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Exclusive clinical experience with a lower profile device for resuscitative endovascular balloon occlusion of the aorta (REBOA)

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ABSTRACT

Background: A lower profile, FDA-approved device for aortic occlusion (AO) is available for REBOA.
Methods: Patients who received AO with the new device from February 2016 to February 2017 at 2 urban tertiary care centers were enrolled.
Results: 60 consecutive patients underwent REBOA; 44 (73.3%) following blunt trauma. 52 (88.1%) were male; mean age of 40 ± 18 years. 49 REBOAs were deployed in Zone 1, 11 in Zone 3.67.7% of patients in arrest achieved return of spontaneous circulation (ROSC). Overall in-hospital survival was 43%; 19% for patients in arrest and 69% for patients with refractory hypotension. Access and vascular procedural complications included iliac intimal injury requiring stent-graft (1), patch angioplasty of the CFA (1), and balloon ruptures (3). 5 amputations were required; 2 immediate completion amputations due to initial injury, and 3 delayed amputations after efforts to salvage severely mangled extremities were unsuccessful.
Conclusion: Smaller introducer sheaths for REBOA are safe and effective but do not eliminate the need for surgical common femoral artery access. Patients can benefit from REBOA with acceptable survival rates.

Introduction

Aortic occlusion (AO) has been performed as an adjunct to hemorrhage control since the earliest reported use in 1954.[1] Since that time, endovascular AO has been utilized for a number of decades for temporization of many types of hemorrhage below the diaphragm.[2–5] Recent adoption in two busy tertiary trauma centers has spearheaded the effort to use this method of endovascular hemorrhage control as a bridge to definitive hemostasis along with, or rather than some traditional resuscitative measures. Our earliest experience with REBOA utilized long platform guidewires and large introducer sheaths (12Fr) in order to perform AO which necessitated an open arteriotomy repair at the time of sheath removal. Complications from use of these earlier devices were not minimal, and included arterial injuries and distal ischemia.[6–8] The procedure itself was performed at the bedside making the large devices and multiple steps possible only in resuscitation areas with substantial support. A smaller profile device for AO was approved in October 2015 (ER-REBOA™, Prytime Medical Inc, www.prytimemedical.com) for large vessel occlusion and arterial monitoring. The 6Fr compliant balloon catheter is most compatible with a 7fr introducer sheath, requires no platform guidewire, and provides proximal arterial pressure transduction above the balloon. The two institutions represented in this study transitioned to use of the newer device in February 2016 after completion of training.

The primary aim was to describe the initial use of a newly FDA-approved device for REBOA, examining complications, as well as a secondary investigation of procedural timing and patient outcomes. This is the first description of exclusive use of the ER-REBOA catheter in the US for trauma patients.

Methods

Institutional Review Board (IRB) approval was granted from the University of Maryland (UM) and the University of Texas Medical School Houston (UTH). Patients who received AO with the new

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device from February 2016 to February 2017 were prospectively enrolled. Patients received REBOA with the ER-REBOA™ balloon catheter (Prytime Medical Inc., Boerne TX) according to an institutional algorithm developed at the time of initial adoption of the procedure.[9]

Procedural details were obtained from direct observation by dedicated research staff at UTH. Time-stamped videography was utilized at UM Shock Trauma Center (STC) whereby video recordings of REBOA patients were identified by research staff, retrieved, and secured. Timing metrics were recorded by 2 independent physician reviewers who were blinded to the purpose of obtaining the procedural time points. Systolic blood pressure was recorded before and after aortic occlusion from continuous blood pressure transduction systems or blood pressure cuff. Time to common femoral artery (CFA) access was defined as time from initial skin puncture or skin incisions to placement of the arterial line or micropuncture catheter. If percutaneous cannulation was attempted but abandoned in favor of open cut down, this time was included in the time to CFA access. Time to AO was defined as time from upsizing of arterial line catheter to time of balloon inflation. Hospital course, demographics, and outcome data were obtained by research staff through direct observation and/or medical records.

The Fischer's exact test was used to compare proportions between groups. Student's t-test was used to compare normally distributed variables and the Mann-Whitney U test was used to compare non-normally distributed variables. Normality was assessed using the Kruskal-Wallis test. All analyses were performed using GraphPad 7.03 (GraphPad Software, La Jolla, CA).

Results

60 consecutive patients underwent REBOA with the ER-REBOA device; 44 (73.3%) following blunt trauma. 52 (88.1%) were male with mean age of 40 ± 18 years. 49 REBOAs were deployed in the distal thoracic aorta (Zone 1) and 11 in the distal abdominal aorta (Zone 3). Systolic blood pressure (SBP) increased significantly from 48.1 ± 39.2 to 103.3 ± 59.7 mmHg after AO ($p < 0.0001$). Mean time of occlusion in Zone 1 was 59.8 + 43.7 min, and 73.8 + 42.9 min in Zone 3.21 patients were in arrest at the time of AO.

Percutaneous cannulation was achieved in 41 patients, including 14 in arrest (45.2%). The remaining 19 patients were cannulated via open surgical cut down; 17(89%) of those were in arrest at the time of REBOA. Mean time to arterial cannulation was 315 ± 356 s, with percutaneous access (251.6 ± 306.9) significantly faster than surgical cut down (423.7 ± 422.9 s, $p = 0.016$). Mean time to AO including femoral artery cannulation was a mean of 435 ± 299 for both methods, with percutaneous cannulation more rapid than open cutdown overall to achieve AO (382.1 ± 306 vs 527.9 ± 279.0 s, $p < 0.009$). There was no difference in cannulation times between percutaneous and open in traumatic arrest (386 ± 479 vs 430.2 ± 435 s, $p > 0.29$).

Overall in-hospital survival was 43%; 19% for patients in arrest and 69% for patients with refractory hypotension. Sixty seven percent (67.7%) of patients in arrest achieved return of spontaneous circulation (ROSC) after balloon inflation. Outcomes for patients by mechanism and physiology are listed in Fig. 1.

Sequelae of patients who received REBOA are listed in Table 1. Access and vascular procedural complications included iliac intimal injury requiring stent-graft,[1] patch angioplasty of the CFA,[1] and balloon rupture[3] secondary to over-inflation in 2 of the 3 cases. 5 amputations were required; 2 immediate completion amputations due to initial injury, and 3 delayed amputations after efforts to salvage severely mangled extremities were unsuccessful, Fasciotomies, thrombectomies, and vascular repairs were required in these patients during the course of salvage attempts. One patient with a lower extremity injury later received a fasciotomy on the opposite side of the sheath for compartment syndrome at the fracture level. Three patients without extremity injury underwent thrombectomy at the time of sheath removal for subjectively reduced back bleeding, however no thrombus was retrieved; all of these had open surgical exposure for initial access.

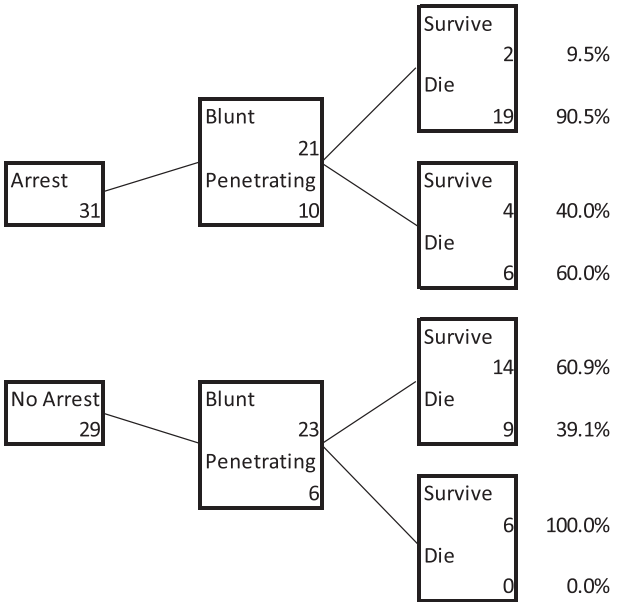

Fig. 1. Outcomes of patients receiving REBOA with the ER-REBOA catheter.

Discussion

The overall survival rates particularly for those patients in arrest at the time of REBOA, are higher than our initial combined experience using the larger devices; overall survival was 37.5%, and 0% for patients in arrest at the time of REBOA.[14] Whether this improvement is due to more rapid time to AO, proficiency with the procedure, advancement in resuscitation strategies, or patient selection is unclear. A survival rate of 10% in this study for the subgroup of patients in arrest from blunt trauma, and a survival rate of 40% for patients in arrest from penetrating sub-diaphragmatic hemorrhage suggests this may be one cohort of patients who could benefit significantly from including REBOA in resuscitation efforts. While numbers are small, all patients with hypotension

Table 1
Sequalae of patients receiving REBOA.

Total REBOA patients (N = 60)	Number of patients[a] N (%)
AKI requiring HD	7(11.6)
Non-survivable TBI	4(6.6)
Withdrawal of care	2(3.3)
Paraplegia[b]	1(1.6)
ECMO	2(3.3)
Sepsis	9(15)
ARDS	4(6.6)
CVA	1(1.6)
Myocardial Infarction	1(1.6)

HD: hemodialysis, TBI: traumatic brain injury, ECMO: extracorporeal membrane oxygenation, ARDS: acute respiratory disease syndrome, CVA: cerebrovascular accident.

[a] Some patients had more than 1.

[b] Due to initial injury, cervical spine transection.

secondary to penetrating injury survived out of the hospital, also suggesting REBOA is a feasible adjunct in the resuscitation of these patients. Clinical comparisons with similar patients are currently ongoing in multi-institutional, industry-sponsored trials.

The new device was effective in providing a significant increase in SBP after balloon inflation as has been shown in multiple series from both institutions.[7,10,11] The ability to provide central perfusion to critical organs, particularly in patients in arrest, may translate to higher rates of end tidal carbon dioxide EtCO2 levels[12] and survival out of the ED.[13,14] The reported rate of ROSC in this study is higher than one institution's early experience.[7] Data comparing resuscitative thoracotomy (RT), aortic cross-clamp, and open cardiac massage with closed chest compressions suggests that opening the chest solely to cross clamp the aorta may be of no benefit as measured by EtCO2 levels.[15] The ability to perform high-quality CPR throughout the entire REBOA procedure may account for higher rates of ROSC and survival out of the ER as reported in a more recent study comparing patients in arrest from abdominal and/or pelvic hemorrhage who received either RT, aortic cross-clamping, and open cardiac massage or closed chest compression with REBOA.[12] REBOA utilization for non-hemorrhagic cardiovascular collapse was demonstrated by one patient with cervical spine injury who survived to the ICU but ultimately had care withdrawn. REBOA could play a critical role in cases of cardiac arrest by augmenting central perfusion and permitting ROSC.[16]

While percutaneous access is occurring more often as our experience increases, the majority of patients in arrest at the time of REBOA are still requiring surgical exposure for cannulation as described in earlier reports.[7,10] Ability to perform a cutdown is critical, and the ability to perform it rapidly even more so. Improved percutaneous access rates are a positive finding, as long as the time taken to perform access and AO overall is at least as rapid, and time and/or resources are not taken away from other important resuscitation strategies. The initial REBOA experience with patients in arrest at one institution demonstrated a similar time to CFA cannulation between percutaneous and surgical cut down, as well as more rapid time to AO once arterial access is established.[17] Open surgical cut down is favored by most providers at both institutions as the initial approach to access in patients in arrest, and the few attempts at percutaneous cannulation were abandoned rapidly in favor of open exposure, considering the urgency of aortic occlusion. Open surgical cutdown rates were approximately 50% using the larger device system.[7,10] Comparisons of time to aortic occlusion with REBOA to RT were demonstrated in a multi-institutional trial reporting no difference in time to AO with earlier devices for patients in arrest and hypotensive.[10] In the current data set, percutaneous methods were found to be more rapid than open access, which could be due to increased provider experience (particularly in patients in arrest), placement of CFA access earlier in the resuscitation phase before severe intravascular depletion, and/or fewer steps required with the new device, none of which were quantified in these assessments but serve as important metrics for future study. The ability to occlude the aorta at the bedside with a short, wire-free device may contribute to this decrease in procedure time as noted in another study which also demonstrated a survival advantage in patients receiving REBOA with the wire-free device.[18]

Vascular access and procedural complications from REBOA were noted during this initial experience with the new device. Complications from the larger devices were found to be up to 30%.[7,10,14] Series from the US and abroad eries suggest use of 7Fr sheaths can result in zero complications,[11,19] however, we were not able to replicate these results in this study. As the devices used to obtain initial access have not changed with the use of the lower profile device, there are still complications such as dissections which can occur during the initial access procedure. Utilizing the correct size and length wire is critical in exchanging the arterial line catheter for a larger sheath, as is attention to tactile feedback when inserting the devices. Additionally, using an 18gauge needle and immediately inserting a 7Fr sheath over the guidewire can cause intimal injury due to the large incremental diameter change. We recommend starting with a routine femoral arterial line catheter (4Fr) which can be rapidly upsized to a 7Fr sheath.

It is unclear if and how much ischemia due to AO contributed to these delayed amputations in severely mangled extremities. Surely the combination of proximal AO plus a partially occlusive sheath in one CFA affects distal extremities to some degree, but the contribution to distal perfusion is unclear and multi-factorial particularly in patients with significant bony, vascular injury, and/or soft tissue injury. Regardless of etiology, these patients underwent extensive procedures including fasciotomies, thrombectomies, vascular repairs, and/or soft tissue debridements reported in detail in publications from each institution.[6,20] There were several patients in this series without extremity injuries who required additional procedures to address complications due exclusively to REBOA. Some complications were identified at the index operation by clinical suspicion (inflow reduction from iliac artery dissection) or observation (arteriotomy repair). Vigilant surveillance of distal perfusion including monitoring of extremity compartments is prudent in patients with or without extremity injury who receive REBOA.

A largely unanticipated device complication was balloon rupture which has been the most common device complication noted with the new balloon catheter. Although the device utilizes a compliant balloon, the tactile feedback at moderate resistance is not as easily appreciated as with the larger balloon catheters. Upon review of the balloon ruptures, particularly with investigation of imaging taken after balloon inflation, it is clear that the majority were due to over-inflation of the balloon relative to the aortic diameter. “Shouldering” of the balloon, or uneven inflation at its common rupture point can be noted on imaging. The aortic diameter varies significantly with age, volume status, and anatomic level. The maximum diameter of the ER-REBOA balloon is 3.2 cm with injection of its recommended maximum volume of 24 cc. Most patients in hemorrhagic shock have much smaller aortic diameters particularly in Zone 3.[2] The mean inflation volumes for REBOA is currently under investigation. The balloon ruptures in this series emphasize the importance of anticipating aortic diameter at the intended level of inflation,[21] the importance of utilizing adjuncts such as arterial wave form monitoring proximal to the balloon through the arterial line port, and/or loss of contralateral femoral pulse to identify initial AO avoiding over-inflation or balloon rupture. In addition, obtaining imaging after inflation (if time permits) can help to identify over-inflation which can be rectified prior to balloon rupture by removal of several cc of fluid.

Systemic complications were noted in those patients who survived out of the ER. Some of these included patients with non-survivable TBI who died due to injury burden or whose care was withdrawn, similar to our earlier experience.[14] Eleven patients suffered from severe AKI and required hemodialysis. Although likely multi-factorial in REBOA patients, AKI may be explained by the direct ischemic burden and/or the burden of distal extremity ischemia in Zone 1. Zone 3 AO may contribute to AKI due to ischemic metabolites resulting from decreased distal perfusion. Animal models of hemorrhagic shock demonstrate significantly reduced renal blood flow after AO which does not return to baseline after balloon deflation.[22] These findings underscore the importance of purposeful AO at Zone 1 when indicated, rapid hemorrhage control, and balloon deflation as soon as possible. Post-operative care requires vigilant assessment of ischemic burden and aggressive treatment.

Conclusion

Smaller introducer sheaths for REBOA are safe and effective alternatives to large-bore sheaths, and may decrease arterial access complications but do not eliminate the need for surgical common femoral artery access. Patients who arrive in extremis, including those in arrest with ongoing CPR and those in arrest from non-hemorrhagic etiology, can benefit from REBOA with acceptable rates of ROSC and survival.

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Conflicts declared

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2. Past grant funding from the Department of Defense (grant W81XWH- 15-1-0025).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2018.11.029.

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