Original Article

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Place the Sheath: Emergent 7 French Femoral Sheath Placement is Low Risk During Initial Trauma Resuscitation

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Background: We hypothesized that emergent placement of 7 French (Fr) common femoral artery (CFA) sheaths during trauma resuscitation for potential resuscitative endovascular balloon occlusion of the aorta (REBOA) carries a low complication rate.
Methods: Trauma patients at a Level I trauma center with emergent CFA access from January 2016 through to December 2020 were reviewed. CFA access was categorized as (1) 7 Fr sheath plus REBOA (REBOA) and (2) 7 Fr sheath without REBOA (Sheath). Outcomes included mortality and vascular complications.
Results: 157 patients underwent emergent CFA access. Sixty-nine (43.9%) patients had a 7 Fr CFA sheath, and 88 (56.1%) progressed to REBOA. The mortality rate was similar (Sheath 30.4% vs. REBOA 34.1%, $p = 0.63$). The REBOA cohort had a significantly higher complication rate (22.7%) compared to the Sheath cohort (4.3%, $p = 0.001$).
Conclusions: Emergent 7 Fr CFA sheath placement during trauma resuscitation is low risk, suggesting empiric sheath placement is warranted in potential REBOA candidates.

Keywords: *Trauma Resuscitation; Emergent Common Femoral Artery Access; Resuscitative Endovascular Balloon Occlusion of the Aorta; Endovascular Resuscitation Complications*

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INTRODUCTION

There have been substantial advancements in trauma resuscitation through newly developed devices and re-emphasized techniques. The resuscitative endovascular balloon occlusion of the aorta (REBOA) is a popular yet controversial modality in managing trauma. REBOA is a valuable adjunct during the resuscitation of advanced hemorrhagic shock [1–3]. Multiple institutions and several multicenter studies have evaluated REBOA indications, outcomes, and complication rates. Current literature establishes the efficacy of this procedure for use by skilled trauma surgeons within the hospital setting [2–5], and multiple studies report that the critical, time-consuming step to ensure REBOA success is obtaining rapid and safe femoral artery access [6,7].

Early common femoral artery (CFA) access for REBOA is associated with improved time to definitive hemorrhage control with improved survival [7,8]. This suggests that CFA access should be initiated early in the clinical course [8]. However, little research has focused on potential complications associated with emergent CFA access. Complications during CFA access in non-emergent procedures, such as percutaneous coronary and endovascular interventions for peripheral and central vascular disease, vary based on definitions but range from 1.2 to 2.8% for access site hematomas [9,10], and are as high as 5.7% for any access-related complication [11].

Current Advanced Trauma Life Support guidelines do not recommend emergent CFA access during trauma resuscitation [12]. Reticence regarding access complications delays this procedure until the patient meets REBOA indications. However, several theoretical advantages are

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associated with the empiric sheath placement in unstable trauma patients, including monitoring of continuous central aortic blood pressure and rapidity of REBOA deployment should the patient decompensate further. If the patient progresses to this point before obtaining access, placement of the CFA sheath becomes more difficult.

Early REBOA cases were performed through CFA cutdown and had multiple access-related complications [13]. Technological evolution led to ultrasound (US) guided CFA access with smaller, 7 French (Fr) sheaths [14]. In 2020, our level 1 trauma center initiated a specific protocol emphasizing early US-guided 7 Fr CFA access for potential ER-REBOA (Prytime Medical Devices, Inc., Boerne, TX) use. We hypothesized that placement of a 7 Fr CFA sheath under emergent trauma resuscitation conditions is a low-risk procedure. We compared the complication rates following 7 Fr CFA sheath placement with the complications rates of CFA sheath plus REBOA catheter placement.

METHODS

This is a retrospective and prospective cohort study of 7 Fr CFA sheath placement during initial trauma resuscitation at a single, urban level 1 trauma center. The Institutional Review Board approved the study under protocol #18-1953. Subjects were identified using registry data from January 2016 to December 2020. Inclusion criteria included all admitted patients aged 15 years and older following the highest level of trauma team activation who underwent 7 Fr CFA placement for potential ER-REBOA. Over the study period, the decision to place a sheath was at the discretion of the trauma attending but generally included a presenting systolic blood pressure <90 mmHg. Furthermore, general indications for REBOA deployment included transient or non-response to blood products in the setting of blunt and penetrating trauma. CFA access for an interventional radiology procedure or hemodynamic monitoring was excluded. Subjects admitted from a custody facility were also excluded.

Identified patients underwent chart review by two separate individual reviewers. De-identified data were collected and managed using Research Electronic Data Capture (REDCap) tools [15,16]. Data collected included: demographics; mechanism of injury; injury severity score; procedural information, including the time and location of CFA sheath and REBOA placement; mortality, and arterial and procedural complications; and treatment of complications. The principal investigator further evaluated all complications and respective treatment plans. Complications were considered related to CFA access or REBOA procedure if they met three requirements: (1) arterial abnormality or organ dysfunction diagnosed by clinical exam (hematomas only), labs, or imaging; (2) temporal and spatial relationship to the CFA access or REBOA procedure; and (3) determined to be unrelated to the initial trauma. A practice change was initiated in 2020 in which all patients who underwent emergent CFA access had a duplex US evaluation within 48 hours of sheath removal.

Patients were stratified for analysis into a 7 Fr sheath only group (Sheath) and a 7 Fr sheath plus REBOA group (REBOA). Data analysis occurred in SAS® Software Version 9.4 (SAS Institute, Cary NC). The primary outcome was the complication rate for each procedure. Secondary outcomes included mortality rate, number of complications requiring interventions, and yearly trends in Sheath and REBOA procedures and complication rates. Univariate analysis was performed to compare baseline characteristics between groups. Where appropriate, categorical variables were compared using the Chi-square test or Fisher's test. Continuous variables (Abbreviated Injury Scale (AIS), Injury Severity Score (ISS)) underwent distribution analysis with the Kolmogorov–Smirnov test and were analyzed using the Wilcoxon rank sum test (non-parametric). A p-value of <0.05 was considered significant.

Ethical Approval and Informed Consent

Ethical approval to report these cases was given by the Colorado Multiple Institutional Review Board, under protocol #18-1953. A waiver of informed consent was approved by the Institutional Review Board.

RESULTS

A total of 14,480 patients were admitted to the trauma registry during the study period. Two hundred thirty-four (1.6%) underwent CFA access, of which 157 (67.1%) were performed under emergent conditions and included in the analysis. The majority of patients were middle age (median: 43; IQR: 30–54), White (67.1%), and male (73.2%). Sixty-nine (43.9%) patients underwent a 7 Fr CFA sheath only, and 88 (56.1%) progressed to REBOA. A single patient in the REBOA cohort required surgical cutdown while all others underwent percutaneous CFA access. There were no significant demographic characteristic differences between the cohorts (Table 1).

Most injuries were due to blunt mechanisms (76.4%), with motor vehicle crashes being the most common (35.0%). The REBOA cohort had a higher percentage of injuries due to motorcycle crashes and pedestrians struck ($p = 0.01$). The REBOA cohort had more severely injured patients ($p = 0.01$), specifically with higher abdomen/pelvis ($p = 0.003$) and extremity AIS scores ($p = 0.001$). Injury characteristics are reported in Table 2.

Procedural information is reported in Table 3. The Sheath cohort comprises patients admitted in 2020, while the REBOA cohort is more evenly spread across all five study years ($p = 0.001$). The REBOA cohort had all CFA access procedures in either the emergency department (ED) or operating room (OR). The Sheath cohort had access most commonly in the ED, with the

Table 1 Demographic breakdown of patients who received a CFA Sheath only and those who progressed to REBOA placement.

Variables	*Total N = 157*	*Sheath N = 69*	*REBOA N = 88*	*P Value*
Age, years	43 [30–54]	46 [35–54]	40 [26–54]	0.10
Gender:				0.87
Female	42 (26.8%)	18 (26.1%)	24 (27.3%)	
Male	115 (73.2%)	51 (73.9%)	64 (72.7%)	
Ethnicity:				0.43
Missing	5 (3.18%)	4 (5.80%)	1 (1.14%)	
Hispanic	40 (25.48%)	15 (21.74%)	25 (28.41%)	
Not Hispanic	112 (71.34%)	50 (72.46%)	62 (70.45%)	
Race:				0.05
Missing	2 (1.27%)	1 (1.45%)	1 (1.14%)	
African American	18 (11.46%)	9 (13.04%)	9 (10.23%)	
Asian	2 (1.27%)	2 (2.90%)	0	
Native American	1 (0.64%)	1 (1.45%)	0	
Other/unknown	30 (19.11%)	7 (10.14%)	23 (26.14%)	
White	104 (66.24%)	49 (71.01%)	55 (62.50%)	

For categorical groups, total N and (%) are reported. For numerical variables, median and interquartile range are reported.

Table 2 Injury characteristics of the Sheath cohort compared to the REBOA cohort.

Variables	*Total (N = 157)*	*Sheath (N = 69)*	*REBOA (N = 88)*	*P Value*
Mechanism of injury				0.38
Missing	1 (0.64%)	1 (1.45%)		
Blunt	120 (76.43%)	50 (72.46%)	70 (79.55)	
Penetrating	36 (22.93%)	18 (26.09%)	18 (20.45)	
Cause of injury				0.01
Missing	1 (0.64%)	1 (1.45%)		
Assault	3 (1.91%)	2 (2.90%)	1 (1.14%)	
Bike crash	3 (1.91%)	2 (2.90%)	1 (1.14%)	
Fall	11 (7.01%)	9 (13.04%)	2 (2.27%)	
Gunshot wound	24 (15.29%)	9 (13.04%)	15 (17.05%)	
Motor vehicle crash	55 (35.03%)	23 (33.44%)	32 (36.36%)	
Motorcycle crash	19 (12.10%)	4 (5.80%)	15 (17.05%)	
Other	6 (3.82%)	4 (5.80%)	2 (2.27%)	
Pedestrian vs. auto	25 (15.92%)	7 (10.14%)	18 (20.45%)	
Sport injury	1 (0.64%)	1 (1.45%)		
Stab wound	9 (5.73%)	7 (10.14%)	2 (2.27%)	
ISS	29 [20–41]	26 [17–35]	34 [25–41]	0.01
AIS head and neck	0 [0–3]	0 [0–4]	1 [0–3]	0.85
AIS face	0 [0–1]	0 [0–1]	0 [0–1]	0.91
AIS chest	3 [0–3]	3 [0–3.5]	3 [0–3]	0.76
AIS abdomen and pelvis	2 [0–3]	0 [0–3]	2 [0–4]	0.003
AIS extremities	3 [0–4]	2 [0–3]	3 [2–4]	0.001
AIS external	1 [1–1]	1 [1–1]	1 [1–1]	1.0

For categorical groups, total N and (%) are reported. For numerical variables, median and interquartile range are reported. ISS, Injury Severity Score; AIS, Abbreviated Injury Scale.

second most common location being the surgical intensive care unit (ICU). The mortality rate was the same for both cohorts (Sheath mortality rate, 30.4% vs. REBOA mortality rate, 34.1%, $p = 0.63$). The REBOA cohort had a significantly higher complication rate of 22.7% (20 out of 88 patients) compared to 4.3% (three out of 69 subjects) in the Sheath cohort ($p = 0.001$).

Table 3 Procedural characteristics of the Sheath cohort and the REBOA cohort, and complication and mortality rates.

Variables	*Total N = 157*	*Sheath N = 69*	*REBOA N = 88*	*P Value*
Year of admission				0.001
2016	10 (6.4%)	2 (2.9%)	8 (9.1%)	
2017	40 (25.5%)	14 (20.3%)	26 (29.5%)	
2018	24 (15.3%)	7 (10.1%)	17 (19.3%)	
2019	21 (13.4%)	6 (8.7%)	15 (17.0%)	
2020	62 (39.5%)	40 (58.0%)	22 (25.0%)	
Location where access first obtained				0.0005
Missing	4 (2.55%)	4 (5.80%)	0	
ED	123 (78.34%)	51 (73.91%)	72 (81.82%)	
ICU	9 (5.73%)	9 (13.04%)	0	
OR	21 (13.38%)	5 (7.25%)	16 (18.18%)	
Complication rate secondary to femoral arterial access				0.001
No	134 (85.3%)	66 (95.6%)	68 (77.2%)	
Yes	23 (14.7%)	3 (4.3%)	20 (22.7%)	
Final outcome				0.63
Deceased	51 (32.5%)	21 (30.4%)	30 (34.1%)	
Alive	106 (67.5%)	48 (69.6%)	58 (65.9%)	

Data are reported as total N and (%).

All three complications identified in the Sheath group were access site hematomas without further surgical intervention. The REBOA cohort had a total of 23 complications: two instances of acute renal infarction or acute kidney injury (AKI); two incidents of lower extremity ischemia resulting in one amputation and one four-compartment fasciotomy; six arterial occlusions; four vasospasms; two dissections; two incidents of non-vasospasm related arterial stenosis; one access site hematoma; and one contrast extravasation of undetermined significance. Five of these complications required non-surgical intervention. The dissections and stenoses were treated with anticoagulation. One patient with an AKI was treated with continuous venovenous hemofiltration. Five complications required surgical intervention, of which two were immediately treated following REBOA removal in the OR, and three required a separate operative procedure. Of the 2020 cohort who underwent routine CFA duplex US sheath or REBOA placement, two complications were identified in the REBOA cohort: one dissection and one stenosis.

Temporal trends showing REBOA volume and associated complications are shown in Figure 1. There was a significant difference in the number of REBOAs placed over time ($p = 0.03$). The REBOA complication rate decreased over the first three years and trended up from 2019 to 2020. These differences were not significant ($p = 0.46$) and likely reflect the practice change of

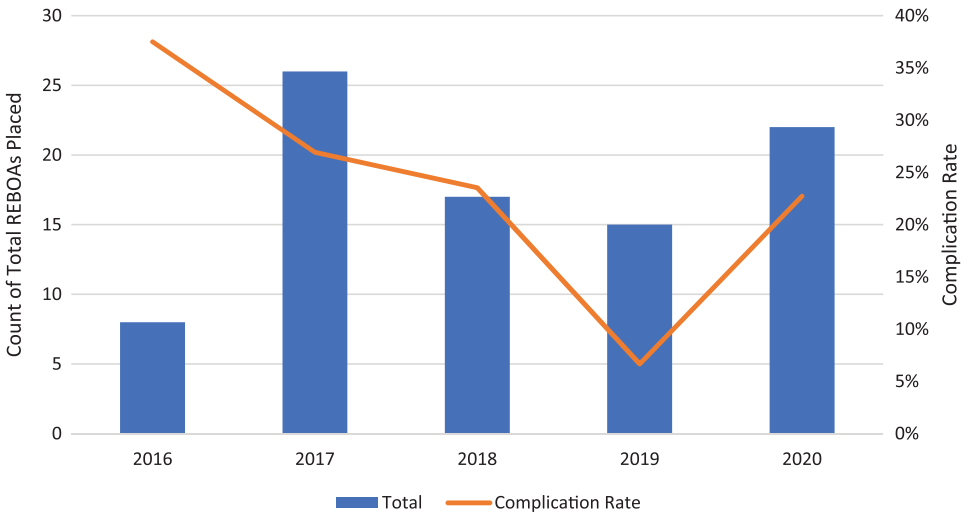

Figure 1 Yearly counts of REBOA catheters placed and corresponding complication rate per year. Yearly complication rate is as follows: 2016, 38%; 2017, 27%; 2018, 24%; 2019, 7%; in 2020, 23%.

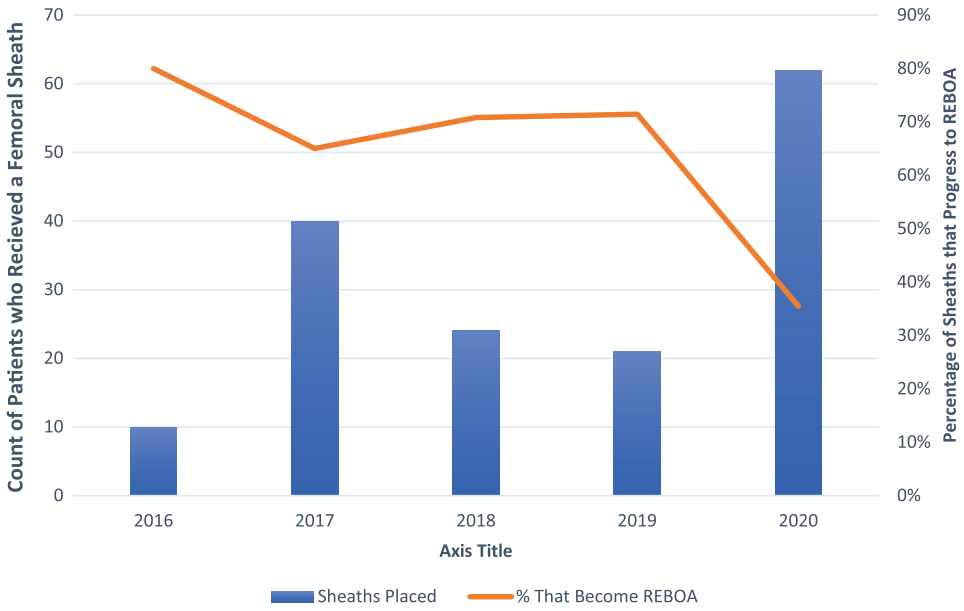

Figure 2 Total count of CFA sheaths placed during emergent resuscitation per year and corresponding conversion to REBOA with aortic occlusion. Yearly rate in sheath to REBOA progression is as follow: 2016, 80%; 2017, 65%; 2018, 71%; 2019, 71%; in 2020, 35%. CFA: common femoral artery access. REBOA: resuscitative endovascular balloon occlusion of the aorta.

routine arterial duplex following sheath removal. Figure 2 shows the number of CFA sheaths per year with the subsequent sheath conversion rate for that year. There was a significant change in sheath conversion rate over time (p = 0.001). In 2016, 80% of femoral sheaths progressed to REBOA compared to 35% in 2020.

DISCUSSION

The objective of this retrospective single-center cohort study was to compare the complication rates following emergent 7 Fr CFA sheath placement with those that progressed to REBOA. In patients who underwent a

CFA sheath only, the complication rate was below 5%, while the complication rate in the patients who progressed to REBOA was 23%. After femoral sheath placement alone, the only complication that developed were access site hematomas that did not require any interventions. This suggests that early placement of femoral arterial sheaths is a safe practice that could benefit trauma resuscitation protocols by allowing for rapid endovascular interventions, such as REBOA deployment, in the event of hemodynamic decompensation.

The rate-limiting step of REBOA deployment is obtaining CFA access [6, 17–21]. This finding has been supported by several studies and acknowledged by the joint statement from the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP) [22]. One multicenter study evaluating the feasibility of REBOA in patients with critically low systolic blood pressures found that only 58.5% of patients had successful arterial access completed on the first attempt [19]. Another single-center review found that more than 50% of the time spent initiating REBOA was dedicated to obtaining CFA access [6]. When the authors compared the time it took to perform a resuscitative thoracotomy (RT) with aortic occlusion, they found that successful aortic occlusion during RT was more than 2 minutes faster than REBOA. However, if REBOA was deployed with CFA access already established, the time to aortic occlusion was significantly shorter for REBOA. Successful CFA access was achieved in 86% of patients in hemorrhagic shock, but only 14% of patients in cardiac arrest [6]. Obtaining early CFA access when a patient is hypotensive but not in extremis should improve the time to aortic occlusion with REBOA.

Here, we provide evidence that emergent 7 Fr CFA sheath placement is a low-risk procedure that can be safely incorporated into trauma resuscitation protocols. Barriers to obtaining successful vascular access in emergency scenarios range from low vascular volume, active CPR, unfamiliarity with endovascular access procedures, the chaotic environment of the trauma bay, and the stress added by the emergent nature of the procedure. Early and standardized preemptive CFA cannulation may mitigate many of these barriers. Additionally, lower thresholds for cannulation can lead to improved training opportunities and experience for both resident and attending physicians. Routine preemptive 7 Fr catheter placement for the mildly hypotensive patient during trauma resuscitation may decrease access complications associated with REBOA by increasing experience with its rate-limiting step. Several studies have shown that experience is related to improved outcomes following REBOA [23,24]. Our institution began using aortic balloon occlusion techniques in 2015. We transitioned to the ER-REBOA catheter in 2016. This analysis confirms improved complication rates following increased ER-REBOA catheter experience in a single institution over five years (Figure 2). Our rise in complication rates for REBOA patients in 2020 is likely due to additional routine arterial duplex US screening after catheter removal.

The time-consuming and challenging process of obtaining access to the CFA has likely contributed to the slow pace of adaptation of REBOA into trauma resuscitation protocols. Initially, REBOA usage was commonly described as an alternative to RT [13,25,26], but more contemporary databases show that using REBOA as a last attempt to prevent circulatory collapse is associated with worse outcomes [14,27]. This supports the use of REBOA as an early adjunct to provide circulatory support instead of a procedure to reverse circulatory collapse [28,29]. More recent studies demonstrate that early CFA access in REBOA patients is associated with improved time to definitive hemorrhage control and increased survival [7,8] providing evidence that early 7 Fr CFA access should be incorporated into standardized trauma resuscitations protocols. At Maine Medical Center, emphasis is placed on early CFA access for invasive monitoring with a "Step Up" approach to REBOA [29]. This is a very limited experience without evaluation of complications that could have been associated with emergency CFA cannulation. Our study builds upon this experience.

Limitations of this study include its retrospective nature for most patients. Firstly, REBOA details regarding procedural success and times are often missing from clinical charts, limiting REBOA success or failure evaluation. Secondly, we cannot determine the cause of REBOA complications as we could not definitively determine the etiology of access site hematomas in the REBOA cohort. Additionally, in severely injured patients who require REBOA, ischemic and vascular anomalies identified as complications are often multifactorial. They could be caused by the combination of preexisting hemorrhagic shock and ischemia, which may be exacerbated by catheter insertion and aortic occlusion. We could not reliably obtain systolic blood pressures at the precise time of cannulation, as retrospective chart review showed this vital sign was not commonly reported with accuracy at the time of cannulation, but instead was reported with the time of aortic occlusion for the REBOA cohort. Lastly, this study does not consider the number of attempts to obtain femoral access or how many were successfully placed by US-guided access versus the landmark technique. We were also unable to identify any failed attempts at REBOA catheter placement.

CONCLUSION

Routine placement of 7 Fr CFA sheaths during emergent trauma resuscitation resulted in a low rate of complications and was limited to local hematomas not requiring intervention. This patient population represents an excellent opportunity for trauma surgeons and emergency

physicians to gain experience in endovascular techniques while expediting REBOA catheter placement in cases of hemodynamic compromise by providing reliable hemodynamic monitoring and access for endovascular interventions.

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

The authors declare that they have no conflicts of interest.

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Author Contributions

All the authors substantially contributed to the study and manuscript writing.

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