To Ultrasound or not to Ultrasound: A REBOA Femoral Access Analysis from the ABOTrauma and AORTA Registries

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Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is becoming a standardized adjunct in the management of non-compressible hemorrhage. Ultrasound (US)-guided femoral access has been taught as the best practice for femoral artery cannulation. However, there is a lack of evidence to support its use in patients in extremis with severe hemorrhage. We hypothesize that no differences in outcome will exist between US-guided and to blind percutaneous or cutdown access methods.

Methods: This was an international, multicenter retrospective review of all patients managed with REBOA from the ABOTrauma Registry and the AORTA database. REBOA characteristics and outcomes were compared among puncture access methods. Significance was set at P < 0.05.

Results: The cohort included 523 patients, primarily male (74%), blunt injured (77%), with median age 40 (27–58), and an Injury Severity Score of 34 (25–45). Percutaneous using external landmarks/palpation was the most common femoral puncture method (53%) used followed by US-guided (27.9%). There was no significant difference in overall complication rates (37.4% vs 34.9%; P = 0.615) or mortality (47.8% vs 50.3%; P = 0.599) between percutaneous and US-guided methods; however, access by cutdown was significantly associated with emergency department (ED) mortality (P = 0.004), 24 hour mortality (P = 0.002), and in-hospital mortality (P = 0.007).

Conclusions: In patients with severe hemorrhage in need of REBOA placement, the percutaneous approach using anatomic landmarks and palpation, when compared with US-guided femoral access, was used more frequently without an increase in complications, access attempts, or mortality.

Keywords: Resuscitative Balloon Occlusion of the Aorta; Femoral Artery; Arterial Access; Non-compressible Torso Hemorrhage

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INTRODUCTION

Uncontrolled hemorrhage after severe trauma leads to cardiovascular collapse and ultimately death if not managed and controlled in a timely manner [1,2]. As a consequence of anatomic location, non-compressible torso hemorrhage (NCTH) is the leading cause of potentially preventable death in both military and civilian populations, accounting for 30–40% of trauma-related mortality [3–5]. Hemorrhage within the torso is particularly challenging to control because the injured area(s) is/are

not amendable to compression as in an extremity injury and require(s) invasive intervention such as surgery or angioembolization to prevent exsanguination.

Resuscitative balloon occlusion of the aorta (REBOA) has become a widely used resuscitation adjunct to temporize NCTH and buy time for definitive hemorrhage control. Like its predecessor, resuscitative thoracotomy with aortic cross-clamping (RTACC), REBOA serves to support proximal pressure and stem hemorrhage, thus acting as a bridge to definitive control [6,7]. The procedure involves maneuvering a compliant balloon into the aorta where it is then inflated, obstructing blood flow into distal circulation [8]. The rate limiting and crucial first step of the procedure is arterial access, usually via the common femoral artery (CFA). In trauma situations, arterial access is typically gained in one of three ways: a "blind" percutaneous approach using anatomic landmarks and palpation, ultrasound (US)-guided percutaneous access, or surgical cutdown to facilitate direct visualization and access. Currently, US-guidance is recommended for successful cannulation of the CFA in all REBOA procedures. For elective, non-emergent interventions, US-guided access should be the gold standard approach for arterial access; however, its superiority in patients with NCTH has not been demonstrated. We hypothesize that no differences in outcomes will exist between US-guided in comparison with the blind percutaneous access method in a trauma patient population.

METHODS

Study Design and Data Sources

This was a retrospective, pooled data analysis of two prospectively collected, de-identified REBOA registries. The ABOTrauma registry is an international, multicenter, prospective observational database funded and maintained by the Department of Cardiothoracic and Vascular Surgery at Örebro University Hospital in Örebro, Sweden and the EVTM research group. The subjects included in the registry were enrolled between July 2014 and June 2018. The Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry is an American Association for the Surgery of Trauma sponsored multi-center, prospective observational examination of the utilization of aortic occlusion in the acute resuscitation of trauma and acute care surgery patients in shock. Subjects from the AORTA registry included in the present analysis were enrolled between November 2013 and September 2018. The two registries were combined to create a pooled database. Variables defined and collected similarly in each database were combined. Vital signs such as heart rate and systolic blood pressure (SBP) were reported as categorical values in the ABOTrauma registry and as continuous values in AORTA. Therefore, AORTA variables were converted to categorical in order to combine the datasets.

Variables that were differently defined or collected were excluded. For example, the ABOTrauma registry captures transfusion products for the first 24 hours following REBOA, whereas the AORTA database captures transfusion products for the first 24 hours, including the time before aortic occlusion. Therefore, data regarding transfusion products were not examined. Subjects who were dead on arrival (DOA) to the emergency department (ED) or with missing femoral access method were excluded.

Data Elements and Definitions

Demographic and clinical data elements collected included: age, gender, Injury Severity Score (ISS), admission vital signs and lab values, injury descriptors, puncture method of REBOA placement, zone of aortic balloon deployment, SBP pre- and post-balloon insertion, complications, and ED, 24 hour, and in-hospital mortality. Access complications included primary access failure, access site hematoma, and conversion to open aortic occlusion. In-hospital complications included sepsis, pulmonary failure, multiorgan dysfunction syndrome, renal failure, distal embolism, and extremity ischemia. Polytrauma was defined as two or more anatomic regions injured. Subjects were classified as DOA if first ED SBP and post-aortic occlusion (AO) SBP were both zero.

Statistical Analysis

Categorical variables were reported as frequencies and represented as n (%) and examined using univariate chi square analysis, while continuous variables were described using median and interquartile range (IQR) and examined using the independent samples Mann-Whitney U test. Univariate and multivariate logistic regression analyses were performed to examine associations of patient, injury, and femoral access variables with odds of mortality. Significance was set at the level of P <0.05. All analyses were executed using IBM SPSS, version 26.0 (Armonk, NY).

Ethical Approval and Informed Consent

The study was determined exempt from Institutional Review Board (IRB) oversight, as collaborating centers obtained approval from their local IRB or ethics boards prior to enrolling patients.

RESULTS

The initial iteration of the pooled study population included 655 patients (Figure 1). Of those, 113 were excluded as DOA and 19 were excluded for missing femoral access method. The remaining 523 subjects were included in the present analysis and are described in Table 1. The population was primarily male (74.2%), blunt injured (78.1%), with median (IQR) age and ISS 82

Total patients from pooled databases (n = 655)Access method not documented (n = 19)Subjects included in analysis (n = 523)Percutaneous Ultrasound-guided Surgical cutdown (n = 277) (n = 146)(n = 100)

Figure 1 Study flow chart.

of 40 years (27-58) and 34 (25-45), respectively. Abdominal/pelvic (66.3%) injury was the most common followed by thoracic injury (50.7%). Polytrauma occurred in 56.2% of the cohort. Percutaneous using external landmarks/palpation was the most common femoral puncture method used (53.0%) followed by US-guided (27.9%). The anatomic location of injury and ISS did not differ between groups. The proportion of obese patients (body mass index (BMI) \geq 30) did not differ between access groups. Median (IQR) hemoglobin was 11.1 (9.2-12.9) and did not reach a level of significance between groups (P = 0.052). Similarly, median (IQR) lactate (7.0 (4.4-11.3)) and international normalized ratio (1.4 (1.2-1.7)) were not different between groups (P = 0.082 and P = 0.380, respectively). Subjects who underwent cutdown to facilitate direct visualization for femoral access prior to REBOA were younger and more likely to be injured by the penetrating mechanism than their counterparts in the percutaneous or US-guided subgroups. The cutdown cohort was also frequently more severely hypotensive (SBP <50 mmHg), bradycardic, and had lower median pH compared to the other access groups. The cutdown group was also significantly more likely to have received cardiopulmonary resuscitation (CPR) pre-hospital and upon arrival to an ED (P = 0.004 and P = 0.013, respectively). Median (IQR) time from injury to arrival was 45 min (28-77) and did not differ between groups (P = 0.655). The number of intensive care unit (ICU) and ventilator days were significantly lower in the cutdown group (P < 0.001for both), but there was no statistical difference in ICU days or ventilator days between percutaneous and US-guided cohorts (P = 0.374 and P = 0.372, respectively). The overall in-hospital complication rate was 35.6%. The complication most often incurred was renal failure (17.0%) followed by multiorgan dysfunction syndrome (15.9%). Hematoma at access site, distal embolism, and extremity ischemia were relatively infrequent with overall incident rates of 2.1%, 4.2%, and 5.4%, respectively. The incidence of individual complications did not differ between access methods. Overall mortality was 52%. Access by cutdown had significantly higher ED (P = 0.004), 24 hour (P = 0.005), and in-hospital mortality (P = 0.007).

Procedural descriptors for the different access method groups are described in Table 2. Aortic occlusion was primarily performed in the ED for all three access groups. However, femoral access by surgical cutdown was more commonly performed in an operating room compared with the other groups. Attending trauma surgeons were the most common operator (68.4%) and were more likely to utilize US-guidance for percutaneous CFA access. ED/ICU attending physicians were the second most common operators (12.7%) and were more likely to obtain femoral artery access via the blind percutaneous approach than other methods. Overall primary access success was 88.1%. Cutdown was associated with significantly higher access success with a rate of 97.0% (P = 0.007). Initial attempt success rates did not differ significantly between the blind and US-guided percutaneous groups (P = 0.436). Primary access failure was then examined by the operator for each access technique. ED/ICU physicians failed on the initial access attempt in 69.8% (37/53) of patients undergoing blind percutaneous access, while attending surgeons were the least likely to fail the initial attempt in this cohort, requiring a second attempt in only 4.2% (7/168) of patients (P < 0.001). There were no overall significant differences in primary failure attempts by the operator in the US-guided cohort (P = 0.130). However, attending surgeons failed primary attempts significantly less than ED/ICU physicians (10.4% vs 25.0%, respectively; P < 0.050). No differences in initial attempt failure rate existed among operators in the surgical cutdown cohort (P = 0.703). BMI examined as a continuous variable was not significantly associated with primary access success (P = 0.076), and as a categorical variable, BMI \geq 30 did not increase risk of primary access attempt failure (relative risk 0.929, 95% confidence interval 0.849-1.017; P = 0.147). Conversion to open aortic occlusion occurred significantly more in the US-guided group (P = 0.007), but frequency did not differ between operators (P = 0.634). A subgroup analysis of 350 patients from the AORTA registry revealed median (IQR) time from admission to successful aortic occlusion to be significantly shorter in the surgical cutdown cohort (21 (13-36) min vs 36 (21-31) min for blind percutaneous and 30 (19–55) min for US-guided; P = 0.005). Comparison of time to successful AO between US-guided access and percutaneous using anatomic landmarks was not statistically different (P = 0.220).

The relative risks for specific complications and mortality in US-guided femoral artery access versus percutaneous using anatomic landmarks and palpation are detailed in Table 3. There was no significant difference in overall complication rates (37.4% vs 34.9%; P = 0.615) or mortality (47.8% vs 50.3%; P = 0.599) between percutaneous and US-guided arterial access methods. Event

	Total	Percutaneous	US-guided	Cutdown	
	(n = 523)	(n=277, 53.0%)	(n = 146, 27.9%)	(n = 100, 19.1%)	Р
Descriptor					
Åge, years‡	40 (27–58)	44 (28–60)	42.5 (28–56)	30.5 (23–47)	< 0.001
Male gender	388 (74.2)	201 (72.6)	117 (80.1)	70 (70.0)	0.136
BMI≥30	108 (25.5)	56 (24.0)	37 (28.5)	15 (24.6)	0.641
ISS [‡]	34 (25–45)	36 (26–45)	34 (25–43)	34 (25–48)	0.162
MOI					
Blunt	404 (78.1)	225 (82.1)	124 (84.9)	55 (56.7)	<0.001
Penetrating	110 (21.3)	47 (17.2)	22 (15.1)	41 (42.3)	<0.001
-					
Both	3 (0.6)	2 (0.7)	0	1 (1.0)	
Injury location					
Abdominal/pelvic	347 (66.3)	188 (67.9)	95 (65.1)	64 (64.0)	0.726
Thoracic	265 (50.7)	144 (52.0)	79 (54.1)	42 (42.0)	0.143
Head	232 (44.4)	122 (44.0)	70 (47.9)	40 (40.0)	0.463
Polytrauma	294 (56.2)	159 (57.4)	84 (57.5)	51 (51.0)	0.505
PH GCS	3 (3–14)	3 (3–14)	3 (3–14)	3 (3)	< 0.001
PH CPR	90 (17.5)	43 (15.8)	19 (13.1)	28 (28.0)	0.004
ED arrival					
Time from injury to arrival,	45 (28–77)	43 (27–73)	42.5 (30-81)	51 (30–82)	0.655
minutes [‡]					
CPR in progress	67 (13.6)	32 (12.1)	14 (10.3)	21 (23.1)	0.013
No pupil response	198 (39.8)	100 (39.5)	96 (34.2)	51 (51.5)	0.082
pH [‡]	7.17 (7.04–7.27)	7.19 (7.06–7.30)	7.17 (7.04–7.26)	7.13 (6.97–7.23)	0.023
HR, bpm					
None	21 (4.0)	8 (2.9)	1 (0.7)	12 (12.0)	< 0.001
<50	7 (1.3)	3 (1.1)	2 (1.4)	2 (2.0)	1010 0 1
50-100	133 (25.4)	67 (24.2)	44 (30.1)	22 (22.0)	
101–119	105 (20.1)	62 (22.4)	33 (22.6)	10 (10.0)	
120+	208 (39.8)	113 (40.8)	60 (41.1)	35 (35.0)	
	200 (39.0)	113 (0.0)	00 (111)	(0.0)	
SBP, mmHg		44 (15 0)	10 (6 0)	21 (21 0)	
<50	85 (16.3)	44 (15.9)	10 (6.8)	31 (31.0)	<0.001
51-80	165 (31.5)	80 (28.9)	54 (37.0)	31 (31.0)	
81–100	90 (17.2)	48 (17.3)	37 (25.3)	5 (5.0)	
>100	143 (27.3)	77 (27.8)	41 (28.1)	25 (25.0)	
Unmeasurable	27 (5.2)	17 (6.1)	4 (2.7)	6 (6.0)	
Not recorded	13 (2.5)	11 (4.0)	0	2 (2.0)	
Outcomes					
ICU LOS, days [‡]	4 (1–13)	4 (1–13)	6 (1–15)	1 (0-6.25)	< 0.001
Ventilator days [‡]	2 (1-8)	2 (1-9)	3 (1-12)	1 (1-4)	< 0.001
Complication	186 (35.6)	104 (37.5)	51 (34.9)	31 (31.0)	0.494
In-hospital mortality	271 (52.0)	132 (47.8)	73 (50.3)	66 (66.0)	0.494
	Z/ I (JZ.U)	152 (77.0)			
24-hour mortality	174 (33.2)	85 (30.7)	42 (28.8)	47 (47.0)	0.005

Table 1 Cohort demographic and clinical descriptors of study population.

All values are frequencies reported as n (%) unless denoted by ‡, which indicates median (IQR). BMI: body mass index; ISS: Injury Severity Score; MOI: mechanism of injury; PH: pre-hospital; GCS: Glasgow Coma Score; CPR: cardiopulmonary resuscitation; ED: emergency department; HR: heart rate; bpm: beats per minute; SBP: systolic blood pressure ICU: intensive care unit; LOS: length of stay.

	Total	Percutaneous	US-guided	Cutdown	
Descriptor	(n = 523)	(n = 277)	(n = 146)	(n = 100)	Р
Pre-AO insufflation SBP [‡]	64 (49–80)	65 (50–85)	66 (50–80)	50 (16–70)	0.001
Post-AO insufflation SBP [‡]	110 (90–129)	110 (94–130)	108 (90-124)	100 (85–130)	0.065
Femoral access location					
Pre-hospital	2 (0.4)	2 (0.7)	-	-	< 0.001
Emergency Department	357 (68.4)	189 (68.5)	114 (78.1)	54 (54.0)	
Operating room	134 (25.7)	65 (23.6)	24 (16.4)	45 (45.0)	
Angiohybrid	18 (3.4)	14 (15.1)	3 (2.1)	1 (1.0)	
Intensive care unit	1 (0.2)	1 (0.4)	-	-	
Floor/Other	10 (1.9)	5 (1.8)	5 (3.4)	-	
Zone of deployment					
Zone 1	354 (68.1)	205 (74.3)	66 (45.8)	83 (83.0)	< 0.001
Zone 2	10 (1.9)	8 (2.9)	1 (0.7)	1 (1.0)	
Zone 3	156 (30.0)	639 (22.8)	77 (52.5)	16 (16.0)	
Operator					
ED/ICU Attending	65 (12.7)	53 (19.3)	12 (8.6)	-	< 0.001
Attending Surgeon	351 (68.4)	168 (61.1)	106 (75.7)	77 (77.0)	
Vascular surgeon	39 (7.6)	17 (6.2)	3 (2.1)	19 (19.0)	
IR	22 (4.2)	14 (5.1)	8 (5.7)	0	
ED/ICU + IR	1 (0.2)	1 (0.4)	-	-	
Surgery resident/fellow	35 (6.8)	22 (8.0)	11 (7.9)	2 (2.0)	
Primary access success	461 (88.1)	241 (87.0)	123 (84.2)	97 (97.0)	0.007
Access site hematoma	11 (2.1)	4 (1.4)	5 (3.4)	2 (2.0)	0.401
Conversion to open AO	23 (4.4)	8 (2.9)	13 (8.9)	2 (2.0)	0.007

All values are frequencies reported as n (%) unless denoted by ‡, which indicates median (IQR). REBOA: resuscitative balloon occlusion of the aorta; AO: aortic occlusion; SBP: systolic blood pressure; ED: Emergency department; ICU: intensive care until IR: interventional radiology.

Table 3 Relative risk for complications in ultrasound-guided femoral access versus percutaneous access for REBOA.

	Event Rate for Percutaneous (%)	Event Rate for US-guided (%)	Relative Risk	95% Confidence Interval
Complication				
Initial access failure	13.0	15.8	0.825	0.509-1.338
Conversion to open AO	2.9	8.9	1.074	1.018-1.133
Access site hematoma	1.4	3.4	0.420	0.115-1.541
Renal failure	17.6	20.5	0.858	0.571-1.290
MODS	15.8	11.6	1.359	0.806-2.292
Respiratory failure	13.4	11.0	1.214	0.700-2.107
Sepsis	14.6	8.9	1.640	0.899-2.976
Extremity ischemia	5.1	6.8	0.735	0.335-1.614
Distal embolism	3.2	6.8	0.473	0.196-1.137
Mortality				
ED	6.9	4.8	1.426	0.614-3.313
24-hour	30.9	29.2	1.060	0.777-1.445
In-hospital	47.8	50.3	0.947	0.722-1.160

REBOA: resuscitative balloon occlusion of the aorta; US: ultrasound; AO: aortic occlusion; MODS: multiorgan dysfunction syndrome; ED: emergency department.

rates of individual complications also did not differ significantly between the two groups.

DISCUSSION

Mortality from severe hemorrhage often occurs in the first 3-6 hours following injury, particularly in the

setting of NCTH [9–12]. Shorter times to hemostatic intervention and definitive surgical control can preserve volume not yet lost and reduce mortality from exsanguination [13,14]. In the setting of REBOA, achieving CFA access is the rate limiting step to aortic occlusion and volume preservation. A 2013 study analyzed continuous video recordings to compare times to aortic occlusion

with REBOA and RTACC, including and excluding the time required for cannulation of the CFA. The study reported that time to aortic occlusion was longer with REBOA when considering the time consumed to obtain CFA access, which accounted for 50% of the overall procedure time [15]. However, once arterial access was achieved, time to AO was significantly faster with REBOA, highlighting the importance of rapid CFA access. A more recent analysis found no difference between REBOA and open approaches such as RTACC to time of successful aortic occlusion, potentially suggesting that increasing use of the procedure and dedicated competency training of the endovascular approach have improved efficiency [16–18].

Obtaining arterial access can result in serious complications and poor outcomes for patients. The traditional mainstay of CFA access has been a percutaneous approach using anatomic landmarks and palpation [19,20]. However, with the advent of portable, affordable US devices, physicians gained the ability to locate the artery under direct guidance in patients with weak or absent arterial pulses as well as in obese patients with larger leg circumferences [20,21]. US-guided puncture of the CFA has been reported to reduce the number of attempts and time to access in central venous cannulation compared with other techniques [20-23]. As each attempt at CFA access increases risk of complications, successful cannulation on the initial attempt is optimal, particularly in a time critical illnesses such as NCTH. While pooled data was not available to compare the total number of attempts, our findings demonstrated no difference in requirement for a second access attempt between the percutaneous approaches. In addition, obesity was not associated with access approach utilized or with primary access failure.

A third approach, surgical cutdown to facilitate direct visualization and access, has been reported to be a more reliable method than blind or US-guided percutaneous access [24]. Our results align with previous reports. Low et al. reported a success rate of 91.7% in hypotensive patients, a rate similar to the 97.0% demonstrated by our analysis [24]. However, our results revealed this method to be associated with a higher incidence of mortality compared with the percutaneous approaches. This may be due not to the femoral access approach, but rather to the severity of the illness, as surgical cutdown was the preferred approach for patients who presented severely hypotensive, had undergone CPR in the field, or were undergoing CPR upon ED arrival. This preference possibly suggests a higher degree of confidence in this approach among providers to locate and cannulate the CFA when faced with a patient in extremis [15,16].

In the setting of severe hemorrhage, each minute of unabated blood flow leads to increased volume depletion. A delay in femoral access for patients who are REBOA candidates is a delay of both hemostasis and resuscitation. Previous data has revealed no difference in time to compete CFA cannulation between percutaneous and surgical cutdown approaches or guided percutaneous access vs blind [15,25]. Here, a subgroup examination of 350 patients contributed by the AORTA registry revealed no difference in time to successful aortic occlusion across puncture methods. This is not a direct measure of time to cannulation; however, similar overall time to balloon insufflation across access methods suggests that access can be obtained with comparable efficiency. This lends support to the supposition that proficiency across methods has increased as REBOA use has become more widespread and as endovascular hemostatic skills have been taught by dedicated courses to trauma surgeons and emergency medicine physicians.

There is a lack of consensus in the existing literature regarding incidence of complications with US-guided access vs other methods. Some reports state US-guided puncture of the CFA reduces complications compared with other access techniques, while other studies report no difference [19,21,23,26]. Our analysis aligned with the latter and revealed no difference in overall complication rates, rates of specific complications, or relative risk of developing complications. Discrepancy among reports may be due, at least partly, to population differences, both in terms of patient population and primary operators. Previous reports that demonstrated lower complication rates in US-guided access have often been in scheduled diagnostic or interventional coronary or peripheral procedures in which the operators were cardiologists or interventional radiologists [19,23]. In trauma situations, the primary operator is most often a trauma surgeon, and the procedure is unplanned, emergent, and often conducted in the chaos of the trauma resuscitation room [16]. In addition, ultrasonography is well known to be user dependent, and differences in level of proficiency may contribute to variation in reported complication rates.

This report has several important limitations. The most significant is due to the pooled analysis, which combined two large REBOA registries. This provided the advantage of a larger study population, as most REBOA studies are limited by small sample sizes. However, the tradeoff is loss of granularity of detail, as some variables are collected differently in each database and could not be combined for analysis. Resuscitation requirements were one such variable as there were differences in how blood products were reported in each registry. Other variables such as need for amputation or time to aortic occlusion were only captured by one database, also precluding pooled analysis. Another limitation is that each database is based on data collected from various institutions in different regions and countries and was not standardized for all data points. Lastly, there was no data available to assess variations in risk factors, procedure volume, or outcomes by center.

In summary, US-guided puncture of the CFA has been promoted as best practice to improve primary access success and reduce complications compared to other techniques. However, in hypotensive patients with ongoing NCTH who are suitable for REBOA, the percutaneous approach was used more frequently without an increase in complications, access attempts, or mortality compared with US-guided femoral access. Future prospective randomized study is necessary to further evaluate these findings.

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Ethics Statement

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

Conflicts of Interest

MB is on the clinical advisory board for Prytime Medical Inc., a medical device company which manufactures the ER-REBOA catheter. TER holds patents in REBOA and REBOA-like technologies. He has no financial conflicts of interest to disclose and receives no consulting fees, travel support, stocks, or other financial support for these patents.

The other authors have no conflicts to declare.

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Author Contributions

J Duchesne and DT contributed to the study conception and design. DM, J DuBose, KN, and TH were responsible for the acquisition of data. DT, J Duchesne, DM, TH, KN, MB, and J DuBose were responsible for the analysis and interpretation of the data. DT, J Duchesne, TH, KN, and DM were involved in the drafting of the manuscript. J Duchesne, DT, TH, KN, J DuBose, DM, MB, and TER were responsible for critical revision.

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