Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) training and practical implementation

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Part II. Vascular access training for REBOA placement

Chapter 5.

Vascular access training for REBOA placement: a feasibility study in a live tissue-simulator hybrid porcine model

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ABSTRACT

Introduction: The use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in patients with severe hemorrhagic shock is increasing. Obtaining vascular access is a necessary prerequisite for REBOA placement in these situations.

Methods: During the EVTM workshop (September 2017, Örebro, Sweden), 21 individuals participated in this study, 16 participants and five instructors. A formalised curriculum was constructed including basic anatomy of the femoral region and basic training in access materials for REBOA placement in zone 1. Key skills: (1) preparation of endovascular toolkit, (2) achieving vascular access in the model and (3) bleeding control with REBOA. Scoring ranged from 0 to 5 for non-anatomical skills. Identification of anatomical structures was either sufficient (score=1) or insufficient (score=0). Five consultants performed a second identical procedure as a post test.

Results: Consultants had significantly better overall technical skills in comparison with residents ($p=0.005$), while understanding of surgical anatomy showed no difference. Procedure times differed significantly ($p<0.01$), with residents having a median procedure time of 3 min and 24 s, consultants 2:33 and instructors 1:09.

Conclusions: This comprehensive training model using a live tissue-simulator hybrid porcine model can be used for femoral access and REBOA placement training in medical personnel with different prior training levels. Higher levels of training are associated with faster procedure times. Further research in open and percutaneous access training is necessary to simulate real-life situations. This training method can be used in a multistep training programme, in combination with realistic moulage and perfused cadaver models.

INTRODUCTION

Endovascular balloon occlusion of the aorta is a technique where a compliant balloon is advanced into the aorta and then inflated, obstructing flow into the distal circulation. This has the effect of increasing cardiac afterload and proximal aortic pressure, resulting in an increase in myocardial and cerebral perfusion [1]. These effects may be particularly beneficial in the initial management of patients in hemorrhagic shock and circulatory collapse, either while resuscitation is being initiated or for patients who do not respond optimally to initial resuscitative efforts.

Obtaining vascular access is a prerequisite for placement of a resuscitative endovascular balloon occlusion of the aorta (REBOA) catheter in these situations. The most commonly used access site for this procedure is the common femoral artery. In the setting of acute decompensation, however, obtaining this access expediently can prove challenging. For this reason, some experts have advocated that a 5–8 Fr sheath be routinely placed in the femoral artery in broad categories of patients sustaining major trauma, in order to both optimally monitor hemodynamic changes and to facilitate expedient REBOA placement should it be necessary. With this strategy, it has been suggested to add another A for vascular access to the traditional ATLS ABCDE strategy (AABCDE of initial trauma care) [2].

The principles of REBOA use have been used as part of the endovascular and hybrid trauma and bleeding management (EVTM) concept in the hospital setting, combat environments and even in the earliest phases of prehospital care. Rees et al recently reported on how REBOA could be delivered using equipment currently available in the Royal Navy Role 2 Afloat equipment module and in other military settings where access to an operating table might be compromised. This could include use by the Commando Forward Surgical Group in support of littoral operations by the Royal Marines or by British Army Role 2 Light Manoeuvre units [3].

Organized as a group to study the use of REBOA and other EVTM principles, the mission of the EVTM International Collaboration Workgroup is to evaluate the safety and the efficacy of EVTM as a potential standard for the emergency care of selected patients. It is unknown whether it is feasible to train medical personnel with limited or no endovascular or surgical experience, including prehospital care providers such as nurses and medics, to perform endovascular procedures. There are a few formal training curricula designed to train the skills necessary to perform REBOA. These include the Basic Endovascular Skills for Trauma™ (BEST) and the Endovascular Skills for Trauma and Resuscitation™ (ESTARS) courses, which are not currently widely available and are focused on training surgeons.

The primary aim of this feasibility study is to evaluate a limited training curriculum (EVTM course) on a porcine model for training adequate placement of an endovascular sheath in a femoral artery model, and subsequently place a REBOA catheter in zone I (Figures 1 and 2) [1].

Figure 1. Aortic zones of placement (I, II and III) [1]

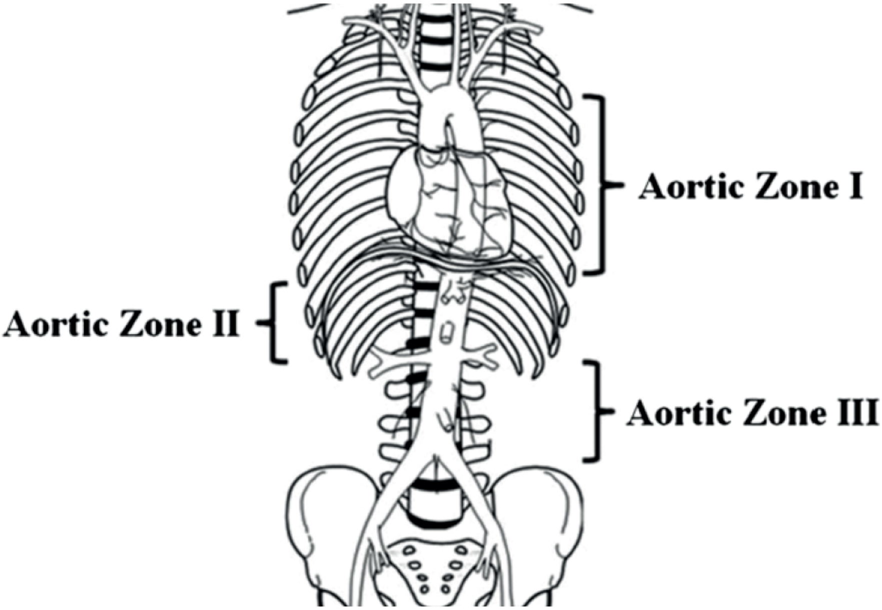
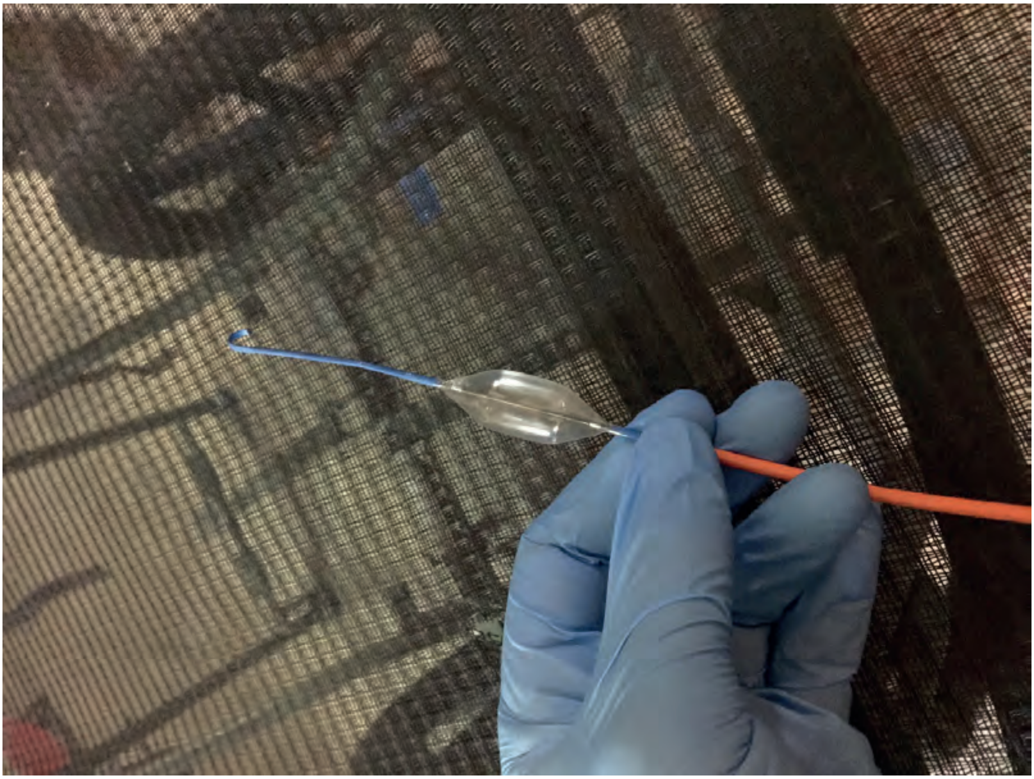


Figure 2. Resuscitative endovascular balloon occlusion of the aorta as used during military deployment.



METHODS

Participants

Five surgical residents, two emergency department (ED) physicians and nine surgeons consisting of four general surgeons, four trauma surgeons and one vascular surgeon with no or limited endovascular experience participated. Five participants (two general surgeons, two trauma surgeons and one ED physician) performed the identical procedure a second time as a post-test several hours after additional endovascular training during the EVTM course. Senior endovascular instructors with expert level of expertise performed the same procedure, serving as controls for the quality of performance.

Curriculum

First, a formalised and comprehensive programme was constructed containing training of basic anatomy of the femoral region and basic training in access materials including a guide wire and introducer sheath. Furthermore, the details and the instructions for use of the ER-REBOA® balloon were explained and demonstrated via an animation video and the necessary steps in the procedure of deployment of the balloon in zone I were discussed step by step [4].

Second, the porcine model was introduced and the trainees were instructed one on one by a vascular surgeon (BLSBvdB) to identify anatomical landmarks and verbalising each step required for adequate achievement of vascular access and REBOA positioning in zone 1. The total duration of this curriculum was 15 min per participant. Key skills were as follows: (1) preparation of endovascular tool kit, (2) achieving vascular access in the model and finally (3) bleeding control with REBOA. Scoring ranged from 0 to 5 for non-anatomical skills. Identification of anatomical structures was either sufficient (score=1) or insufficient (score=0). How to achieve vascular access and place the ER-REBOA® in zone 1 is described in Textbox 1.

Textbox 1. How to achieve vascular access and placement of the ER-REBOA®.

Achieving vascular access is the first step in REBOA placement. This is done using the Seldinger technique. First step in this technique is to identify the artery. This can be done using anatomical landmarks. For the femoral region these are the lateral side of the pubic bone, the superior anterior iliac spine (SAIS) and the inguinal ligament. Approximately halfway between the pubic bone and the SAIS the common femoral artery can be palpated. This is the optimal site for punction of this artery. After successful punction of the artery in a 45-degree angle of the needle, a pulsatile arterial flow will be visible. A 0.035-inch guidewire is introduced through the needle. This is done without force and should be possible without resistance. After introduction of the guidewire, the needle is removed, applying digital pressure to the punction site and leaving the guidewire in situ. A 5mm incision is made to allow the introducer sheath passing through the skin. The introducer sheath consists of two parts; the sheath itself and the dilator. It is important to check that the dilator is fully connected to the sheath in order to prevent intimal damage when introducing the sheath. The introducer sheath is positioned over the guidewire and gently pushed into the artery. The dilator and guidewire are removed, leaving the sheath in situ.

After successful sheath placement the ER-REBOA® catheter can be prepared for introduction. For introduction in zone 1 we measure the distance from the femoral access site to 10cm above the xiphoid bone using the ER-REBOA® catheter on the outside of the patient as a ruler. On the outside of the catheter itself the centimetre markings indicate the distance. Because the ER-REBOA® can be introduced without a guidewire it has a flexible tip. This tip cannot be pushed through the valve of the sheath. An orange peel away sheath is used to straighten the tip. Now the ER-REBOA® catheter can be introduced through the valve of the introducer sheath. It can now be advanced to zone 1, by carefully checking the centimetre markings on the outside of the catheter. As a final step the balloon is inflated using 30 ml saline for full occlusion.

Model

In the animal laboratory of the University Hospital of Örebro, Sweden, a 40 kg pig was placed in supine position under general anaesthesia and the right common femoral artery was dissected to facilitate placement of an 8 Fr introducer sheath. An 8 Fr introducer sheath was used for ER-REBOA to facilitate multiple use of the balloon (7 Fr introducer can be used). A linear silicone tube was secured parallel to the common femoral artery of the porcine model to simulate the common femoral artery. Achieving femoral access was simulated by using the Seldinger technique in the silicone tube [5 6]. A point-of-view GoPro® was used in all participants (via a helmet camera) as well as two additional GoPro® cameras that were positioned to achieve a 360-degree angle of the model and participant (Figure 3A–D). At the beginning of the EVTM course, all participants were familiarised with ethical considerations using live animals for training. After verbalizing every step of the procedure, the actual test started and video recording commenced and procedure time was registered.

Figure 3. (A–D) Images of the porcine model and GoPro set-up.

Scoring system

Participants were evaluated using a modified checklist that was developed as part of a validation study for the Advanced Surgical Skills Exposures for Trauma (ASSET) [7, 8]. This included an individual procedure score, scores on five components of technical and non-technical skills, Global Rating Scale scores, errors and time to complete the procedure of achieving vascular access and balloon placement. Two evaluators (BLSBvdB, DE or RH) located in the same laboratory evaluated performance with a standardised script for data collection.

Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS®, V.24; IBM). All baseline information of the subjects and subsequent follow-up data were registered in an electronic data file. Due to the skewed distribution and small number of participants, the $\chi 2$ test was used to analyse the test scores and the Kruskal-Wallis test for procedure times. For all statistical analyses, a p value equal or less than 0.05 was considered significant.

RESULTS

Twenty-one individuals participated in this study, 16 participants and five instructors. Five surgical residents participated in the test with an average of 2.4 years of experience. The 11 other participants were experienced surgeons or ED physicians. The differences of technical skills between surgical residents and participating consultants can be seen in Table 1.

Table 1. Average results of the surgical residents and the medical consultants.

Technical skill	Resident average median [IQR]	Consultant average median [IQR]	p-value
identifies adequate puncture site CFA	4.0 [3.0 – 4.0]	4.0 [4.0 – 5.0]	0.125
adequate puncture of CFA needle	4.0 [3.5 – 4.0]	4.0 [4.0 – 4.0]	0.211
uses Seldinger technique adequately/sheath placement	3.0 [3.0 – 3.5]	4.0 [4.0 – 5.0]	**0.002**
adequately introduces REBOA catheter	4.0 [2.5 – 4.0]	4.0 [4.0 – 5.0]	0.273
proceeds at appropriate pace with economy of movement	3.0 [2.5 – 4.0]	4.0 [4.0 – 5.0]	0.116
insufflates balloon correctly (full REBOA)	4.0 [3.5 – 4.0]	5.0 [4.0 – 5.0]	0.058
communicates clearly and consistently	4.0 [3.5 – 4.0]	4.0 [4.0 – 5.0]	0.402
follows a logical sequence for the procedure	3.0 [2.5 – 3.5]	4.0 [4.0 – 5.0]	**0.008**
anatomy*: identifies inguinal ligament	1.0 [1.0 – 1.0]	1.0 [1.0 – 1.0]	1.000
anatomy*: identifies CFA	1.0 [1.0 – 1.0]	1.0 [1.0 – 1.0]	0.308
anatomy*: identifies CFV	1.0 [0.0 – 1.0]	1.0 [1.0 – 1.0]	0.350
anatomy*: identifies PFA	1.0 [0.5 – 1.0]	1.0 [1.0 – 1.0]	0.126
anatomy*: identifies SFA	1.0 [0.0 – 1.0]	1.0 [1.0 – 1.0]	0.142
Overall: technical skills for introducing sheath and balloon	3.0 [3.0 – 3.5]	4.0 [4.0 – 4.0]	**0.005**
Overall: understanding of surgical anatomy of the femoral region	3.0 [2.0 – 4.0]	4.0 [3.0 – 5.0]	0.072

QR indicates interquartile range, *CFA*: common femoral artery, *REBOA*: resuscitative endovascular balloon occlusion of the aorta, *CFV*: common femoral vein, *PFA*: profundal femoral artery, *SFA*: superficial femoral artery. *: score ranging from 0 – 1.

Participants in a consultant position had significant better overall technical skills in comparison with the surgical residents, while understanding of surgical anatomy showed no difference. Residents had a median procedure time of 3 min and 24 s, participants in a consultant position 2:33 and instructors 1:09. When residents were compared with participants in a consultant position, the latter were significantly faster (p=0.008) as presented in Table 2. Excluding emergency physicians from the participants in a consultant position group did not alter the median outcome and differences remained statistically significant. Although participants in a consultant position decreased their time needed with an average of 34 s after the first test, when compared with instructors, instructors were still significantly faster (p=0.028).

Table 2. Procedure time (needle in hand to balloon insufflation).

Expert level	Time needed (median in mm:sec) [IQR]	p-value
Resident	3:24 [3:06 – 4:42]	0.008[a]
Surgeon / Consultant	2:33 [2:05 – 2:58]	0.002[b]
Instructor	1:09 [0:50– 1:23]	0.001[c]

mm: sec indicates minutes: seconds, *IQR*: Interquartile range.
[a] Resident vs Consultant, [b] Consultant vs Instructor, [c] Resident vs Instructor

DISCUSSION

This feasibility study provides evidence that training of REBOA placement for medical personnel with no prior endovascular experience is possible using a live tissue-simulator hybrid porcine model. A formalised and comprehensive curriculum including basic anatomy of the femoral region and basic training in endovascular access materials in a porcine model could be used in future training programmes. Our results show that residents and medical consultants with no prior endovascular experience were able to perform REBOA placement within acceptable procedure times. REBOA seems to be a less invasive alternative to an emergency thoracotomy for bleeding control [9]. As expected, consultants were significantly faster in achieving femoral access in this model, and the instructors were significantly faster than the consultants in completing the procedure, indicating that higher level of training improves procedure time. This finding is substantiated by the result that every surgical participant showed improvement in their procedure time in the post test they performed.

Teeter et al described US Army Special Operations Command medical personnel without prior endovascular experience were included in the BEST™ course [10]. Their results concur with our finding that procedure time after basic training of medical personnel of various backgrounds and limited prior endovascular experience can be improved. Brenner et al studied obtaining endovascular skills (such as REBOA placement) with virtual reality simulation and found significant improvements in knowledge ($p=0.0013$) and procedural task times ($p<0.0001$) at the completion of the course that consisted of a didactic and instructional session and subsequent testing on the Vascular Intervention System Training Simulator-C [11]. Significant improvements in procedural time and knowledge were achieved regardless of endovascular experience in residency, years since residency or other parameters.

There are limitations in this feasibility study. The use of a silicone tube for performing the Seldinger technique does not faithfully represent reality. On the other hand, it provided standardization and was necessary to allow for multiple attempts on the same model without damage to the femoral artery. Open exposure by cut down and dissection of the femoral artery should be included in an ideal REBOA training model. In a porcine model, however, this is technically challenging because of the small artery size and depth and toughness of the tissues, which are not comparable with humans. Percutaneous femoral access training in a porcine model is possible; however, our EVTM collaboration group will focus on combining training methods in upcoming REBOA tests. Further training using ultrasound is required.

Confirmation of a correct position in this model was not verified by conventional means (fluoroscopy or ultrasound). Rees et al recently published results on an intravascular ultrasound (IVUS), performed during REBOA in a porcine model of severe ballistic trauma. They demonstrated that IVUS-REBOA is feasible and confirms both correct balloon placement and hemostasis [12]. This could be added to our training module. A multistep programme is advocated, including realistic moulage, animal life tissue and perfused cadaver models for percutaneous and open access training and achieving access in a hypotensive model with collapsed vessels. Our group currently uses REBOA trainer for endovascular access; ultrasound pads are used for puncture and the Seldinger technique and cadavers for (semi) open access. For evaluation of the participants, we used a modified checklist (ASSET). In the evaluation of residents, several medical schools are using the system of the entrustable professional activities (EPAs). The EPAs might also be a useful comparison tool because it assesses the full range of medical education.

To our knowledge, this is the first feasibility study on medical personnel on REBOA placement in a porcine model and to establish the guidelines for this adjunct in the management of hemorrhagic shock in any phase of medical care.

CONCLUSIONS

This comprehensive theoretical and practical training programme using a live tissue-simulator hybrid porcine model can be used for femoral access and REBOA placement training of medical personnel with different prior training levels. Higher levels of training are associated with faster procedure times. Further research in open dissection and percutaneous access training is necessary to simulate real-life situations. The training method proved useful and can be used in a multistep programme, in combination with a realistic moulage and perfused cadaver models, for percutaneous and open access training.

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