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Use of Resuscitative Endovascular Balloon Occlusion of the Aorta for Proximal Aortic Control in Patients With Severe Hemorrhage and Arrest

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IMPORTANCE Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a percutaneous transfemoral balloon technique used in select centers for resuscitation and temporary hemostasis, often instead of emergency department thoracotomy. The ability to perform aortic occlusion (AO) with an intravascular device allows focused occlusion at the most distal level to perfuse proximal regions while slowing hemorrhage to injured areas.

OBJECTIVE To describe what is to date the largest single-institution experience with REBOA in the United States.

DESIGN, SETTING, AND PARTICIPANTS Use of REBOA at an urban tertiary care facility for severe traumatic hemorrhage, traumatic arrest (AR), or nontraumatic hemorrhage (NTH) was investigated from February 1, 2013, to January 31, 2017, among 90 patients who were not responsive or were transiently responsive to resuscitation measures, or were in arrest, from presumed hemorrhage below the diaphragm. Possible causes were trauma or nontrauma-related hemorrhage. Patients with ruptured aortic aneurysms were excluded.

MAIN OUTCOMES AND MEASURES In-hospital mortality.

RESULTS Of the 90 patients in the study (15 women and 75 men; mean [SD] age, 41.5 [17.4] years), 29 underwent REBOA for severe traumatic hemorrhage, 50 for AR, and 11 for NTH. For the patients with severe traumatic hemorrhage and AR, the median age was 36.2 years (interquartile range, 25.3-55.5 years), mean (SD) admission Glasgow Coma Scale score was 6 (5), and median Injury Severity Score was 39 (interquartile range, 10-75). The distal thoracic aorta was occluded in 73 patients (81%), and in all patients with AR. A total of 17 patients (19%) had distal abdominal AO. Mean (SD) systolic blood pressure improved in patients with severe traumatic hemorrhage, from 68 (28) mm Hg prior to AO, to 131 (12) mm Hg after AO ($P < .001$). Percutaneous access was used in 30 patients (33%), including 13 patients with AR (26%), and groin cutdown in 60 patients (67%), including 37 patients with AR (74%). Overall 30-day mortality was 62% (n = 56): 11 (39%) in patients with severe traumatic hemorrhage and 45 (90%) in patients with AR. Of the patients with AR, 29 (58%) had return of spontaneous circulation and 11 of those patients (38%) survived to the operating room. All patients who survived AR gained full neurologic recovery. No aortoiliac injury or limb loss occurred from REBOA use. Eleven patients underwent REBOA for NTH; 7 (64%) were in arrest. Overall in-hospital mortality for patients with NTH was 36% (n = 4). No procedural complications occurred in this group.

CONCLUSIONS AND RELEVANCE REBOA is a minimally invasive alternative to emergency department thoracotomy with aortic cross-clamp to temporize noncompressible torso hemorrhage and obtain proximal control in both traumatic and nontraumatic causes of hemorrhage. REBOA can also be used for more targeted AO in the distal aorta for pelvic, junctional, or extremity hemorrhage.

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Initially described in the Korean War by Hughes,[1] the use of aortic balloon occlusion has evolved over the past several decades. Few early case reports in trauma patients suggested that the procedure may be beneficial[2,3]; however, with advances in technology and the adoption of endovascular procedures by vascular surgeons,[4,5] aortic occlusion (AO) became standard first-line treatment for the management of ruptured abdominal aortic aneurysms. Military and civilian collaboration during the past decade has led to further advances specifically for trauma patients. Training bedside clinicians rather than having to rely on trained endovascular specialists,[6,7] as well as the development of low-profile devices designed specifically for rapid and blind AO, has resulted in trauma centers adopting and refining this procedure.[8-10] In these centers, resuscitative endovascular balloon occlusion of the aorta (REBOA) has become an important adjunct to the treatment of life-threatening abdominal, pelvic, and junctional hemorrhage and has replaced emergency department thoracotomy with aortic cross-clamp (EDTCC) in cases of traumatic arrest (AR) from hemorrhage in those same locations.[9]

Herein we describe our experience with REBOA: its establishment at our center, patient demographics and outcomes, and the resultant paradigm shifts in clinical practice.

Key Points

Question Is resuscitative endovascular balloon occlusion of the aorta (REBOA) a feasible option for proximal aortic control?

Findings This single-institution series of 90 patients describes the use of REBOA for a variety of causes, such as severe traumatic hemorrhage, traumatic arrest, or nontraumatic hemorrhage. REBOA can be safely performed by acute care surgeons with focused training.

Meaning REBOA may be a feasible option for aortic occlusion in patients in extremis from hemorrhage below the diaphragm.

Methods

Study Design, Setting, and Participants

We prospectively enrolled all patients who received REBOA for severe traumatic hemorrhage, AR, or nontraumatic hemorrhage (NTH) between February 1, 2013, and January 31, 2017. Patients with ruptured aortic aneurysms were not included in this study. The resuscitation measures used were standardized institutional protocols for resuscitation, and REBOA was performed based on an institutional algorithm.[6] The site of AO was at the distal thoracic AO (zone 1) for bleeding below the diaphragm, distal abdominal AO (zone 3) for bleeding in the pelvis or below, and zone 1 for all patients in arrest. Time to common femoral artery (CFA) access was measured as time between first needle stick and placement of the arterial catheter or microcatheter, captured by time-stamped videography of the resuscitation area. Demographics and imaging findings were obtained from medical records. Systolic blood pressure (SBP) measurements in patients with severe traumatic hemorrhage and patients with AR were obtained by continuous vital sign monitoring if a systemic arterial line was available, or by standard cuff measurements. The pre-AO SBP is the last measured value prior to AO, and the post-AO SBP is the first measurable SBP within 5 minutes of AO, or the 5-minute mean SBP if continuous vital sign monitoring was available. Return of spontaneous circulation in patients in arrest and patients with NTH was defined as return of heart rate and SBP for longer than 5 minutes. Information on patients with NTH was obtained from medical records. The main outcome measure was in-hospital survival. This study was approved by the University of Maryland Institutional Review Board, which did not request patient consent for the procedure.

For the first 36 months of the study, a 260-cm stiff guidewire, 12F catheter sheath, and 32-mm compliant balloon were used for AO. The US Food and Drug Administration–approved wire-free device (ER-REBOA; Prytime Medical Inc) was used exclusively for the last 11 months of the study. Sheath indwelling time was measured only for patients who survived long enough to have the sheath removed.

Statistical Analysis

Descriptive statistics were calculated using SAS, version 9.1 (SAS Institute Inc). Variables with normal distribution are reported as mean (SD). Any variable skewed from normal is reported as median and interquartile range. All SBP comparisons used paired 2-tailed *t* tests. Significance was set at $P < .05$ (2-sided).

Results

A total of 90 patients received REBOA for severe traumatic hemorrhage, AR, or NTH during the observation period. Demographics, pre-AO and post-AO SBP measurements, and duration of AO for the severe traumatic hemorrhage and AR groups are listed in **Tables 1**, **2**, and **3**, and mean sheath indwelling time is listed in **Table 4**. Time to CFA access and time to AO for the severe traumatic hemorrhage and AR groups are listed in **Table 5**. A total of 72 REBOAs (80%) were performed by acute care surgeons without formal endovascular training. The remaining procedures were performed by clinicians with board certification in vascular surgery. No adverse exposure event occurred to any of the clinicians or support staff during REBOA placement.

Patients With Severe Traumatic Hemorrhage and AR

A total of 29 of 48 REBOAs (60%) performed with the 12F catheter system required cutdown, and 15 of 31 REBOAs (48%) performed with the 7F catheter system required cutdown. Technical success, as defined by AO at the intended level (zone 1 or 3), occurred in 44 of the 53 patients (83%) who had radiographic, fluoroscopic, manual, or computed tomographic (CT) confirmation of the balloon. The remaining identified malpositioned catheters were repositioned immediately to a slightly more proximal location (proximal zone 2 to distal zone 1) without clinical sequelae. Seven patients underwent REBOA at zone

1, which was then purposefully repositioned to zone 3 after intra-abdominal hemorrhage was ruled out by imaging (n = 3) or surgical exploration (n = 4).

Results of 5 pelvic angiograms after AO showed no evidence of arterial injury and required no treatment; 3 patients had CT results demonstrating large pelvic hematomas prior to angiography, and 2 patients underwent angiography without CT angiography for presumed pelvic hemorrhage. Eleven patients underwent CT after REBOA; 2 patients had nonsurvivable traumatic brain injury, and 1 elderly patient had severe comorbidities and injuries. Ten of 79 patients (13%) had traumatic brain injury confirmed on CT imaging.

Only 1 patient in this series survived after more than 1 hour of inflation at zone 1. The only patient who died of bowel necrosis had an inflation time longer than 2 hours. Two patients received REBOA and immediate lower extremity completion amputation. Three patients required fasciotomy followed by amputation after attempted limb salvage; all had severe extremity vascular or bony injury on the side of sheath placement, as did the remaining 8 patients who required fasciotomy but did not require amputation.

One interposition graft for bifurcation reconstruction and 1 patch angioplasty were required with use of the 12F catheter sheath, and 1 patch angioplasty was required on removal of the 7F catheter sheath. Ipsilateral thrombectomies were required at the time of sheath removal in 9 patients, 6 of whom were cannulated with the 12F catheter sheath. All thrombectomies and arterial repairs and/or reconstructions were performed at the index operation. Balloon rupture occurred in 1 patient owing to overinflation of the balloon in zone 3, while the cause of a second balloon rupture is unknown.

Table 1. Demographic Characteristics for Patients With Severe Traumatic Hemorrhage and Traumatic Arrest Who Received REBOA

Characteristic	Value[a] (n = 79)
Age, mean (SD) [range], y	40 (18) [16-81]
Male sex	66 (84)
Blunt trauma	54 (68)
Penetrating trauma	24 (30)
Admission GCS score, mean (SD)	6 (5)
ISS, median (IQR)	39 (10-75)
Zone 1 REBOA[b]	64 (81)
Zone 3 REBOA[b]	15 (19)
12F catheter sheath	48 (61)
7F catheter sheath	31 (39)
Duration of AO, mean (SD), min	53 (51)
ICU LOS, mean (SD), d	16 (23)
Hospital LOS, mean (SD), d	21 (27)
In-hospital mortality	56 (71)

Abbreviations: AO, aortic occlusion; GCS, Glasgow Coma Scale; ICU, intensive care unit; IQR, interquartile range; ISS, Injury Severity Score; LOS, length of stay; REBOA, resuscitative endovascular balloon occlusion of the aorta.

[a] Data are presented as number (percentage) of patients unless otherwise indicated.

[b] For a description of zones 1 and 3, see the Study Design, Setting, and Participants subsection of the Methods section.

Patients With Severe Traumatic Hemorrhage

Among the 29 patients who received REBOA for severe traumatic hemorrhage, 30-day survival was 59% (n = 17). Indications for REBOA in this group were transient responders or

Table 2. Systolic Blood Pressure Before and After AO

Patient Group	Systolic Blood Pressure, Mean (SD), mm Hg		*P* Value
	Before AO	After AO	
Severe traumatic hemorrhage	68.0 (27.9)	131.4 (12.1)	<.001
Traumatic arrest	15.1 (30.2)	71.0 (74.2)	<.001

Abbreviation: AO, aortic occlusion.

Table 3. Duration of AO by Group and Location of AO

Duration of AO	Duration, min		
	Mean (SD)	Median (IQR)	Maximum[a]
Clinical indication			
Severe traumatic hemorrhage group[a]	82.7 (60.9)	69.1 (35.3-123.3)	233.5
Traumatic arrest group[a]	35.5 (34.8)	18.5 (12.0-47.0)	127.0
Location of AO[b]			
Zone 1	48.6 (51.2)	30.0 (12.8-74.5)	233.5
Zone 3	73.9 (43.9)	63.4 (35.5-115.7)	143.0

Abbreviations: AO, aortic occlusion; IQR, interquartile range.

[a] The maximum is defined as total occlusion in zone 1, zone 3, or zone 1 and 3.

[b] For a description of zones 1 and 3, see the Study Design, Setting, and Participants subsection of the Methods section.

Table 4. Mean, Median, and Maximum Sheath Indwelling Time in Patients Who Survived to Sheath Removal

Characteristic	Duration, min		
	Mean (SD)	Median (IQR)	Maximum
Severe traumatic hemorrhage and traumatic arrest groups (n = 31)	210.7 (265.0)	169.9 (50.0-237.4)	1440.0
12F catheter	244.0 (105.8)	222.9 (202.6-289)	482.3
7F catheter	185.2 (342.5)	91.5 (25.4-143.4)	1440.0

Abbreviation: IQR, interquartile range.

Table 5. Time to CFA Access and Time to AO

Group	Time, Mean (SD), s		
	To CFA Access	To AO	Total to AO[a]
Severe traumatic hemorrhage group (n = 29)	141 (105)	344 (264)	481 (282)
Traumatic arrest group (n = 50)	300 (201)	264 (192)	537 (257)
P value	<.001	.13	.47

Abbreviations: AO, aortic occlusion; CFA, common femoral artery.

[a] Total time to AO is defined as time to CFA access plus time to AO once access has been achieved.

nonresponders who remained severely hypotensive despite resuscitation efforts. Major intrathoracic injury was excluded using chest radiography and ultrasonography, and intra-abdominal hemorrhage was presumed with positive or equivocal results from FAST (Focused Assessment With Sonography for Trauma). A total of 18 patients (62%) received REBOA in zone 1, while 11 patients with severe hemorrhage from the pelvis or below (38%) received REBOA in zone 3. Twelve patients received REBOA in the operating room (OR); the indications (4 patients met >1 indication) included AR or impending AR, refractory hypotension, presence of expanding pelvic hematoma with abdominal hemostasis, and performance of REBOA prior to exploration of a large central hematoma including, in 1 patient, severe adhesions from a previous laparotomy.

Access to the CFA was percutaneous in 22 patients and via surgical cutdown in 7 patients, including 1 patient who had access attempted percutaneously but successfully achieved via cutdown. Nineteen patients were upsized to a 12F catheter sheath, and 10 to a 7F catheter sheath. Once AO was achieved, patients were transported to the OR (n = 8), a hybrid OR (n = 8), or to receive a CT scan (n = 11).

Patients With AR

A total of 50 patients received REBOA while in arrest. Patients received a REBOA in zone 1 if results of ultrasonography ruled out pericardial tamponade, and finger or tube thoracostomies ruled out major causes of intrathoracic hemorrhage or tension pneumothoraces. A total of 16 patients (32%) were in arrest from penetrating trauma (in-hospital mortality, 12 of 16 [75%]), while 34 (68%) were in arrest from blunt trauma (in-hospital mortality, 35 of 36 [97%]). Penetrating thoracic injury was a contraindication to REBOA, whereby EDTCC was performed as standard of care. Access to the CFA was percutaneous in 13 patients and via surgical cutdown in 37 patients, including 8 patients who had access attempted percutaneously but completed via cutdown. Patients received cardiopulmonary resuscitation throughout the REBOA procedure. The 12F catheter sheath was used in 29 patients, while the 7F catheter system was used in 21 patients. Return of spontaneous circulation occurred in 29 patients (58%): 20 (40%) of those survived to the OR, and the 30-day survival rate was 10% (n = 5). All patients who survived AR were neurologically intact; 1 patient was discharged to subacute rehabilitation, 2 were discharged to acute rehabilitation, 1 was discharged home, and 1 patient was still in the hospital but awaiting subacute rehabilitation.

Patients With NTH

A total of 11 patients had REBOA performed for a variety of reasons: visceral artery aneurysm rupture (n = 3), upper gastrointestinal bleeding (n = 3), hemorrhagic necrotizing pancreatitis (n = 2), iatrogenic liver hemorrhage (n = 1), renal artery rupture (n = 1), and internal iliac artery rupture (n = 1). A total of 9 patients (82%) had AO performed in the OR, while the remaining patients underwent the procedure in the intensive care unit or another hospital location. A total of 7 patients (64%) with NTH were in arrest at the time of REBOA; 5 (45%) of those survived to discharge. The 12F sheath was used in 8 patients, and the 7F catheter system in 3 patients. Overall in-hospital mortality for patients with NTH was 36% (n = 4). No procedural complications were observed.

Discussion

REBOA has significantly altered the treatment algorithm for patients arriving with AR and presumed hemorrhage below the diaphragm. Traditional results of survival from EDTCC are dismal; our results show a survival rate of 10%, and, more important, neurologic recovery for all survivors. The patients with NTH and AR who survived all received REBOA in the OR, where definitive hemostasis was available more rapidly than in the resuscitation area. This location of treatment may account for the relatively higher survival rate (57%) in these patients.

The risks of clinician exposure and the morbidity of opening the thorax to cross-clamp the aorta make REBOA a more attractive procedural option than EDTCC. Additional benefits of REBOA include the ability to provide continuous closed chest compressions during the procedure, as well as the opportunity for training, long argued by those in favor of EDTCC in patients for whom treatment is futile. Emergency department thoracotomy with aortic cross-clamp requires some time that the patient is without cardiac compressions, since entering the thoracic cavity, while rapid, is not conducive to concurrent cardiac massage. One comparison of 19 patients who underwent REBOA with 28 patients who underwent EDTCC demonstrated the total cardiac compression time to be significantly greater in patients who received REBOA vs EDTCC.[6] It is premature to suggest that the higher return of spontaneous circulation seen in patients undergoing REBOA, or their location of death (OR or intensive care unit rather than the emergency department for patients undergoing EDTCC) is caused by this entity.[11] Results of a comparison between EDTCC and closed chest compression showed end tidal CO_2 values to be similar between groups, suggesting that EDTCC for the sole purpose of resuscitative cardiac compression and AO may not be necessary with the advent of REBOA.[12] Early adopters of REBOA saw a paradigm shift in practice even as early as the first 6 months of use,[9] a trend that has continued and resulted in an abandonment of EDTCC in favor of REBOA for select pa-

tients with AR at our institution. Patients who experience AR secondary to penetrating thoracic trauma still receive EDTCC because REBOA offers no ability for treatment and occluding the descending aorta may worsen proximal hemorrhage.

Location of AO for patients with AR should always be in zone 1 regardless of the source of hemorrhage; REBOA is primarily a resuscitative tool providing augmented coronary and cerebral perfusion. Temporization of hemorrhage is a secondary benefit, and the balloon can be adjusted later once return of spontaneous circulation has occurred and the site of bleeding has been identified in a more distal location.

REBOA has also changed our management of the patient in extremis from severe pelvic hemorrhage, and has become an important adjunct in this complex treatment algorithm. Previously, patients with ongoing resuscitation, temporary pelvic stabilization, and persistent hypotension would require pelvic packing if angioembolization was not immediately available. We are now able to perform REBOA and move to the hybrid OR suite for a series of hemostatic interventions. This change has enabled us to almost abandon pelvic packing except in 2 cases of iliac vein transection and pelvic arterial hemorrhage for which AO and packing were required to sustain the patients long enough to receive definitive treatment. We have also found that REBOA may be enough to temporize pelvic venous hemorrhage in the absence of arterial injury. Reduction of arterial inflow with REBOA in conjunction with pelvic stabilization and resuscitation appeared to be sufficient for definitive hemostasis in 5 patients.

We have observed an expansion in our indications for the use of REBOA over time, largely owing to a combination of clinicians' increased comfort level and ease of use of the new low-profile balloon catheter. For large central hematomas, for an abdomen full of severe adhesions, or instead of opening the chest to cross-clamp the distal thoracic aorta, REBOA was used for proximal control. The benefit of performing the procedure with an open abdomen includes the ability to palpate the balloon for confirmation of placement as well as for avoiding potential pitfalls associated with aortic cross-clamping. In addition, systemic arterial pressure can be transduced through the device if an arterial line is challenging or unavailable. The ease of use contributed to a 3-fold increase in the use of REBOA during the study period.

The ability of REBOA to temporize hemorrhage has been found to buy time to gather results of diagnostic imaging, particularly when other injuries may alter the treatment algorithm. Use of REBOA allowed time for consultation and discussion with family regarding the patient's prognosis and wishes, with the benefit of having the family present at the time care is withdrawn. In one case, REBOA sustained a patient with severe traumatic brain injury and abdominal hemorrhage until the organs could be donated. In other patients, the decision to proceed with angiography before abdominal exploration or vice versa was determined by results of additional imaging. In institutions in which resources are limited and/or achieving hemostasis requires patient transport to more than 1 location, REBOA can be extremely valuable.

The duration of AO permitted to prevent a clinically significant distal ischemic burden is unknown. Zone 1 occlusion times of less than 1 hour appear to be tolerated in patients with a reasonable survival, whereas survival is dismal when occlusion is longer than 1 hour. Not surprisingly, zone 3 occlusion is well tolerated for several hours with constant monitoring of distal perfusion. The extent to which AO plus an indwelling catheter sheath on one side contributes to distal ischemia is unknown but certainly must play a role. Vigilant assessment of perfusion is critical before, during, and after REBOA in all patients, particularly those with injuries of the extremities.

The consequences of extended occlusion are critical aspects of REBOA, particularly in patient care settings without the resources for definitive hemorrhage control. No patient in this series was transferred out of the hospital with AO in place, nor do we recommend that as a temporary measure at this time. Proximal occlusion is not tolerated for prolonged periods; once REBOA is performed at zone 1, patients should be transported to the OR for hemostasis and balloon deflation as soon as possible. Although patients do seem to tolerate several hours of occlusion at zone 3 and are seemingly amenable to transfer, the health care professionals who transport the patients have no training in REBOA and are not able to troubleshoot the device. Furthermore, the accepting physicians may not be facile with REBOA or its potential complications. Advances in technology, training, and education can help mitigate these hurdles.

A focus of current investigation is partial or variable AO, which has been demonstrated to improve distal ischemia in animal models.[13] This scenario may provide the opportunity for more prolonged AO in cases in which transport and/or treatment delay is unavoidable. Improvements in technology, such as systems to detect proximal hypertension and triggering automated balloon deflation and inflation, are on the horizon. Although proximal hypertension is rare, we currently manage it with temporary balloon deflation. One study using an animal model has suggested that massive resuscitation is more harmful to the injured brain than either full or partial AO.[14] Although both hypertension and hypotension can be detrimental to the injured brain, the role of AO in these patients is far from understood.

Complications

Complications in our series were related to groin access, technique, and duration of AO. All 3 minor reconstructions were owing to low cannulation of the CFA, either at the bifurcation or in the superficial femoral artery. It is clear that while the 7F catheter sheath may offer an improved safety profile owing to its smaller diameter, complications can still occur. The ER-REBOA balloon has a maximal diameter of 32 mm with 24 mL of inflation. Particularly at zone 3, where the aortic diameter of a patient with hypotension is usually 10 to 15 mm and as small as 6 to 8 mm, overinflation can apparently and fortunately result in balloon rupture rather than aortic rupture.

As with any new procedure, especially when performed by a new subset of physicians, attention must be focused as much on complications as on any other component. Privileges for REBOA at our institution are granted after completion of the Basic Endovascular Skills for Trauma course, recently adopted by the American College of Surgeons Committee on Trauma.[15] The training of our faculty and others has been

validated by clinical investigations citing good outcomes and minimal complications.[8-10] Endovascular skills required for REBOA can be acquired regardless of previous catheter experience,[6] and transfer of those skills has been demonstrated in the clinical setting.[16] Time to AO with the original devices has also been found to be similar to that with EDTCC.[10] A subset of our early patients who underwent REBOA demonstrated that time to CFA access is the rate-limiting step to REBOA when compared with EDTCC.[17] Once the CFA was established, time to AO was significantly less in the REBOA group. This finding emphasizes the need for rapid arterial access and has prompted some centers to place small-bore CFA access in all hypotensive patients.

Limitations

This is a purely observational series investigating the implementation and use of REBOA as well as the outcome of patients receiving REBOA for proximal aortic control.

Conclusions

REBOA is a minimally invasive alternative to EDTCC to temporize noncompressible torso hemorrhage and obtain proximal control in both traumatic and nontraumatic causes of hemorrhage. REBOA can also be used for more targeted AO in the distal aorta for pelvic, junctional, or extremity hemorrhage.

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