

# Resuscitative Endovascular Balloon Occlusion of the Aorta

## Pushing Care Forward

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### ABSTRACT

**Background:** Resuscitative endovascular balloon occlusion of the aorta (REBOA), used to temporize noncompressible and junctional hemorrhage, may be deployable to the forward environment. Our hypothesis was that nonsurgeon physicians and high-level military medical technicians would be able to learn the theory and insertion of REBOA. **Methods:** US Army Special Operations Command medical personnel without prior endovascular experience were included. All participants received didactic instruction of the Basic Endovascular Skills for Trauma Course™ together, with individual evaluation of technical skills. A pretest and a posttest were administered to assess comprehension. **Results:** Four members of US Army Special Operations Command—two nonsurgeon physicians, one physician assistant, and one Special Operations Combat Medic—were included. REBOA procedural times moving from trial 1 to trial 6 decreased significantly from  $186 \pm 18.7$  seconds to  $83 \pm 10.3$  seconds ( $p < .0001$ ). All participants demonstrated safe REBOA insertion and verbalized the indications for REBOA insertion and removal through all trials. All five procedural tasks were performed correctly by each participant. Comprehension and knowledge between the pretest and posttest improved significantly from  $67.6 \pm 7.3\%$  to  $81.3 \pm 8.1\%$  ( $p = .039$ ). **Conclusion:** This study demonstrates that nonsurgeon and nonphysician providers can learn the steps required for REBOA after arterial access is established. Although insertion is relatively straightforward, the inability to gain arterial access percutaneously is prohibitive in providers without a surgical skillset and should be the focus of further training.

**KEYWORDS:** REBOA; resuscitative endovascular balloon occlusion of the aorta; training; virtual reality simulation; junctional hemorrhage; noncompressible torso hemorrhage

### Introduction

The continuous conflict of the last 15 years in the Middle East has led to an unprecedented honing of the medical evacuation and treatment systems of the US military

and coalition forces. Survival to a Role 3 medical treatment facility is associated with a greater than 98% overall survival.<sup>1</sup> [“A basic characteristic of organizing modern health services support is the distribution of medical resources and capabilities to facilities at various levels of command, diverse locations, and progressive capabilities. This is referred to as the four roles of care (Roles 1–4).” Role 1 is point of injury care; Role 2 is characterized by basic primary care capabilities and, if augmented can potentially provide surgical capabilities; Role 3 is characterized by full surgical and short-term intensive care unit capabilities.<sup>11</sup>]

During the first 10 years of the conflict in the Middle East, 90.9% of potentially survivable causes of death among US military casualties were hemorrhage, of which most were truncal (67.3%).<sup>2</sup> The Military Health System Research Symposium of 2015 highlighted a change in the goals of combat casualty care innovation going forward because of evolving areas of operation, calling on researchers to “. . . innovate for scenarios in which level 2 and 3 care is performed aboard transport vehicles or within local structures of opportunity . . . field care may be prolonged, lasting for days or even weeks. . . .”<sup>3</sup> Although efforts to push forward resuscitation adjuncts into the hands of prehospital providers are already underway, most of the currently available interventions will provide little benefit in the setting of major vascular or solid organ injuries. Current hemorrhage control strategies are either impractical or impossible, representing a major gap in the ability to meet these goals for resource-constrained environments.

Major sources of potentially survivable hemorrhage are noncompressible torso hemorrhage and junctional hemorrhage. These conditions are classically temporized with gravely morbid operative interventions such as thoracotomy or laparotomy,<sup>4</sup> with limited practicality before arrival to a medical treatment facility. This has necessitated the development of forward deployable techniques for hemorrhage control by physicians and first responders. A technique of inserting an endovascular

balloon into the aorta to occlude blood flow proximal to an injury has been developed and shown to be effective as an alternative to thoracotomy.<sup>5-8</sup> Resuscitative endovascular balloon occlusion of the aorta (REBOA) can delay life-threatening hemorrhage, allowing more time for triage, transport, and definitive surgical treatment. REBOA is currently being used and studied in the civilian trauma clinical setting.<sup>9</sup> Military enthusiasm for this adjunct has been demonstrated in its inclusion in the June 2014 Joint Trauma System Clinical Practice Guidelines: it “is recommended as an adjunct to control life-threatening hemorrhage in the setting of truncal and extremity injury,”<sup>10</sup> but is currently authorized only at Role 3 facilities.

Analysis of battlefield deaths confirms that earlier control of hemorrhage decreases mortality. One of the main impediments to deployment of this adjunct into the field is that, until recently, the procedure required long platform guidewires and a large-bore arterial sheath. These devices are awkward when deployed and require a surgeon’s intervention for removal, which is not feasible in the forward setting. A smaller bore device has recently gained Food and Drug Administration approval in the United States and has seen success in its initial clinical use. This smaller device requires fewer procedural steps, can be easily upsized from a percutaneously placed arterial line, and requires only direct pressure for hemostasis upon device removal. Unlike the far more invasive thoracotomy and laparotomy, which are often performed after the patient has had a hypotensive cardiac arrest, the minimally invasive REBOA device has the potential to be placed preemptively in patients who are at risk of decompensating during their prolonged extraction.

Although REBOA remains an adjunct used solely in the armamentarium of specialized physicians, its efficacy will remain limited to only those patients who survive to arrival at a Role 3 medical treatment facility. With the changing landscape of military operations and the shift to smaller teams in disparate locations, arrival to a physical Role 2 or 3 facility may no longer be feasible within the golden hour. Additional methods for temporizing noncompressible torso hemorrhage and junctional hemorrhage must be moved forward into the field. Our hypothesis is that nonsurgeon physicians and high-level military medical technicians (i.e., Ranger Medics, Special Forces Medical Sergeants, Pararescuemen, and Independent Duty Corpsmen) can learn the technical skills required for REBOA and the theory behind the procedure.

## Materials and Methods

Ethical approval was obtained from the institutional review board at the University of Maryland School of Medicine.

## Participants

US Army Special Operations Command medical personnel with no prior experience of endovascular techniques were included in this study. All participants received didactic instruction of the Basic Endovascular Skills for Trauma (BEST) Course™ together, with individual evaluation of technical skills. Of the four participants, two were nonsurgeon physicians (one was an emergency medicine and the other, a family medicine physician), one physician assistant, and one Special Operations Combat Medic. Before this training, none of the participants had any experience with REBOA. The evaluators were all physicians on staff at the University of Maryland Shock Trauma who had clinical experience placing REBOA.

## Simulator

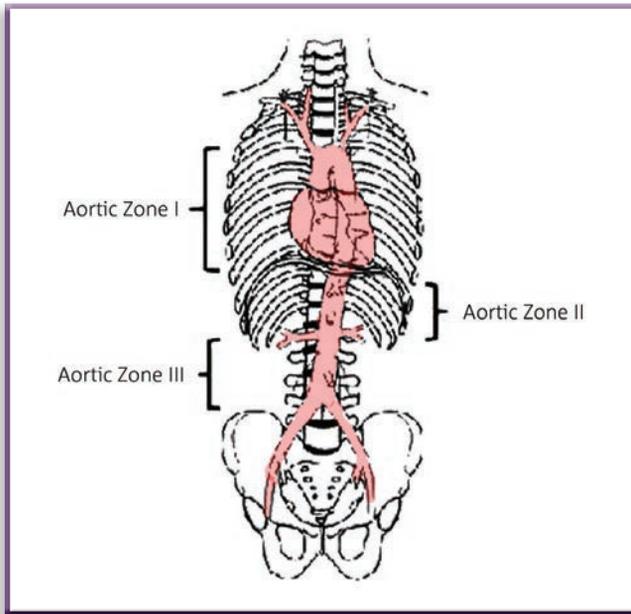
The VIST-C (Mentice, <http://www.mentice.com>) uses computer software coupled with equipment that uses haptics when devices are inserted or manipulated. Haptics uses force feedback to provide tactile feedback, which is essential to the performance of endovascular skills. This is of critical importance in this situation because the endovascular insertion of devices, as with REBOA, is largely based on feel. This tactile feedback is reinforced with static fluoroscopic images, which are used to confirm wire placement.

## BEST Course and Testing Scheme

The BEST course is a structured, day-long course consisting of 4 hours of instructor-led didactics followed by a simulation session and then cadaver laboratory session. A pretest was administered before the didactic portion of the course. This was followed by several lectures describing indications, insertion, and pitfalls of REBOA, and an individual demonstration of the procedure by an instructor.

Immediately after the didactic sessions, participants were familiarized with the equipment and the procedure was demonstrated once. REBOA was then performed a total of six times: three times each at a simulated aortic level for the distal thoracic aorta (zone 1) and proximal to the iliac bifurcation (zone 3) (Figure 1). Each task, from the insertion of the guidewire to inflation of the REBOA balloon, was performed as quickly as possible without compromising safe use of the endovascular equipment. Each step of the procedure was evaluated by the instructors and assigned a score from 1 to 5. No interruption or evaluation was provided between the attempts. The time to complete the procedure and correct performance of each step were recorded on a standardized evaluation form (Figures 2 and 3). Because REBOA is performed in the resuscitation area with the use of only digital x-ray imaging, when the trainee reached the portion of the procedure where confirmation of the guidewire

**Figure 1** Graphic representation of zones 1 and 3.



Based on Stannard et al, *J Trauma*. 2011;71:1869-1872. <https://www.ncbi.nlm.nih.gov/pubmed/22182896>

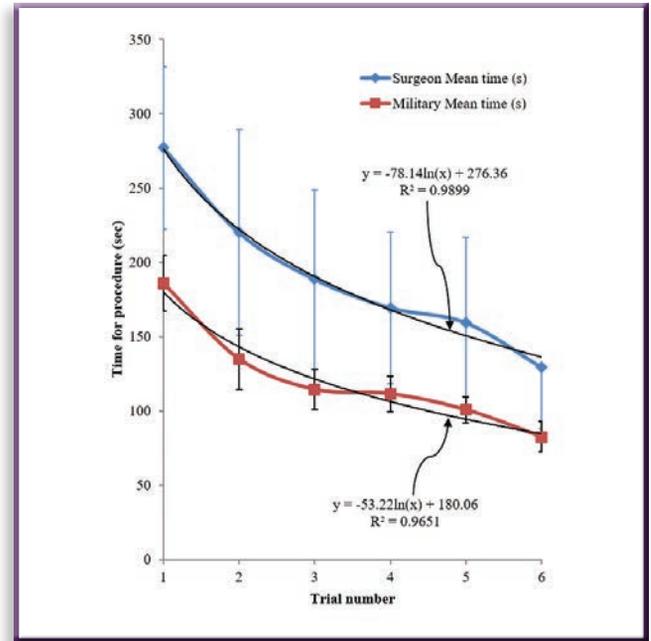
**Figure 2** Evaluated steps of REBOA task performance.

1	Access of the common femoral artery. Verbalizes use of femoral arterial line kit, external landmarks, optional use of ultrasound, importance of needle entry and cannulation.
2	Insert Amplatz Guidewire into the arterial line catheter to proximal Zone 1 using external landmarks (below 2nd rib space).
3	Upsize a-line catheter to 12 Fr sheath. Verbalizes knowledge of 8 and 10Fr dilators for gentle upsizing, and when those may be required.
4	Advance sheath to the proximal common iliac artery (external landmark: below the umbilicus). Verbalized need for dilator to be used in every case of sheath advancement, whether initial or in the event that the sheath retracts slightly during manipulation of balloon.
5	Advance balloon to distal Zone 1 (external landmark: xiphoid) and inflate to moderate resistance.
6	Verbalizes need to observe changes in hemodynamics while continuing resuscitation and diagnosis / treatment of hemorrhagic source as indicated.
7	Once need for occlusion has passed, removal of the balloon. Verbalizes cutting down on the common femoral artery and obtaining proximal and distal control, removal of sheath, wire, and repair artery as indicated.

Fr, French.

placement was required, a static fluoroscopic image was shown as a surrogate for a portable radiograph. After the skills performance, a posttest was administered and comparisons made to the pretest.

**Figure 3** Procedure time per trial by group.



### Evaluations

The examiner evaluated each participant on the simulated performance of REBOA. The examiner subjectively evaluated performance on a scale of 1 to 5 (Likert scale) for the following tasks: microcatheter exchange, guidewire manipulation, balloon manipulation, balloon inflation, and balloon and guidewire removal.

A score of 5 would be awarded for demonstration of consistent and proper handling of wires and balloon, economy of motion, sound knowledge of the indications for REBOA, and completion within the required time limit. Criteria for a score of 1 included inability to identify indications for REBOA, choosing tools incorrectly, overinflating the balloon, inability to perform the procedure within 5 minutes, and performing the skills out of sequence. The numeric evaluation was based on novice performers; thus, a score of 5 corresponded to an excellent performance for a novice or beginner.

### Data Analysis

Summary descriptive statistics for normally distributed variables are reported as mean  $\pm$  standard deviation or median (interquartile range), as appropriate. The unpaired Student *t* test was used to analyze continuous data and the Fisher exact test was used to compare categorical data. Statistical significance was set at .05 and all tests were two-tailed.

### Results

Within our study group, there was a significant decrease in the procedural times moving from trial 1 to trial 6. Overall time for REBOA completion decreased from

186 ± 18.7 seconds to 83 ± 10.3 seconds ( $p < .001$ ), a mean improvement difference of 104 ± 12.3 seconds from the first to the sixth trial. The mean time difference between trials was most marked between the first and second trial, with a 51 ± 8 second reduction in time compared with the second trial ( $p = .011$ ). After a decrease in trial time of 21 ± 12 seconds to the third trial, the performance times shortened a further 3 ± 9, 11 ± 10, and 18 ± 4 seconds at each subsequent trial, respectively (all  $p > .16$ ).

All participants demonstrated safe handling of the endovascular equipment, and correctly verbalized the indications of and need for REBOA placement, and the indications for discontinuation. This trend continued through all six tasks. The performance of all five procedural tasks over the six trials was judged by the evaluator as 4 of 5 on the Likert scale for each participant. There was no variation observed from this trend across the trials or participants. All balloon inflations were at the correct level within the aorta.

There was significant improvement in comprehension and knowledge between the pretest and posttest for the study group. The participants' average performance improved significantly from 67.6 ± 7.3% to 81.3 ± 8.1% ( $p = .039$ ).

## Discussion

The improvement seen from trial 1 to trial 6 is similar to our initial published study on REBOA.<sup>12</sup> In that study, participants improved their times by a mean of 148 ± 44.8 seconds.<sup>12</sup> The current group did not improve its times as dramatically ( $p = .08$ ), but the participants' initial starting times were significantly faster during the first trial—186 ± 18.7 seconds, compared with the 277 ± 54.7 seconds reported for a group of acute-care surgeons<sup>12</sup> ( $p = .006$ ). Through all six trials, this study group improved at a significantly faster rate, with the scores of five of six trials being significantly different. Although this may seem to suggest that nonsurgeon and nonphysician military medical personnel may be able to perform the procedural tasks more quickly, there was a low level of variation within the dataset due to the small number of participants tested. In fact, the improvement from trial to trial was similar to that of the previous group,<sup>12</sup> despite significant differences in trial times for five of six performance repetitions. The procedural times between the two groups' trends are consistent with logarithmic improvement in skill times, meaning performance improved to a plateau, with time reaching a minimum. These data suggest that the compressed learning curve for REBOA is applicable to nonphysicians, indicating that the technique is readily trainable and teachable to forward care providers.

The participants' knowledge and comprehension were significantly improved after the course; they performed better on the posttest by approximately 14%. A similar rate was seen in the previous group with an improvement in test performance of approximately 13.7%<sup>12</sup> ( $p = .97$ ). This evaluation was identical to that used previously and demonstrates our hypothesis that non-surgeon physicians and advanced nonphysician practitioners exhibit similar comprehension and knowledge of endovascular techniques after formal training.

Due to the small sample population, this case series is submitted as a white paper with the goals of establishing a proof of concept and beginning the discussion of the available literature. Herein, we have described the feasibility of military nonsurgeon and nonphysician prehospital providers learning the steps to perform REBOA after arterial access is established. However, the results of this case series should not be generalized to all prehospital personnel, because these practitioners are all particularly trained in the management of traumatic hemorrhage, which may not necessarily be in the skillset of every provider.

Furthermore, two major skills were not evaluated in this cohort: the ability to determine who needs a REBOA and to obtain common femoral artery (CFA) access, both which are essential to the success of the procedure. The indications for REBOA may be straightforward in the setting of traumatic amputation not amenable to tourniquet placement; however, patients with intra-abdominal hemorrhage or severe pelvic hemorrhage may present a diagnostic dilemma in the field where ultrasound and other imaging modalities are not readily available.

Although the technique of inserting balloon catheter for REBOA is relatively straightforward, cannulation of the CFA can be technically difficult and, when performed incorrectly, can result in damage to the superficial femoral artery or femoral bifurcation. In the clinical setting, acute-care surgeons who are not able to access the CFA percutaneously are required to perform a groin cut-down. This underscores the importance of nonsurgeon providers becoming extremely facile with the use of ultrasound-guided CFA access, because the inability to access percutaneously is prohibitive for REBOA in providers without a surgical skillset.

This study demonstrates that nonsurgeon and nonphysician providers can learn the steps required for REBOA placement after arterial access is established and can perform the procedure correctly and rapidly as assessed by virtual reality simulation. It is certainly the first step in driving REBOA beyond the confines of hospitals. In countries such as Japan and the United Kingdom, REBOA has been placed in the prehospital setting by

non-surgeons; however, no published data are available, to our knowledge, regarding the efficacy or outcomes of these patients, or details of the providers.

Technology will undoubtedly help push REBOA into the prehospital environment as lower-profile devices are developed and are Food and Drug Administration approved. The newest balloon catheter, and the only one made specifically for REBOA, is now available and is compatible with a 7F sheath, making upsizing less difficult than the sheaths initially available on the market (11F–14F). However, regardless of how small the device and sheath become in the future, the ability to perform REBOA will be contingent on accessing the CFA rapidly and correctly, and choosing the appropriate patient. Along with the actual technique, these areas should become a focus of training.

## Disclosures

The authors have nothing to disclose.

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