

Implementing a REBOA Program Outside Large Academic Trauma Centers: Initial Case Series and Lessons Learned at a Busy Community Trauma Program

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Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) has become an established adjunct to hemorrhage control. Prospective data sets are being collected, primarily from large high-volume trauma centers. There are limited data and guidelines, to direct the implementation and use of REBOA outside these highly resourced environments. Smaller centers interested in adopting a REBOA program could benefit from closing this knowledge gap.

Methods: A clinical series of cases utilized REBOA at a busy community trauma center (ACS Level 2) from January 2017 to May 2018. Seven cases are identified and reported, including outcomes. Considerations and 'lessons learned' from this early institutional experience are discussed.

Results: REBOA was performed by trauma and acute care surgeons for hemorrhage and shock (blunt trauma $n = 3$, penetrating trauma $n = 2$, no trauma $n = 2$). All were placed in Zone 1 (one was placed initially in Zone 3 then advanced). The mean (SD) systolic pressure (mmHg) before REBOA was 43 (30); post-REBOA pressure was 104 (19). Four of the patients were placed via an open approach, and three were percutaneous ($n = 2$ with ultrasound). All with arrest before placement expired ($n = 3$) and all others survived. Complications are described.

Conclusions: REBOA can be a feasible adjunct for shock treatment in the community hospital environment, with outcomes comparable to large centers, and can be implemented by acute care and trauma surgeons. A rigorous process of improvement programs and critical appraisal are critical in maximizing the benefit in these centers.

Keywords: REBOA; Community; Lessons Learned

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INTRODUCTION

While resuscitative endovascular balloon occlusion of the aorta (REBOA) has been described as a tool for the control of exsanguinating hemorrhage since 1954 [1], there has been an explosion in its use globally within the last decade [2–5]. Although practiced in Japan and Europe for longer, there has been a recent increase in the utilization of REBOA in the trauma systems of the United States. Initial studies utilizing REBOA have been performed at large highly resourced trauma centers with reassuring results. The American Association for the Surgery of Trauma (AAST) prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry continues to collect and analyze data on utilization and trends for REBOA use.

While the defined role of the multi-institutional study is to “capture contemporary methods of aortic occlusion (AO) with the purpose of refining clinical protocols and future data collection”, the database fails to capture much of the available data regarding REBOA use at smaller trauma centers not enrolled in the study. Illustrating this point, 103 centers out of the 256 hospitals currently using the newer ER-REBOA catheter®, are Level II or III trauma facilities [6]. The AORTA database includes data from roughly 22 centers, while the National Trauma Data Bank reports over 60 centers using REBOA, therefore, the AORTA database only captures a small portion (approximately 1/3) of the available usage data. Thus, preliminary published results may disproportionately skew findings toward large and robust trauma systems due to the higher use of REBOA at those institutions [5].

In an attempt to increase awareness of REBOA complications and pitfalls, the Basic Endovascular Skills for Trauma (BEST) study group has published consensus guidelines on the implementation, pitfalls and best practices for the application of REBOA – comprised primarily of expert opinion, a compilation of case reports, and anecdotal evidence [7]. Military use has also been carefully utilized, with associated guidelines that could serve as a starting point for institutional implementation [5]. Currently, there is a lack of published data on the implementation and institutional ‘lessons learned’ from smaller trauma centers in the United States and guidance on best practices for the safe institutional adoption of REBOA for early hemorrhage control.

The following case series represents the early experience of a smaller trauma center serving multiple counties in coastal South Carolina, following the adoption of REBOA technology. When the FDA approved Prytime Medical’s ER-REBOA® catheter for medical use in October 2015, the decision was made to include REBOA as a potential alternative to Emergency Department (ED) thoracotomy at this institution in January 2017, while it was still a growing Level II trauma center. We report our early institutional successes, as well as lessons learned, during the initial 16 months after implementation.

PATIENTS AND METHODS

A clinical series of all cases utilizing REBOA, from January 2017 to May 2018, were included. The use of REBOA was considered part of the routine clinical care for traumatic, vascular, and/or acute surgical bleeding. Indications for use were for the emergent management of hemorrhage. In all cases, the ER-REBOA® was placed by acute care and trauma surgeons. Observations and data extraction were performed retrospectively, with an exempt determination from the Edward Via College of Osteopathic Medicine Institutional Review Board.

Case Study 1

A 52-year-old male presented to an outside hospital with shortness of breath and left lower quadrant pain. He was diagnosed with a 7.8 cm × 7.8 cm ruptured infra-renal abdominal aortic aneurysm with extensive retroperitoneal hemorrhage, and transferred to this institution (Table 1). Prior to arrival, the patient had multiple episodes of hypotension and was transiently responding to 2 liters of normal saline and 2 units of packed red blood cells (PRBCs). Upon arrival, the patient was confused, pale, cool and diaphoretic. Blood pressure was unobtainable with non-invasive blood pressure cuffs. Access for REBOA was initially unsuccessful with palpation alone (by the accepting vascular surgeon), but subsequently obtained with ultrasound (US) guidance (US-guided percutaneous, 18 gauge access to the right common femoral artery (CFA), upsized over a .035 wire directly to a 7-Fr sheath) by the on call trauma surgeon. The ER-REBOA balloon was positioned into Zone 1 using anatomic landmarks, placement confirmation was made with portable chest x-ray, and the balloon was inflated with 10 ml of contrast/saline mix (Figure 1). Systolic blood pressure (SBP) became obtainable at 110 mmHg (sustained), massive transfusion protocol (MTP) was initiated and the patient was taken for laparotomy. The aortic rupture was identified, proximal and distal control obtained, and the REBOA balloon was deflated under direct visualization. The aorta was repaired with a tube graft. Post-operative care was uncomplicated (sheath removal by vascular surgery on post-operative day (POD) 1) with the exception of temporary acute kidney injury (creatinine elevation to 2.30 POD 2). The patient was discharged home POD 11 following resolution of his acute kidney injury.

Case Study 2

A 45-year-old male presented after a fall from five stories (Table 1). The patient was alert but confused, with a heart rate of 115 b/m and SBP of 130. The initial physical exam revealed bruising to the abdomen, an unstable pelvis, and an open left elbow deformity. The initial extended focused assessment with sonography

Table 1 Demographics and summary of REBOA use in seven patients. Time to occlusion is calculated from the time that REBOA is decided upon (verbal confirmation or obtaining the access kit) until the balloon is verbalized to be inflated.

	Patient						
	1	2	3	4	5	6	7
Age (yrs)	52	45	82	71	37	19	20
Sex	Male	Male	Female	Female	Female	Male	Male
Indication/mechanism	Ruptured AAA	Fall	MVC	Found down	GSW	GSW	Crush
Injury severity score (ISS)	n/a	22	21	0	25	25	18
Access method	Ultrasound	Ultrasound	Cut down	Cut down	Percutaneous	Cut down	Cut down
SBP before REBOA, mmHg	60	63	0	0	70	60	50
SBP after REBOA, mmHg	110	116	131	70	110	90	100
Cardiac arrest before REBOA	No	No	Yes	Yes	No	Yes	No
Zone of Inflation	1	3, 1	1	1	1	1	1
Admission pH	7.18	7.20	n/a	7.81	7.10	6.54	7.24
Admission base deficit	-8	-11	n/a	>30	-14	<-30	-5
Time to occlusion, min	11	4, 6	7	6	2	n/a	n/a
Time of occlusion, min	28	32	n/a	n/a	19	n/a	9
Surgery after REBOA	Yes	Yes	Yes	No	Yes	Yes	Yes
Embolization after REBOA	No	Yes	No	No	No	No	No
Complication	Temporary acute kidney injury	No	No	No	Transient ischemia, pulmonary embolism	No	Ischemia, amputation, pseudo-aneurysm
Outcome	Alive	Alive	Death	Death	Alive	Death	Alive

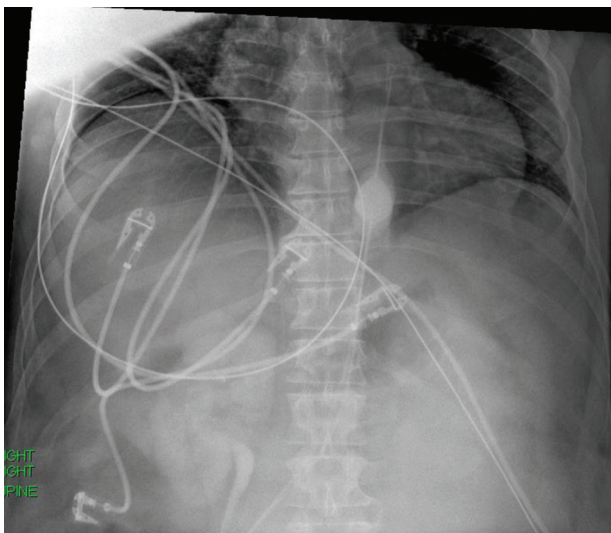


Figure 1 ER-REBOA balloon inflated in Zone 1 via landmarks. Case 1.

for trauma (eFAST) exam was negative for fluid, with the absence of lung sliding on the left chest suggesting a pneumothorax. The patient rapidly declined, becoming obtunded, leading to intubation and tube thoracostomy,

which resulted in no rush of air nor evacuation of significant blood. SBP after intubation and insertion of chest tube was 100 mmHg and deteriorated to 63 mmHg despite 1 L of normal saline and 1 unit of PRBCs, and MTP was activated. As the patient was felt to be in a ‘peri-arrest’ condition, despite initial blood product resuscitation, REBOA was placed (US-guided percutaneous, 18 Gauge access to the right CFA, upsized over .035 wire directly to a 7-Fr sheath) in Zone 3 (using anatomic landmarks) and inflated with 5 ml of saline. The SBP did not respond (via cuff measurement) after 4 minutes of balloon inflation, therefore the balloon was deflated, advanced to Zone 1, and re-inflated with 8 ml of saline. This resulted in a stable SBP of 116 mmHg. The patient was taken to CAT scan in an effort to rapidly rule out neurologic injury and evaluate the extent of the pelvic fracture (and facilitate mobilization of the interventional radiology team), followed immediately by the operating room (OR) for exploration.

Operatively, the ileo-colonic mesentery was found to be avulsed with active bleeding. A non-expanding Zone 2 retroperitoneal hematoma, grade 1 liver and splenic lacerations were identified and packed. The REBOA balloon was deflated after 32 minutes. Devitalized bowel was resected and the patient’s abdomen was left open.

He was then taken to the interventional radiology (IR) suite for pelvic angiography and no active extravasation was found. After stabilization in the ICU, the REBOA sheath was removed (approximately 8 hours later). The patient underwent subsequent surgical correction of multiple fractures. On hospital day 6, the patient was neurologically intact and transferred to a hospital closer to his home (at family request) for recovery.

Case Study 3

An 82-year-old female presented after a motor vehicle crash (MVC) from a distant rural county (Table 1). The patient was unresponsive on presentation, cold, pale, and mottled, with a thready femoral pulse. Initial chest x-ray was negative for hemorrhage. Within minutes of arrival, the patient lost a palpable pulse (PEA on monitor). CPR was started, and the patient was intubated. Bilateral finger thoracostomies resulted in no blood or rush of air. An eFAST exam was indeterminate but revealed no pericardial tamponade. The decision was made to utilize REBOA (Cut down, 18 Gauge access to the right CFA, upsized over .035 wire directly to a 7-Fr sheath). The balloon was placed and inflated in Zone 1 (anatomic landmarks with recorded insertion distance of 35 cm measured at the sheath, 8cc saline inflated) and confirmed with x-ray. Continued CPR and MTP resulted in the return of spontaneous circulation (ROSC). Post-ROSC vitals revealed an SBP of 131 mmHg and a heart rate of 121. A diagnostic laparotomy in the trauma bay revealed hemoperitoneum. She again became pulseless, and ROSC was achieved a second time. The patient was taken to the OR, where she was found to have a grade 3 splenic laceration, multiple mesenteric rents, Zone 1 and bilateral Zone 2 retroperitoneal hematomas. The patient lost her pulse again in the OR, further resuscitation was felt to be futile and the patient expired.

Case Study 4

A 71-year-old female presented after a reported fall from standing, 6 hours prior, where she struck her right hip (Table 1). She had no external signs of trauma. Medical history included uncontrolled diabetes and dementia, and was noted by Emergency Medical service personnel to have elevated blood glucose (BG > 500 mg/dl). Upon presentation, the patient was alert but confused, with bilateral breath sounds, but hypotensive (SBP 88) and tachycardic (HR 130). Chest x-ray and eFAST exam were unremarkable. Her mental status rapidly declined, requiring intubation, and precipitated subsequent cardiac arrest. CPR was started. Two units of PRBCs were rapidly administered in addition to a liter of normal saline. Rather than proceed directly to thoracotomy in this elderly patient with a questionable history for traumatic arrest, a REBOA catheter was placed (Cut down, 5-Fr sheath access to the right CFA, upsized over .035

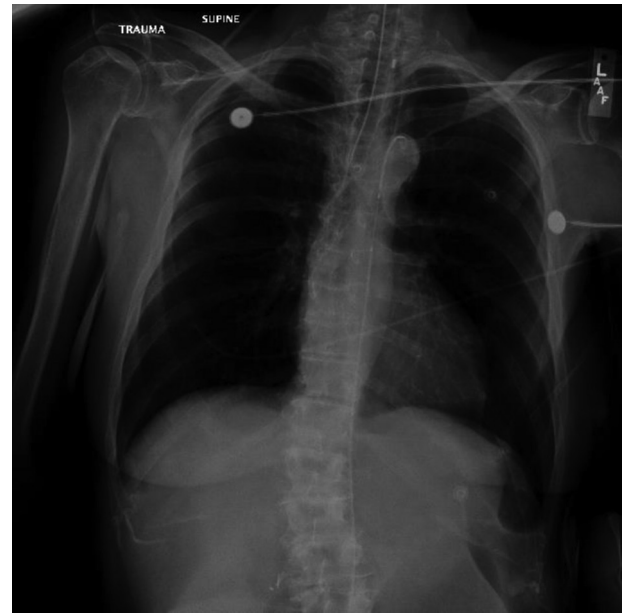


Figure 2 ER-REBOA catheter positioned in Zone 1 via anatomic landmarks. Case 4.

wire directly to a 7-Fr sheath) and inflated in Zone 1 (anatomic landmarks, Figure 2), with a return of carotid pulses after AO. No effort at imaging confirmation was made due to the desire for uninterrupted CPR. Arterial blood gas results revealed a profound alkalosis (pH 7.81, pCO₂ > 50, HCO₃ 63.3, Base Excess > 30), lactate of 10.11, and glucose 547, and hemoglobin 5.4 mg/dl. The patient went into persistent PEA and expired.

Case Study 5

A 37-year-old female presented after sustaining a close proximity gunshot wound to the left lower quadrant of the abdomen (Table 1). She arrived neurologically intact. Initial SBP was 143 and was tachycardic (125 bpm). She was taken immediately to the OR for exploratory laparotomy, and upon induction of anesthesia became hypotensive. MTP was activated. Laparotomy revealed an expanding Zone 3 retroperitoneal hematoma with extension to Zone 2 on the left. During exposure, significant bleeding was encountered, and despite packing, the patient's SBP fell below 70 mmHg. A REBOA catheter was inserted into Zone 1 (percutaneous via palpation, 5-Fr sheath access to the right CFA, upsized over .035 wire to a 7-Fr sheath). AO resulted in normalization of SBP and cessation of intra-abdominal hemorrhage, allowing identification and local vascular control of a partially transected (<50% circumference) left external iliac artery. The aortic balloon was deflated, and the arteriotomy was repaired. The femoral 7-Fr sheath with REBOA catheter were left in place post-operatively with the balloon fully deflated, she was left in discontinuity with an open abdomen, and transferred to the ICU for further management.

In the ICU the patient was noted to have loss of pulses distal to the REBOA access site. The catheter and sheath were then removed, resulting in the return of palpable distal pulses. Further operative care was routine, though complicated by respiratory failure (secondary to pulmonary embolus, heparin-induced thrombocytopenia, and IVC filter placement). She was discharged home on POD 16.

Case Study 6

A 19-year-old male was transferred from an outside hospital after suffering a gunshot wound to the right lower abdomen and right buttock (Table 1). During transport via helicopter, the patient arrested twice, was intubated and resuscitated with ROSC. The patient received 5 liters of saline, 10 units of PRBCs, and tranexamic acid prior to arrival. Upon arrival, the Glasgow Coma Scale (GSC) was 3. Airway was confirmed, bilateral chest tubes were placed with a minimal return of blood or air. The patient had palpable femoral pulses and was tachycardic. MTP was continued with a focus on recovering a balanced blood product resuscitation. Epinephrine, sodium bicarbonate, and calcium chloride were given. SBP declined to <60 mmHg, with intermittent bradycardia, and so a REBOA was placed (cut down, 5-Fr sheath access to the right CFA, upsized over .035 wire to a 7-Fr sheath), inserted in Zone 1 via anatomic landmarks and inflated. The patient had a transient SBP increase and was taken to the OR for laparotomy. In the OR, multiple injuries were noted including a transected right iliac artery and expanding hematoma in the pelvis. Despite maximal efforts at bleeding control, including the assistance of the on call vascular surgeon, the patient was unable to be recovered and expired in the OR.

Case Study 7

A 20-year-old male presented after sustaining an abdominal crush injury and pinning from the bucket of heavy excavating machinery (Table 1). The patient had a patent airway, normal neurologic exam and with a GCS of 15 and palpable distal pulses on arrival. He was initially hypotensive, however, became normotensive after receiving crystalloid resuscitation. He had diffuse abdominal tenderness and periumbilical ecchymosis. A FAST exam was negative. He was taken to CT, during which his SBP began to drop. MTP was initiated and he was taken to the OR immediately. Significant arterial bleeding was noted near the mesenteric root.

Initial attempts at bleeding control failed and the SBP fell to <50 mmHg. A REBOA balloon was placed (cut down, 5-Fr sheath access to the right CFA, upsized over .035 wire to a 7-Fr sheath), advanced into Zone 1 via anatomic landmarks and inflated. The arterial bleeding at the mesenteric root was then controlled and ligated, after which the REBOA balloon was deflated. No further

injuries were noted. Devitalized bowel was removed, continuity was restored and the abdomen was closed. The REBOA sheath was removed and the left femoral arteriotomy was repaired primarily with the assistance of the on call vascular surgeon. While still in the OR, the patient lost distal pulses and Doppler signals on the left side. The repair was reopened, and Fogarty thrombectomy was performed for the removal of a large amount of clot, and return of dopplerable signal. The patient was then heparinized and was therapeutic. A prophylactic four-compartment fasciotomy was performed and the patient was transferred to the ICU for further management.

On POD 3, after extubation, the patient was unable to move his left toes, foot or ankle. He developed worsening ischemia to the Left Lower Extremity (LLE), resulting in myonecrosis at his fasciotomy site. Despite maximal efforts at limb salvage, the patient required LLE amputation on POD 15. On POD 23, he was noted to have a left femoral pseudo-aneurysm, with bleeding, requiring operative repair. He continued to recover and was discharged to rehab on hospital day 48.

DISCUSSION

This clinical series represents the initial experience of using the REBOA device at a busy ACS Level II trauma center, and offers an opportunity to evaluate successes and pitfalls in this environment. Our institution provides 24/7 in-house trauma surgeons, meaning that the trauma and acute care surgeon is likely to be the first surgical line of defense for a range of traumatic and non-traumatic cases of hemorrhage. A priori, a review of institutional practice for controlling hemorrhage was undertaken and, as is paralleled in the literature, hemorrhage *continues* to be a leading cause of trauma-related mortality. After this review (and with the FDA approval of the Fluoroscopy free, 7-Fr delivery ER-REBOA) it was determined that the addition of a 'new technique' to control hemorrhage may be beneficial.

The initial team exposure and introduction to endovascular aortic occlusion devices occurred via training provided at the Center for Advanced Medical Simulation and Learning (CAMLS) Center in Tampa, Florida. All staff, residents and trauma nurses had the opportunity to participate in practice on the REBOA Access Task Trainer (RATT) at the simulation center, or at a similar local training session. This training and exposure were all simulation based. Two staff surgeons had also previously completed the American College of Surgeons BEST course prior to implementation. No additional local credentialing was required for board-certified critical care surgeons to utilize REBOA, as it is considered a core competency at this institution. Residents were allowed to assist, but not perform, REBOA. After every use, a detailed performance review is performed, with critical appraisal of the indication, technique, and outcomes.

The trauma team initially created its own supplemental catheter insertion kit, which has since been updated to the pre-made Prytime convenience kit. The ER-REBOA catheter and convenience kit are kept together in each primary trauma bay, with another stocked in the main trauma OR. Continuous and portable arterial waveform monitoring capabilities were not initially available, but have been added to the trauma resuscitation bays and are utilized with REBOA when required. Ultrasound is available in all resuscitations. Access choice is currently surgeon preference, but with increasing exposure to US-guided access, we feel that this modality will be chosen more frequently.

Institutional indications for use were initially agreed upon within the trauma team, but not formally defined. These have since been formalized and largely parallel algorithms from larger trauma centers [7]. In general, the critical first step is the recognition of a patient in shock, from both traumatic and non-traumatic causes. SBP <90 mmHg, HR >120 b/m, shock Index >1.3, or BD less than -5 have been used to define shock. Contraindications for REBOA include arrest from non-hemorrhagic causes, PEA arrest >10 min, known proximal traumatic aortic dissection, and cardiac tamponade/obstructive shock. However, as is illustrated in case study 4 (very likely to be a medical arrest) it can be difficult to identify the precipitating cause of cardiac arrest in every situation. When a patient arrives in arrest, with an unknown cause (trauma as a possible mechanism), all efforts are made at resuscitation.

Additionally, we do not consider age as a contraindication to REBOA. When a witnessed traumatic arrest occurs in an elderly patient, we consider it reasonable to resuscitate with the adjunct of an intra-aortic balloon, preferring this over the additional morbidity of an invasive open thoracotomy – although this is highly situation and provider dependent.

All deaths in our cases ($n=3$) were patients that arrested prior to REBOA deployment. All patients that were hypotensive prior to REBOA deployment ($n=4$) survived. Considering the results from the AORTA database and dismal survival rates of all aortic occlusion when a patient is pulseless (3% survival to discharge [5]), it may be reasonable to include prehospital arrest as a contraindication for using REBOA.

The significance of these observations is, of course, limited due to the small sample size, but in general, we feel that *early* utilization of REBOA (prior to arrest) offers an advantage in our institution. In the case of non-traumatic bleeding, where specialty services may be delayed, REBOA may add a layer of security and ‘buy time.’ To illustrate this point, the first application of REBOA at this facility was for a hemodynamically unstable ruptured AAA (rAAA) patient in extremis in the ED, bridging the patient to the successful definitive management of the AAA. It also bears mention that this initial success (seen in case 1) resulted from the collaboration of

the trauma and vascular surgeon, and highlights that team communication, with the inclusion of vascular surgeons, can be an important aspect of safe implementation at smaller facilities. Also of note is the use of REBOA in a rAAA with a wire-free, non-steerable device in the ED. Careful attention to tactile feedback and the use of x-ray permitted safe insertion is required as there is potential for the catheter to advance out into the aneurysm sac and cause further damage.

This retrospective case series also highlights several pitfalls, especially in regards to vascular complications following REBOA. It is important to point out that there were no balloon specific complications – such as aortic lacerations, balloon ruptures, etc. – which are consistent with national data. However, the patients in cases 5 and 7 suffered sheath and access related complications – including one amputation. In case 5, where the sheath was left in place to the ICU, limb ischemia was only transient and resolved with sheath removal. This may be related to the smaller arterial diameter of this female patient, or possibly vascular spasm, but it resolved nonetheless. In case 7, the sheath was removed in the OR, however early thrombosis of the access site led to a period of ischemia that ultimately required limb amputation, despite salvage efforts by trauma and vascular surgeons. While practice patterns are variable, it *may* be prudent to remove the REBOA sheath prior to leaving the OR. Certainly, a high level of vigilance during and after resuscitation is necessary. If the decision to leave the OR with the sheath in place is made, assessment of distal perfusion with angiography and physical exam is highly recommended.

After review, we have implemented new REBOA placement and post-placement management guidelines. For example, in several cases above there is no recording of insertion distance. It is now protocol to record distances. Though still not always recorded, there is now a mechanism for feedback, proper quality assurance, and review. Documented vascular exams pre-insertion, during use and hourly post-placement are also now mandated, and are tracked by the trauma performance improvement (PI) team. Doppler evaluation for insertion site pseudo-aneurysm within 48–72 hours post-insertion is recommended. An angiogram of the access extremity is ordered if the patient shows signs of lower limb ischemia. Vascular surgery is available to assist with any complications, and mandatory vascular consultation for every REBOA case is being considered. All attempts are made to limit each occlusion time to less than 30 minutes (though it is understood that some guidelines allow 30–60 minutes occlusion for Zone 1, longer for Zone 3 [8]), with inflation/deflation times recorded in every case. Our local guidelines recommend removing the sheath ‘as soon as possible once resuscitative goals have been achieved.’ This is purposely ambiguous to allow for practice variability, but the use of thromboelastometry, thromboelastography, or other adjuncts may be helpful

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