity Score (ISS) (39.2 vs. 34.1, $p = 0.028$) and a higher mean GCS at arrival (6.9 vs. 5.6, $p = 0.039$).

Table 1 Comparison of 7 French and 11–12 French device utilization groups from the AORTA registry.

	Total	*7 French*	*11–12 French*	*p-Value*
	N = 242	*N = 124*	*N = 118*	
Age, mean (± SD)	42.3 (18.3)	41.9 (17.6)	42.6 (19.0)	0.798
Male, % (*n*)	75.2% (182)	75.8% (94)	74.6% (88)	0.825
Blunt mechanism, % (*n*)	77.7% (188)	76.6% (95)	78.8% (93)	0.706
MVC, % (*n*)	16.5% (40)	13.7% (17)	19.5% (23)	0.498
MCC, % (*n*)	29.3% (71)	30.6% (38)	28.0% (33)	0.498
Auto vs. Ped, % (*n/N*)	24.0% (58)	26.6% (33)	21.2% (25)	0.498
ISS, mean (± SD)	36.5 (16.0)	39.2 (17.2)	34.1 (14.5)	0.028
Head AIS, mean (± SD)	2.6 (2.1)	2.4 (2.1)	2.8 (2.0)	0.189
Chest AIS, mean (± SD)	2.6 (1.6)	2.6 (1.7)	2.6 (1.5)	0.818
Abdomen AIS, mean (± SD)	2.8 (1.7)	3.0 (1.8)	2.6 (1.7)	0.067
Pre-hospital CPR required, % (*n*)	28.9% (70)	28.2% (35)	29.7% (35)	0.806
Admission SBP, mean (± SD); *n*	77.1 (50.3); 239	79.6 (47.1); 123	74.4 (53.6); 116	0.423
Admission HR, mean (± SD); *n*	92.9 (51.9); 232	97.4 (46.9); 116	88.3 (56.3); 116	0.181
Admission GCS, mean (± SD); *n*	6.2 (4.9); 239	6.9 (5.1); 122	5.6 (4.7); 117	0.039
Admission Hgb (mg/dL), mean (± SD); *n*	10.9 (2.4); 192	11.2 (2.5); 104	10.5 (2.2); 88	0.031
Admission pH, mean (± SD); *n*	7.12 (0.18); 166	7.13 (0.18); 97	7.11 (0.19); 69	0.410
Admission lactate, mean (± SD); *n*	8.9 (5.0); 161	8.8 (5.5); 86	9.1 (4.4); 75	0.794
Location of REBOA				
Emergency Department, % (*n*)	81.0% (196)	84.7% (105)	77.1% (91)	0.161
Operating Room, % (*n*)	18.6% (45)	14.5% (18)	22.9% (27)	0.161
Access technique				
Cut-down, % (*n*)	29.8% (72)	22.6% (28)	37.3% (44)	0.049
Percutaneous landmarks, % (*n*)	40.9% (99)	46.8% (58)	34.7% (41)	0.049
Ultrasound guidance, % (*n*)	26.4% (64)	29.0% (36)	23.7% (28)	0.049
Imaging utilized to facilitate balloon positioning				
None/blind using external landmarks only, % (*n*)	33.5% (81)	34.7% (43)	32.2% (38)	0.096
Plain film, % (*n*)	58.3% (141)	58.9% (73)	57.6% (68)	0.096
Fluoroscopy, % (*n*)	3.3% (8)	0.8% (1)	5.9% (7)	0.096
Ultrasound, % (*n*)	3.3% (8)	2.4% (3)	4.2% (5)	0.096
Aortic zone of balloon deployment				
Zone 1, % (*n*)	66.1% (160)	64.5% (80)	67.8% (80)	0.113
Zone 2, % (*n*)	1.7% (4)	0.8% (1)	2.5% (3)	0.113
Zone 3, % (*n*)	30.2% (73)	30.6% (38)	29.7% (35)	0.113
Balloon migration observed, % (*n*)	5.4% (13)	5.6% (7)	5.1% (6)	0.068
Active CPR during REBOA placement, % (*n*)	34.3% (83)	32.3% (40)	36.4% (43)	0.788
AO initiation SBP [mm Hg], mean (± SD); *n*	54.9 (43.5); 217	60.3 (42.6); 114	48.8 (43.8); 103	0.052
Improvement in SBP observed, % (*n*)	75.6% (183)	73.4% (91)	78.0% (92)	0.317
Increase in SBP [mm Hg], Median (IQR); *n*	43.0 (62); 208	43.0 (61); 108	43.5 (75); 100	0.974
Hemodynamic stability achieved, % (*n*)	57.9% (140)	56.5% (70)	59.3% (70)	0.602
Duration of AO (min), median (IQR), *n*	32.0 (55); 185	32.0 (51); 107	37.5 (60); 78	0.153
Time admission to start of AO (min), median (IQR), *n*	17.0 (32); 201	16.0 (21); 117	19.0 (43); 84	0.018
Time admission to successful AO (mins), median (IQR), *n*	25.0 (38); 191	25.0 (23); 112	30 (56); 79	0.010
Time start of procedure to achievement of aortic occlusion (mins), median (IQR), *n*	7.0 (6); 182	7.0 (6); 109	7.0 (8); 73	0.421
Primary performer, Trauma Acute Care Surgeon, % (*n*)	88.4% (214)	93.5% (116)	83.1% (98)	0.011
Resuscitation requirements survivors at least 24 h				
Packed red cells (units), median (IQR), *n*	12.0 (15); 120	10.0 (10); 72	15.5 (24); 48	0.006
FFP (units), median (IQR), *n*	10.0 (14); 119	7.5 (12); 72	14.0 (18); 47	0.005
Associated procedures (patients surviving to reach OR)				
	N = 192	*N = 100*	*N = 92*	
Exploratory laparotomy, % (*n*)	72.9% (140)	73.0% (73)	72.8% (67)	0.978
Hepatic packing, % (*n*)	20.3% (39)	21.0% (21)	19.6% (18)	0.805
Pelvic packing, % (*n*)	20.8% (40)	26.0% (26)	15.2% (14)	0.066

(Continued)

Table 1 Continued.

	Total	*7 French*	*11–12 French*	*p-Value*
Hepatic resection, % (*n*)	5.7 (11)	5.0% (5)	6.5% (6)	0.650
Splenectomy, % (*n*)	17.2% (33)	17.0% (17)	17.4% (16)	0.943
Bowel resection, % (*n*)	19.8% (38)	190.0% (19)	20.7% (19)	0.774
Craniotomy/craniectomy, % (*n*)	3.6% (7)	5.0% (5)	2.2% (2)	0.447
External pelvic fixation, % (*n*)	13.0% (25)	12.0% (12)	14.1% (13)	0.661
Embolization of liver, % (*n*)	3.1% (6)	4.0% (4)	2.2% (2)	0.684
Embolization of pelvis, % (*n*)	9.9% (19)	10.0% (10)	9.8% (0)	0.960
Outcomes survivors at 24 hours				
ICU LOS (days); median (IQR), *n*	11.0 (12); 110	11.0 (13); 72	8.5 (12); 38	0.645
Hospital LOS (days); median (IQR), *n*	19.0 (29); 121	20.0 (25); 71	18.5 (35); 50	0.639
All patients				
Survivors to reach OR/IR, % (*n*)	79.7% (192)	81.3% (100)	78.0% (92)	0.520
Survivors at least 24 hours, % (*n*)	50.4% (122)	58.1% (72)	42.4% (50)	0.015
In-hospital mortality, % (*n*)	66.1% (160)	57.3% (71)	75.4% (89)	0.003
Mortality location				
ED, % (*n*)	20.2% (49)	18.5% (23)	22.0% (26)	0.032
OR, % (*n*)	17.4% (42)	12.9% (16)	22.0% (26)	0.032
ICU, % (*n*)	27.7% (67)	24.2% (30)	31.4% (37)	0.032

AORTA = Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery; SD = standard deviation; MVC = motor vehicle collision; MCC = motorcycle collision; Ped = pedestrian; AIS = abbreviated injury score; CPR = cardiopulmonary resuscitation; Hgb = hemoglobin; AO = aortic occlusion; SBP = systolic blood pressure; IQR = interquartile range; PRBC = packed red blood cells; FFP = fresh frozen plasma; LOS = length of stay; ED = emergency department; OR = operating room; ICU = intensive care unit.

Overall, there was no difference between the two groups with regards to admission physiology or admission laboratory values (Table 1).

The utilization of the 7 French device was associated with a lower rate of femoral cut-down requirement for access (22.6% vs. 37.3%, $p = 0.049$) and increased ultrasound guidance (29.0% vs. 23.7%, $p = 0.049$) for the purpose of arterial access. There were not, however, any significant differences between the two groups relative to the use of imaging to confirm placement, anatomic aortic zones of balloon deployment or hemodynamic response rates.

Time from admission to both the start of aortic occlusion procedure (median 16.0 vs. 19.0 min, $p = 0.018$) and subsequent successful occlusion (median 25.0 vs. 30 min, $p = 0.010$) were both shorter in the 7 French patient group, but there was no discernable difference between the two groups among those patients who had adequately recorded times from the start of procedure to the achievement of aortic occlusion (Table 1).

Among patients surviving at least 24 hours after admission, 7 French utilization was associated with a significant reduction in required units of packed red blood cells (PRBC) (10.0 vs. 15.5 units, $p = 0.006$) for resuscitation, and also lower fresh frozen plasma (FFP) requirements (7.5 vs. 14.0 units, $p = 0.005$) (Table 1). Utilization of the 7 French device was associated with higher rates of survival beyond 24 hours (58.1% vs. 42.4%, $p = 0.015$) and in-hospital mortality was less likely (57.3% vs. 75.4%, $p = 0.003$) compared to 11–12 French utilization.

Among patients surviving at least 24 hours, captured complications were compared. There was no significant difference in systemic complications among survivors. Among local, access specific complications, 7 French device use was associated with a four times lower rate of distal extremity embolism (20.0% vs. 5.6%, $p = 0.014$; OR 95% CI 4.25 [1.25–14.45]) compared to 11–12 French counterparts (Table 2).

DISCUSSION

Advancements in technologies successfully employed in vascular surgery, over the course of the last decade, have increasingly found potential roles in the realm of trauma surgery. REBOA has emerged as a manifestation of this borrowed experience, derived in part from the published success in the utilization of balloon occlusion during endovascular treatment of ruptured abdominal aortic aneurysms [14]. Initial experience, however, was limited by the absence of devices more specifically suited to trauma applications. As such, early experience with REBOA utilization for trauma was characterized by the need to rely upon larger diameter balloon systems which required over-the-wire placement, additional device exchange steps, and the use of larger profile 11 or 12 French femoral access sheaths.

These limitations represented potential major challenges for the use of REBOA in the scenarios most commonly considered as potentially beneficial after trauma. The recent introduction of a trauma-specific device for REBOA applications was designed to mitigate these

Table 2 Comparison of complications between 7 French and 11–12 French device utilization groups. Local complications among patients surviving at least 24 hours.

Complications	*Total (N = 122)*	*7 French (N = 72)*	*11–12 French (N = 50)*	*p-Value*
Hematoma at operative site, % (*n*)	3.3% (4)	2.8% (2)	4.0% (2)	1.000
Femoral pseudoaneursym, % (*n*)	0.8% (1)	0% (0)	2.0% (1)	0.410
Arteriovenous fistula, % (*n*)	1.6% (2)	2.8% (2)	0% (0)	0.512
Extremity ischemia, % (*n*)	4.9% (6)	6.9% (5)	2.0% (1)	0.399
Arterial stenosis, % (*n*)	0.8% (1)	0% (0)	2.0% (1)	0.410
Distal extremity embolism, % (*n*)	11.5% (14)	5.6% (4)	20.0% (10)	0.014
Need for patch angioplasty, % (*n*)	6.6% (8)	2.8% (2)	12.0% (6)	0.063
Need for amputation, % (*n*)	2.5% (3)	4.2% (3)	0% (0)	0.268

AKI = Acute kidney injury; ALI = Acute lung injury; ARDS = Acute respiratory distress syndrome; CVA = cerebrovascular accident.

challenges. The only trauma-specific device presently approved by the FDA for trauma indication is the Prytime ER-REBOA™ catheter. This device is a 7 French compatible balloon catheter with a nitinol reinforced spine and an atraumatic tip that obviates the need for over-the-wire placement. Among other potentially valuable characteristics, this device is also capable of emergent placement without imaging through a 7 French sheath and possesses a useful arterial monitoring port.

The lack of a need for over-the-wire placement represents a theoretical advantage over 11–12 French devices as it relates to the time for positioning and subsequent aortic occlusion in an emergently decompensating patient. Our present examination of early experience with these new devices demonstrates that an appreciable decrease in the time from start of the procedure to the achievement of aortic occlusion has not yet manifested. There was, however, a significant decrease in the time from admission to both the start of the occlusion procedure and subsequent successful occlusion. This finding may represent a decreased time to set-up the procedure with the simpler 7 French device, which requires less equipment to prepare compared to the multi-step exchanges required with 11–12 French access procedures. It may also, however, simply represent a lower threshold to move expediently to the use of 7 French systems due to their potential lower risk profile and perceived increased ease of utilization.

The 7 French group in our present study was also less likely to require open cut-down exposure for femoral artery access and more likely to undergo ultrasound-guided access compared to larger profile device counterparts. The increasing acceptance of ultrasound-guided access as a routine practice, when possible, in the setting of emergent femoral access likely contributes to this finding. In addition, the reticence to proceed to early cut-down with larger diameter devices may have been influenced by the consideration of subsequent closure approaches among survivors. While not well studied in the trauma realm, 7 French access is commonly considered safe for removal without formal suture closure – provided coagulopathy has resolved and an effective period of direct pressure can be applied to the arteriotomy site. In contrast, traditional thought has mandated that 11–12 French access requires open arteriotomy repair. That these larger diameter arteriotomies would require open repair anyway may have contributed to a lower threshold for initial open exposure during placement.

One interesting finding of our review was that patients using the 7 French required fewer PRBCs and FFP compared to larger diameter counterparts. They also appeared to have improved 24 h and in-hospital survival. This would seem to suggest that there may be a benefit in minimizing delays in aortic occlusion in specific trauma patients nearing extremis. Several groups have previously demonstrated similar findings [2,15]. In a recent review of the AORTA database, Brenner and colleagues demonstrated that the patients most likely to achieve survival after aortic occlusion for trauma were those partial or non-responders who had not yet decompensated to the degree that they required CPR after injury [2]. Although significant additional study is required to delineate optimal patient selection and timing for REBOA, existing data indicates that early identification and the expedient use of occlusion early in the course of worsening decompensation achieves the greatest benefit from REBOA.

One of the most striking differences between the 7 French and 11–12 French cohorts in our study was the rate of thrombo-embolic limb complications. Our exploration showed that the 7 French device use was associated with a four times lower rate of distal extremity embolism (20.0% vs. 5.6%, p = 0.014; OR 95% CI 4.25 [1.25–14.45]) compared to the 11–12 French use. The diameter of access may play an even more important role in trauma applications than among patients undergoing access for traditional vascular surgery. In the latter group, patients are almost universally systemically anti-coagulated in a controlled fashion in order to mitigate the risk for distal thromboembolic events in the distal arterial tree of the accessed extremity. While coagulopathy associated with trauma remains a reality among many

severely injured trauma patients, the degree to which this abnormality manifests is not predictable and cannot be relied upon to provide a reliable anticoagulation milieu to achieve a similar protective benefit to the limb. In addition, active resuscitation in these severely injured patients in the modern era almost universally includes balanced ratios of FFP and even platelets as well as tranexamic acid. Accordingly, and in direct contrast to the manipulation of the coagulation system in endovascular interventions for most other indications, trauma team efforts work to promote conditions that should be expected to increase the risk of thromboembolic events distally. This risk is further exacerbated by the small arterial diameter characteristic of many younger trauma victims. For all of these reasons, it is expected that smaller diameter access would be beneficial for use in severe trauma.

It must be recognized, however, that a myriad of additional influences may have also contributed to our findings. Perhaps the most significant is improved training in the employment of endovascular adjuncts by trauma and acute care surgeon providers. The Basic Endovascular Skills for Trauma (BEST) course of the American College of Surgeons was first formally described in the literature in 2014 [16]. This course is constantly updated to reflect evolving understanding and technologies related to the conduct of REBOA. It is now available at several formal sites throughout the United States, where over a thousand providers have been educated and trained in this procedure. A key element of this curriculum is to increase awareness of the risk for distal thromboembolic complications, including discussion of techniques to mitigate the risk of these adverse events. [12]. The degree to which this training has improved practices at individual centers, and subsequently influenced outcomes, is not directly discernable by our present effort.

In addition to the aforementioned considerations, our present study has other limitations that must be acknowledged. The AORTA registry is the largest prospective registry of aortic occlusion patients in existence and captures a granularity of data that is not discernable from other existing sources. Each of the participating centers, however, have varying degrees of experience with this modality. This experience is almost certainly changing over time as well, influenced not only by provider experience but advances in technology and practices that go beyond the introduction of the first FDA approved lower profile device. This fact must be carefully considered in the interpretation of our present report.

There are other distinct elements of care that might contribute to specific complications but are not readily available in the AORTA registry. Most importantly among these may be the lack of granularity regarding sheath use duration, which has significant potential to impact thromboembolism of the limb. Specifically, the registry does not afford the ability to determine how long after REBOA the utilized sheath remained in the common femoral artery. Finally, there is also no uniform protocol for REBOA use across centers. Our findings must be considered in the context of all of these issues.

CONCLUSION

As REBOA continues to evolve as a trauma tool, the introduction of new low-profile devices appears to be associated with earlier use in the course of decompensation and potential benefits with regards to both transfusion requirements and survival. The introduction of lower profile devices appears to mitigate the risk of distal thromboembolic events relative to older, larger diameter-based platforms. Continued research is required, however, to optimize patient selection and the use of REBOA for trauma applications.

CONTRIBUTORS

The AAST Aorta Study Group: Megan Brenner, MD, Thomas M. Scalea, MD, Todd E. Rasmussen, MD, Philip Wasicek, MD, University of Maryland/R Adams Cowley Shock Trauma Center Baltimore, MD, USA; Laura J. Moore, MD, FACS, Jeanette M Podbielski, RN, CCRP, John B. Holcomb, MD, University of Texas Health Sciences Center – Houston, Houston, TX, USA; Kenji Inaba, MD, Los Angeles County + University of Southern California Hospital, Los Angeles, CA, USA; Scott. T. Trexler, MD, Sonya Charo-Griego, RN, Douglas Johnson, LVN, San Antonio Military Medical Center/US Army Institute of Surgical Research San Antonio, TX, USA; Jeremey Cannon, MD; Mark Seamon, MD; Ryan Dumas, MD, University of Pennsylvania, Philadelphia, PA, USA; Charles J. Fox, MD; Eugene Moore, MD, Denver Health and University of Colorado, Denver, Colorado, USA; David Turay, MD, Cassra N. Arbabi, MD, Xian Luo-Owen, PhD, Loma Linda University Medical Center, Loma Linda, CA, USA; David Skarupa, MD, Jennifer A. Mull, RN, CCRC, Joannis Baez Gonzalez, University of Florida – Jacksonville, Jacksonville, FL, USA; Joseph Ibrahim, MD; Karen Safcsak RN, BSN, Orlando Regional Medical Center, Orlando, FL, USA; Stephanie Gordy, MD, Michael Long, MD, Ben Taub General Hospital/Baylor College of Medicine, Houston, TX, USA, JBSA Fort Sam Houston, TX, USA; Andrew W. Kirkpatrick, MD, Chad Ball, MD; Zhengwen Xiao, MD, MSc, PhD, Foothills Medical Centre, Calgary, Alberta, Canada; Elizabeth Dauer, MD, Temple University, Philadelphia, PA, USA; Jennifer Knight, MD, Nicole Cornell, BS, MS; West Virginia University Hospitals, Morgantown, WV, USA; Joseph Skaja, MD, Rachel Nygaard, PhD, Chad Richardson, MD, Hennepin County Medical Center, Minneapolis, MN, USA; Matthew Bloom, MD, Cedars Sinai Hospital, Los Angeles, CA, USA; Nam T. Tran, MD, Shahram Aarabi, MD, Eileen Bulger, MD; University of

Washington – Harborview, Seattle, WA, USA; Forrest "Dell" Moore III, MD, Jeannette G. Ward, MS-CR, Chandler Regional Medical Center, Chandler, AZ, USA; John K. Bini, MD, John Matsuura, MD, Joshua Pringle, MD, Karen Herzing, BSN, RN, Kailey Nolan, BS, Wright State Research Institute – Miami Valley Hospital, Dayton, OH, USA; Nathaniel Poulin, MD, East Carolina Medical Center, Greeneville, NC, USA; William Teeter, MD, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA.

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