Bringing Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Closer to the Point of Injury

A Simulation Study

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ABSTRACT

Background: The management of noncompressible torso hemorrhage remains a significant issue at the point of injury. Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been used in the hospital to control bleeding and bridge patients to definitive surgery. Smaller delivery systems and wirefree devices may be used more easily at the point of injury by nonphysician providers. We investigated whether independent duty military medical technicians (IDMTs) could learn and perform REBOA correctly and rapidly as assessed by simulation. **Methods:** US Air Force IDMTs without prior endovascular experience were included. All participants received didactic instruction and evaluation of technical skills. Procedural times and pretest/posttest examinations were administered after completion of all trials. The Likert scale was used to subjectively assess confidence before and after instruction. **Results:** Eleven IDMTs were enrolled. There was a significant decrease in procedural times from trials 1 to 6. Overall procedural time (± standard deviation) decreased from 147.7 ± 27.4 seconds to 64 ± 8.9 seconds ($p < .001$). There was a mean improvement of 83.7 ± 24.6 seconds from the first to sixth trial (p < .001). All participants demonstrated correct placement of the sheath, measurement and placement of the catheter, and inflation of the balloon throughout all trials (100%). There was significant improvement in comprehension and knowledge between the pretest and posttest; average performance improved significantly from 36.4.6% ± 12.3% to 71.1% ± 8.5% ($p < .001$). Subjectively, all 11 participants noted significant improvement in confidence from 1.2 to 4.1 out of 5 on the Likert scale ($p < .001$). **Conclusion:** Technology for aortic occlusion has advanced to provide smaller, wirefree devices, making field deployment more feasible. IDMTs can learn the steps required for REBOA and perform the procedure accurately and rapidly, as assessed by simulation. Arterial access is a challenge in the ability to perform REBOA and should be a focus of further training to promote this procedure closer to the point of injury.

Keywords: *hemorrhage control; independent duty medical technician; resuscitative endovascular balloon occlusion of the aorta; REBOA*

Introduction

Nearly two decades of global military conflict have shown the magnitude of potentially preventable battlefield deaths from extremity and torso hemorrhage. These patients died of their injuries before ever reaching a surgeon.[1] Advances in tactical combat casualty care have improved hemorrhage control in the military prehospital care arena, specifically with hemostatic gauze, as well as purpose-derived extremity and junctional tourniquets, and these are becoming a mainstay in nonmilitary, prehospital emergency medical services worldwide. Extremity tourniquets have shown significant improvements in decreasing exsanguination on the battlefield.[2] However, currently, there are limited adjuncts available to the prehospital medic for noncompressible torso hemorrhage (NCTH).

Resuscitative endovascular balloon occlusion of the aorta (REBOA) temporizes noncompressible torso and junctional hemorrhage in select patients in the hospital.[3] The advent of smaller delivery systems and wirefree devices may enhance the ability of nonphysician providers to use this technology more easily at, or near, the point of injury. With limited field supplies and, often, little or no blood products during some military operations, proximal hemorrhage control with a device could stabilize a patient in an austere environment for transfer to a higher level of care with additional resources. In the current conflicts, REBOA has been inflated successfully for hemorrhage control in a building of opportunity, stabilizing casualties for the operating room but not in a true "prehospital" emergency medical services setting.[4]

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As the current major conflict dissipates in the Middle East, more remote operations will take place with limited, embedded, fixed hospitals. Field bleeding control, specifically for NCTH, may be a bridge to get a wounded Soldier to a facility capable of surgical care. Independent duty military medical technicians (IDMTs) are specialized paramedics with more advanced training who typically are embedded in Special Forces units and who may be the first advanced medic reaching injured casualties.

Simulation training is a well-established method of training for skill development in the novice as well as the expert. This training has been used in aviation,[5] military operations,[6] and in emergency medical services, as well as specifically with REBOA training.[7] We investigated IDMTs' ability to learn and perform REBOA correctly and rapidly, as assessed by simulation.

Methods

Ethical approval was obtained from the University of Maryland School of Medicine Institutional Review Board to assess for quality assurance and performance.

Student Selection

Eleven US Air Force (USAF) IDMTs without prior endovascular experience participated. All IDMTs were certified as such by the USAF. Participants were excluded if they had taken any similar endovascular course or previously had similar instruction in devices such as the REBOA. Participants were taken through the didactic portion of the class in groups of one, two, or three; then they were individually observed and monitored performing the procedure.

Instructor

To limit instructor bias, one faculty member from the Division of Trauma and Critical Care at the RA Cowley Shock Trauma Center, University of Maryland Medical Center, Baltimore, Maryland, conducted all teaching and evaluation throughout the entire course. This instructor is a clinically active trauma surgeon with multiple REBOA placements in patients and is an instructor for the American College of Surgeons Basic Endovascular Skills for Trauma (BEST) Course.

Device and Simulator

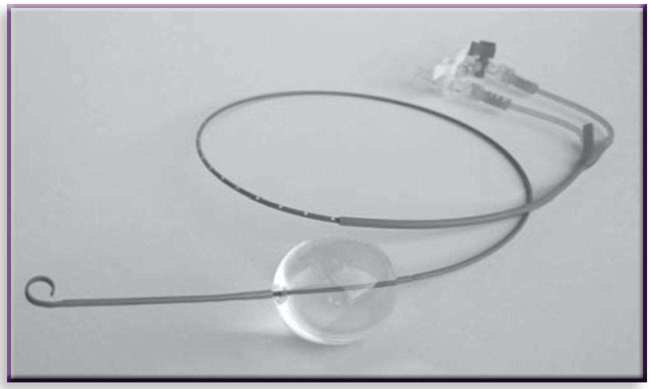
The ER-REBOA (Prytime Medical Devices, http://prytimemedical.com/; Figure 1) was used as the preferred balloon because of its ease of use, 7F size, and current Food and Drug Administration approval as the lowest profile balloon that is clinically being used in the United States for REBOA.

A fixed model (Prytime Medical Devices), a plastic simulator vascular model, was used for the technical portion of the class. This model (Figure 2) consists of plastic femoral vasculature joining an aortic confluence with anatomically correct distances for the renal arteries and the aortic arch vessels. A mannequin torso was used to cover the model to keep the plastic vasculature hidden during placement.

Course

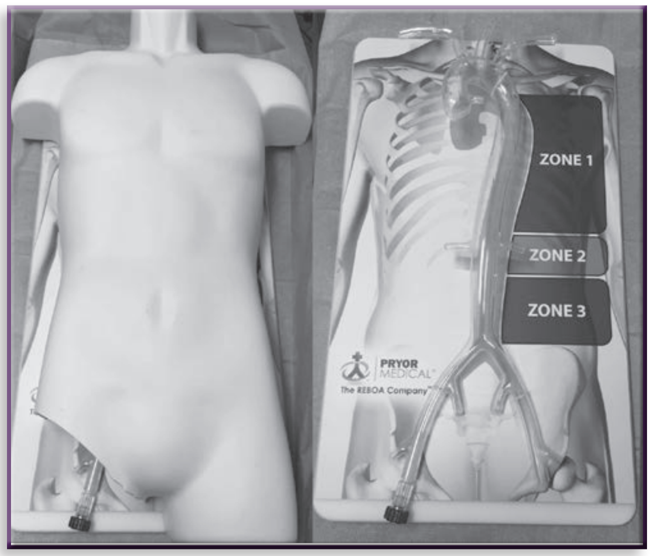
A questionnaire was administered before the didactic portion and skill session of the course to assess the IDMT's age, years as an IDMT, and experience with this technique. The participants rated their comfort with the procedure using a Likert scale of 1 to 5. A pretest was administered that consisted of questions relevant to indications, safe use of REBOA in the clinical setting, anatomy, and technical aspects. The didactic portion of the course consisted of a slide program derived from the BEST course. These slides included indications, steps, pitfalls, and anatomy for common femoral cannulation.

FIGURE 1 *7F ER-REBOA.*



Courtesy of Prytime Medical Devices, Inc.

FIGURE 2 *Plastic mannequin covering (left) over vascular model. Vascular model without covering (right).*



After this session, the participants performed ER-REBOA placement in the plastic model after being given standard patient scenarios. All placements were intended for zone 1 placement, and this was timed and repeated with six sets of patients. For this model, a femoral arterial line was prepositioned in the plastic model, indicating femoral arterial access had already been achieved. Timing began when the participants placed the wire in the femoral arterial catheter and ended when they successfully inflated the ER-REBOA balloon.

A posttest was administered at the completion of the simulation session. The posttest consisted of the same questions as the pretest to record any change from baseline knowledge. A Likert evaluation was again performed, asking the participants how confident they were in performing the procedure after this training.

Evaluations

The examiner evaluated each participant during the placement of the device. The examiner recorded time from insertion to completion, as well as any deviations from the standardized technique.

Statistics

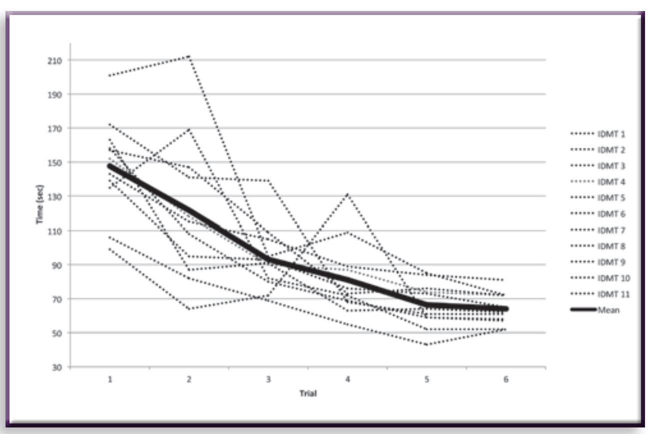
Statistical review of timing, Likert scale scores, and testing data was performed using two-tailed, paired *t* tests with significance assigned at $p < .05$. All tests and descriptive statistics were performed using SAS, version 9.2 (SAS Institute, https://www.sas.com).

Results

Eleven IDMTs were enrolled in training and available for analysis over the 4 months from August 2016 to December 2016. IDMTs ranged in age from 33 years to 39 years (average age, 35.6 years) with years of experience as an IDMT ranging from 2 to 12 years (average, 7.4 years). None of the IDMTs had taken a similar course and none was familiar with REBOA until presented during this training.

There was a significant decrease in procedural times seen from trials 1 to 6 (Figure 3). Overall procedural time (± standard deviation) decreased from 147.7 ± 27.4 seconds to 64 ± 8.9 seconds ($p < .001$). There was a mean improvement of 83.7 ± 24.6 seconds from the first to sixth trial ($p < .001$). Mean difference in procedural time between trials was most marked after the second and third trials, with reductions of 26.1 ± 28.3 seconds and 28.5 ± 37.8 seconds, respectively, between the trials ($p = .015$ and .039, respectively). Time between trials 4 and 5 fell significantly from 81.1 ± 21.0 seconds to 66.4 ± 12.6 seconds ($p = .04$). All participants demonstrated correct placement of the sheath, measurement and placement of the catheter, and inflation of the balloon throughout all six trials (100%).

FIGURE 3 *Time versus trial for each participant.*



Note: Mean improvement in time noted in dark black ($p < .001$). IDMT, independent duty military medical technician.

There was significant improvement in comprehension and knowledge between the pretest and posttest: Average performance improved significantly from 36.4.6% ± 12.3% to 71.1% ± 8.5% ($p < .001$; Figure 4).

Subjectively, all 11 participants noted significant improvement in confidence from 1.2 to 4.1 on the 1–5 Likert scale ($p < .001$; Figure 5).

Discussion

Simulation-based training effectively took this group of endovascular novices and made them competent and confident in procedural skills in an entirely foreign task with much success.

FIGURE 4 *Average pretraining and posttraining test scores ($p < .001$). y-axis, test score; x-axis, participant No.*

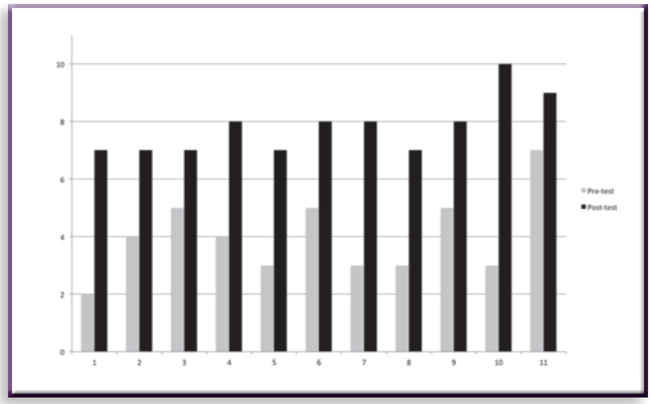
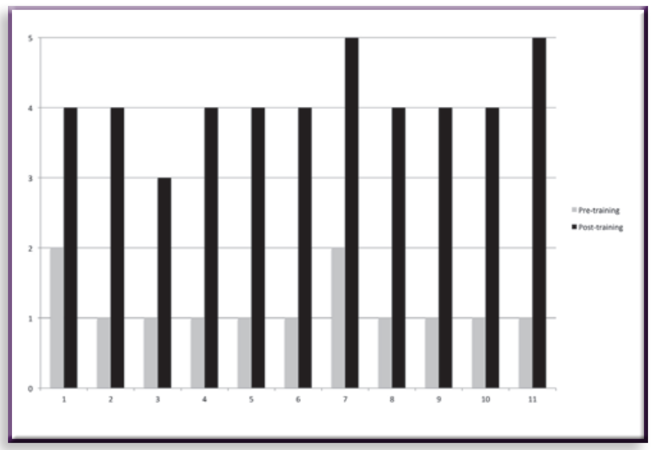


FIGURE 5 *Preprocedure versus postprocedure confidence, assessed by Likert scale score ($p < .001$). y-axis, Likert scale score; x-axis, participant No.*



Based on the completion of this initial training, consideration should be made for additional training for field vascular access to learn the other required skills for successful REBOA placement for NCTH.

NCTH remains a significant cause of preventable death in the battlefield, in which quicker time to proximal control could lead to stabilization of hemodynamics and could improve mortality rates in select populations. Theoretically, with shorter times to occlusion, less hypotension and blood loss should occur and, thus, fewer transfusions.

Morrison et al.[8] reviewed potential for combat intervention with the UK Joint Theater Trauma Registry data during the current military conflicts. They retrospectively looked at casualties with injury patterns and prospective patients in whom REBOA could have been used. Of 1,317 overall patients, 244 patients with injury patterns that had indications for REBOA were identified. Within this group, there were 174 deaths, with 79 at the point of wounding and 66 en route to the hospital. According to Morrison et al., these patients could potentially benefit from a battlefield provider, such as an IDMT with advanced skills and additional hemorrhage control adjuncts.[8]

Prehospital and battlefield deployments are a reality. The first documented prehospital REBOA placement was by the London Air Ambulance. The physician-paramedic team reported successful roadside zone 3 REBOA placement in a 32-year-old patient with presumed pelvic-fracture hemorrhagic shock after falling 15m onto concrete. This patient successfully survived to the hospital and underwent angioembolization and orthopedic surgery. The patient was discharged on hospital day 52.[9]

Our sample of IDMTs underwent simulator training for REBOA placement after didactic training, similar to the acute care surgeon cohort reported on by Brenner et al.[7] Even though acute care surgeons from the University of Maryland have considerable experience with hemorrhage, as well as line placement and some endovascular training, the IDMT group from our study had similar improvements in knowledge and task time, showing that the technique can be taught to a group of motivated, skilled individuals.[7]

Task training to acquire a new skill set has been reviewed by several studies. Aggarwal et al.[10] evaluated novice and experienced endovascular surgeons with interventions using simulation. They noted that after six sessions, the novice participants improved markedly and achieved scores similar to those of the experienced group.

These data support these findings that novice, nonphysician, skilled technicians can successfully be taught the key steps in placement of an endovascular balloon to decrease hemorrhage from a noncompressible torso source. Although these participants had never placed anything similar to this device, these members are highly trained in their respective fields and are very malleable to new technology. With their training comes confidence and skill that can be adapted to various procedures. These motivated individuals are avid learners for new technology to quell bleeding on the battlefield because they may be the only medical provider standing between life and death for the wounded Soldier.

This training was provided in a stable environment with ideal conditions. Battlefield medicine is typically carried out in nonsterile, hectic conditions, which our training did not entertain. Thus, we note the simulator may not provide a realistic experience for the placement of REBOA in a prehospital setting. This training is the first step in acquiring a new skill. The absence of student-performed femoral artery cannulation is a weakness in our model and a necessary skill needed to place this device. Further training should be focused on arterial placement, including landmark guidance, image guidance, and, possibly, open guidance. Also, clear indications need to be set to aid the IDMT in placement after other adjuncts have failed in stabilizing the patient.

Conclusion

Technology for aortic occlusion has advanced to provide smaller, wirefree devices, making field deployment more realistic and feasible. IDMTs can learn the steps required for REBOA and perform the procedure accurately and rapidly, as assessed by simulation, for potential field placement. IDMTs currently lack the skill set to perform percutaneous common femoral artery cannulation. As clinical data demonstrate, arterial access is a significant challenge in the ability to perform REBOA safely and rapidly. Access should be a focus of further training to promote this procedure closer to the point of injury. Clinical judgment will also be critical to use this technology correctly and in the right circumstance. This study demonstrates that IDMTs can learn and retain the technical capabilities to perform REBOA. Additional research is needed to evaluate the feasibility and reproducibility of this intervention under high stress and austere circumstances.

Disclaimer

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Air Force, the Army, the Department of Defense, or the US Government.

Funding

This study was funded in part by a clinical grant from the Department of Defense.

Disclosure

MB is on the Clinical Advisory Board of Prytime Medical Inc. The other authors have no financial relationships relevant to this article to disclose.

Author Contributions

All authors approved the final version of the manuscript.

References

1. **Eastridge BJ, Mabry RL, Seguin P, et al.** Death on the battlefield (2001–2011): implications for the future of combat casualty care. *J Trauma Acute Care Surg*. 2012;73:S431–S437.
2. **Kragh JF Jr, Littrel ML, Jones JA, et al.** Battle casualty survival with emergency tourniquet use to stop limb bleeding. *J Emerg Med*. 2011;41:590–597.
3. **Moore LJ, Brenner M, Kozar RA, et al.** Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage. *J Trauma Acute Care Surg*. 2015;79: 523–530.
4. **Manley JD, Mitchell BJ, DuBose JJ, et al.** A modern case series of resuscitative endovascular balloon occlusion of the aorta (REBOA) in an out-of-hospital, combat casualty care setting. *J Spec Oper Med*. 2017;17(1):1–8.
5. **Garrison P.** *Flying Without Wings: A Flight Simulation Manual*. Blue Ridge Summit, PA: TAB Books; 1985:1–31, 102–106.
6. **Ressler EK, Armstrong JE, Forsythe GB.** Military mission rehearsal: from sandtable to virtual reality. In: Tekian A, McGuire C, McGaghie W, eds. *Innovative Simulations for Assessing Professional Competence*. Chicago, IL: University of Illinois; 1999:157–174.
7. **Brenner M, Hoehn M, Pasley J,** et al**.** Basic endovascular skills for trauma course: bridging the gap between endovascular techniques and the acute care surgeon. *J Trauma Acute Care Surg*. 2014;77:286–291.
8. **Morrison JJ, Ross JD, Rassmusen TE, et al.** Resuscitative endovascular balloon occlusion of the aorta: a gap analysis of severely injured UK combat casualties. *Shock*. 2014;41: 388–393.
9. **Sadek S, Lockey DJ, Lendrum RA,** et al**.** Resuscitative endovascular balloon occlusion of the aorta (REBOA) in the pre-hospital setting: an additional resuscitation option for uncontrolled catastrophic haemorrhage. *Resuscitation*. 2016; 107:135–138.
10. **Aggarwal R, Black SA, Hance JR, et al.** Virtual reality simulation training can improve inexperienced surgeons' endovascular skills. *Eur J Vasc Endovasc Surg*. 2006;31:588–593.

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Spring 2018
Volume 18, Edition 1

THE JOURNAL FOR OPERATIONAL MEDICINE AND TACTICAL CASUALTY CARE

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