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# Resuscitative Balloon Occlusion of the Aorta (REBOA) in non-traumatic out of hospital cardiac arrest – evaluation of an educational program

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**Abstract**

BACKGROUND: Out of hospital cardiac arrest is a critical incident with a high mortality rate. Augmentation of the circulation during cardio-pulmonal resuscitation (CPR) might be beneficial. Use of resuscitative endovascular balloon occlusion of the aorta (REBOA) redistribute cardiac output to the organs proximal to the occlusion. Preclinical data supports that patients in non-traumatic cardiac arrest might benefit from REBOA in the thoracic level during CPR. This study describes a training program to implement the REBOA procedure to a prehospital working team, in preparation to a planned clinical study.

METHODS: We developed a team-based REBOA training program involving the physicians and paramedics working on the National Air Ambulance helicopter base in Trondheim, Norway. The program consists of a four-step approach to educate, train and implement the REBOA procedure in a simulated prehospital setting. An objective structured assessment of prehospital REBOA application (OSAPRA) scoring chart and a special designed training dummy was made for this study.

RESULTS: 7 physicians and 3 paramedics participated. The time needed to perform the REBOA procedure was 8,5 (6,3 – 12,7) min. The corresponding time from arrival at scene to balloon inflation was 12,0 (8,8 – 15) min. The total objective assessment scores of the candidates' competency was 41,8 (39 – 43,5) points out of 48. The advanced cardiovascular life support (ACLS) remained at standard quality, regardless of the simultaneous REBOA procedure.

CONCLUSION: This four-step approach to educate, train and implement the REBOA procedure to a prehospital working team ensures adequate competence in a simulated OHCA setting. The use of a structured training program and objective assessment of skills is recommended before utilizing the procedure in a clinical setting. In a simulated setting the procedure does not add significant time to the prehospital resuscitation time nor does the procedure interfere with the quality of the ACLS.

**Strengths and limitations of this study**

- This study provides insight on the novel use of REBOA on out of hospital cardiac arrest patients.

- It is the first study to describe an extensive educational program for implementing this procedure
- It presents a new objective scoring chart for the REBOA procedure
- It is a single-center study on anesthesiologists, limiting the generalizability of the data.
- Although it is most relevant for physician manned prehospital services, it is also informative for treatment of inhospital cardiac arrest.

## Background

Out of hospital cardiac arrest (OHCA) is a critical incident with a high mortality rate [1]. For non-traumatic cardiac arrest (CA) the most frequent aetiology is cardiac disease [2, 3], with deaths related to failure to achieve return of spontaneous circulation (ROSC), circulatory failure after ROSC or anoxic brain damage [4]. During cardio-pulmonal resuscitation (CPR) the cardiac output is usually not sufficient to maintain consciousness and the lack of oxygen delivery can result in irreversible damage to vital organs [1]. Augmentation of the circulation and hence oxygen delivery to vital organs such as the brain and heart during CPR is therefore beneficial.

Balloon occlusion of the aorta was introduced in the Korean War in 1954 as a means to stabilize soldiers with intraabdominal haemorrhages [5]. After this, resuscitative endovascular balloon occlusion of the aorta (REBOA) has been employed in patients in haemorrhagic shock or CA secondary to trauma. Continuous occlusion of the aorta with REBOA gives a redistribution of cardiac output to the organs proximal to the occlusion including the brain and heart [6]. Several animal studies demonstrate that REBOA during CPR increase both coronary artery blood flow and coronary perfusion pressure and increase the rates of ROSC [7–14]. Aortic occlusion during CPR also gives clinically relevant increased carotid artery blood flow [10, 15], cerebral arterial blood flow [8, 9, 15–17] and cerebral perfusion pressure [8, 9, 15, 18]. Based upon these preclinical data patients in non-traumatic CA might benefit from REBOA in the thoracic level during CPR.

There are no systematic human studies on the use of REBOA for non-traumatic CA. To our knowledge only three case reports are published, of which two patients were considered to have a positive effect of REBOA [19–21]. One explanation for that REBOA is not introduced for OHCA is the feasibility of REBOA insertion in the prehospital setting. However, technological advances in the REBOA technique now allows for fluoroscopy-free aortic occlusion [22] and REBOA is at present used by London's Air Ambulance on trauma patients [23].

The Norwegian physician staffed prehospital emergency medical services (P-EMS) include anaesthesiologists [24]. These physicians will regularly be part of the resuscitation team at OHCA. All anaesthesiologists are skilled in establishing central vascular lines using the Seldinger technique. However, the implementation of a new procedure such as REBOA requires special training before implemented in clinical practice. An educational program was therefore designed to educate, train and implement the REBOA technique to prehospital personnel. In this report, we describe the organization of a team-based REBOA training program and the evaluation of REBOA competencies in a high-fidelity simulation scenario, in preparation for a clinical feasibility study on REBOA in OHCA.

## Methods

### Participants

The physicians and paramedics involved in this study work at the P-EMS base in Trondheim, Norway. The P-EMS has a catchment population of about 700,000 and usually transfer patients with OHCA to one tertiary university hospital (St. Olavs Hospital). The service dispose both a helicopter and a rapid response car. All physicians are board certified qualified anesthesiologist with prehospital work experience from 4 to 18 years. The paramedics have from 11 to 34 years work experience in the service. Seven physicians and 3 paramedics participated.

**REBOA procedure**

Aortic zones are divided in three zones, I, II, and III, spanning from proximal to distal. Zone I is the descending thoracic aorta between the origin of the left subclavian and celiac arteries. REBOA during CA is placed in zone I, for optimal haemodynamic effect [25]. The insertion technique of REBOA is based on identification of the femoral artery by ultrasound, insertion of the REBOA catheter over a guidewire and placement based upon length of catheter from the insertion.

**Educational program**

The educational program is performed in defined steps and is a combined theoretical and practical training program. It is based upon validated educational models for skill training of other procedures performed by physicians from a variety of specialties [26–28]. The educational program is divided in a theoretical part, basic skill training, training in the interventional radiology department and high-fidelity simulation.

**Part 1 - Theoretical part**

The didactic theoretical part of this study is an introduction to the concept of REBOA, as well as placement technique and the necessary equipment, given to both physicians and paramedics. The educational content of this part is a Microsoft PowerPoint presentation and a Q&A discussion.

**Part 2 - Basic skill training**

The physicians and paramedics trained repeatedly on a dummy training model. This dummy was designed specifically for this use, in collaboration with engineers at Norwegian University of Science and Technology (NTNU). The cannulation site is a block made of a mixture of hydrocarbon gel and silicone rubber, measuring 10 x 20 x 6 cm. Two compressible silicone rubber tubes (inner diameter 7 and 12 mm), representing the femoral artery and vein, was molded into the block at a depth of approximately 10 mm. The cannulation site was developed with the capacity of both being replaceable and withstanding several cannulations without leakage or deterioration of the ultrasound image quality. The arterial lumen was of 1 m length and expanded to 3 cm in diameter, allowing placement of the introducer (Super Arrow-Flex, Teleflex, 7 Fr, 45 cm length), guidewire and balloon catheter (REBOA Medical, 7 Fr, 20 mm diameter). This training ensured knowledge of the equipment, correct technique and correct placement of the REBOA catheter. It also allowed the trainees to repeat the procedure as many times as necessary to obtain the proper skill and confidence in performing the procedure. The training was observed by the first author, available for questions and/or guidance. A detailed outline of the procedure is described in appendix 1.

**Part 3 - Interventional radiology department**

The physicians attended one day at the interventional laboratory, St. Olavs Hospital. Similar guidewires, introducers and catheters as used in REBOA are in daily use at this laboratory. The physician participated in inserting the equipment in patients scheduled for angiography under guidance and supervision of an experienced interventional radiologist. Vascular access was achieved using ultrasound guidance. After training each operator was approved for the REBOA procedure by a consultant interventional radiologist.

**Part 4 - High fidelity simulation**

This part was held in the Centre for Medical Simulation, St. Olavs Hospital. The facility simulated a prehospital setting and was equipped with sound- and video-recording and a one-way mirror window. Video sequences were used in the debriefing session.

The scenario started with establishing advanced cardiovascular life support (ACLS) according to current guidelines from The Norwegian Resuscitation Council [29]. Ambulance personnel and/or medical students trained in ACLS participated, which is representative of the personnel resources usually available at scene. After endotracheal intubation, establishing manual chest compression and intravenous access on the upper body, the decision to insert a REBOA-catheter was made. The simulation mannequin used is not designed for use of a mechanically chest compression machine, therefore only manual chest compressions was performed. The ultrasound guided femoral artery access was performed on the designed cannulation block, integrated into the simulation mannequin.

All teams where given the same case; a 59-year-old man with known hypertension, monotherapy antihypertensive treatment, suffering from a cardiac arrest at his home, wife present and by-stander CPR of good quality until the ambulance crew arrived. Initial rhythm was ventricular fibrillation (VF), and this VF was refractory regardless of other treatment than REBOA. ROSC was simulated 1 minute after balloon occlusion. The scenario was aborted after the team recognized ROSC and started to prepare for departure to hospital.

**Assessment of performance**

Global rating scale (GRS) is an assessment tool based on different aspect of quality in operative performance, adapted from a validated scoring system [30]. It is a quantitative marker of performance and is not specific to the REBOA procedure and may apply to other endovascular or technical procedures. It is shown that procedure specific rating scales can be used to assess trainee's competence in endovascular procedures [31] or other bedside procedures [26]. Since a GRS for a prehospital REBOA procedure does not exist, an

Objective Structured Assessment of Prehospital REBOA Application (OSAPRA) chart, modified for the REBOA procedure, was developed (Appendix 2). The OSAPRA consist of 12 5-points categorical scores each anchored 0 – 4. Cut scores for adequate performance had to be determined without previous empirical data. Based on what was considered as the minimum level of performance, the investigators agreed upon a cut score of 30 of a total of 48 points on the OSAPRA. Each assessment was performed based upon video recording and done independently by two observers. If major discrepancies between the observer ratings occurred, a third observer performed an independently assessment, then the observers discussed until agreement.

**Debriefing**

After every session, a semi-structured debriefing was held, led by the two observers. The use of debriefing after a simulation event is an important tool for learning [32] and can be used to develop and implement a new procedure [33]. All members of the resuscitation team participated in this open discussion. The debriefers ensured that following questions were answered: Was the physician able to maintain in control of the resuscitation? Did the patient receive standard care? Did the procedure interfere with the resuscitation? Did the resuscitation interfere with the procedure? Did the two teams, ambulance crew and P-EMS crew, cooperate well? Was this training program feasible for implementing this new procedure?

**Statistics**

All data is descriptive and given as absolute numbers. Due to the descriptive nature of the study no formal sample testing was performed.

## Results

### Completion of the training program

The theoretical education and mannequin training was completed within two days, with half of the crew (physicians and paramedics) present each day. This ensured a common understanding of the theoretical background and purpose of the intervention, as well as building a consensus on logistics and work pattern. In addition to this training session a mannequin was installed at the helicopter base, enabling the crew to practice the procedure.

The cannulation block made for training was well appraised. The tactile sensation, needle puncturing and inserting of guidewire, introducer and balloon sheaths was of life-like quality. The ultrasound quality was also adequate, hence reflecting a realistic situation. Each training block tolerated more than 20 punctures.

The patient cannulation in the radiological department was completed over a period of 3 weeks. All 7 physicians were approved for competency by the consulting interventional radiologist.

The high-fidelity simulations were completed over a period of 4 days, with one or two physicians participating each day. One of the paramedics attended two days.

### Time for REBOA procedure at simulation

The time needed to perform the REBOA procedure was 8,5 (6,3 – 12,7, SD 2,2) min (Figure 1). The time interval started when the physician called procedural start and stopped when the balloon was inflated. The corresponding time from arrival at scene to balloon inflation was 12,0 (8,8 – 15, SD 2,1) min.

*Figure 1. Time (minutes) used to perform the procedure for the 7 candidates.*

**Competency assessment of REBOA procedure in simulation**

The total objective assessment scores of the candidates' competency was 41,8 (39 – 43,5, SD 1,4) points out of 48 (Figure 2). All scores are mean values from the two observers. No major discrepancies in grading of the candidates occurred between the observers.

*Figure 2. OSAPRA-scores for the 7 candidates*

The scores for each part of the global rating scale is given in Table 1.

| **Physician nr** | **1** | **2** | **3** | **4** | **5** | **6** | **7** |
|---|---|---|---|---|---|---|---|
| Obtains relevant medical history and physiological values | 3.5 | 4 | 3.5 | 4 | 4 | 4 | 3.5 |
| Informs crew about the decision | 4 | 4 | 3.5 | 3.5 | 4 | 3.5 | 4 |
| Prepares the patient | 3.5 | 3 | 3.5 | 3.5 | 3 | 3.5 | 3 |
| Proficiency in ultrasound imaging | 3 | 3.5 | 4 | 4 | 3 | 3.5 | 4 |
| Intraarterial cannulation | 1.5 | 3.5 | 3 | 2.5 | 2.5 | 3.5 | 3 |
| Inserting guidewire | 2.5 | 2.5 | 2.5 | 4 | 3 | 2.5 | 3 |
| Inserting introducer | 3.5 | 3.5 | 3.5 | 3 | 3 | 4 | 4 |
| Inserting the REBOA catheter | 2.5 | 3.5 | 3.5 | 3.5 | 3.5 | 4 | 3.5 |
| Fixation | 4 | 3.5 | 4 | 3.5 | 4 | 3.5 | 3.5 |
| Deflation of the balloon | 4 | 4 | 4 | 4 | 4 | 3.5 | 4 |
| Communication | 4 | 3 | 3.5 | 4 | 4 | 4 | 3 |
| Use of assistant | 3 | 3.5 | 4 | 3 | 3.5 | 4 | 4 |
| **Mean value** | **39** | **41.5** | **42.5** | **42.5** | **41.5** | **43.5** | **42.5** |

*Table 1. The physicians individual scores for each part of the global rating scale. Each score ranges from 0 to 4.*

**Debriefing after simulation**

All resuscitation teams regarded the ACLS to be of standard quality. None of the teams felt that neither the REBOA procedure nor the ACLS interfered with each other negatively. The team leaders (physicians) all considered themselves to "be on top of the situation", even though they concentrated on performing a new specialized procedure. Another factor that were emphasized is that the paramedics are not used to sterile procedures and in this specific procedure they have a crucial role in handling equipment to the physicians. The participants considered this four-step training to implement the REBOA technique to be adequate and recommended before use in a clinical setting.



**Discussion**

This study showed that a team based four-step educational program resulted in adequate performance of a REBOA procedure in a simulated OHCA setting.

This educational program's stepwise combination of theory, training on mannequins and patients and the use of high-fidelity simulation provides the trainees with adequate competency in a simulated model. The time needed to establish a REBOA catheter was approximately 8,5 minutes. Based on the feedback from the participants and the observers we observed that the procedure did not interfere with the quality of the ACLS given simultaneously. This indicates that the procedure does not add significant time to the prehospital resuscitation time and will not interact negatively on established care.

An objective measurement of skills is difficult. Checklists are easy to use, but to evaluate clinical skills, studies suggest that GRS is a more dependable measure [26, 34–36]. Cut scores are often used to assess performance and the selection of a cut score risk to be biased by evaluators opinions. There are recommendations for how to decide cut scores or define adequate performance [37–39]. However, a GRS for a prehospital REBOA procedure does not exist and cut scores to the OSAPRA score had to be determined without previous empirical data. A possible method to set the cut score is the Angoff method [40], in which a group of experts establishes the cut score based on a fictitious "borderline" candidate. Experts present a description of a performance that they believe is on the borderline between competent and incompetent, and the cut score is set based on the score of this performance. Borderline cases can also be identified by that the raters record "red flag" performances, using a global impression. The reasons to identify a "red flag" performance for interventional procedures are often significant breaches of sterility or performances leading to damage to important structures or organs [26]. We believe that a combination of cut scores and an overall global impression on safety and competence can be used as foundation to deem adequate competency.

Applying high-fidelity simulation to an educational program provides a powerful platform for evaluating technical skills as well as team work and communication. In addition to the actual training we consider the debriefing sessions as important for the learning effect. The debriefers role in the debriefing session is important and difficult, and the learning effect of such a session is dependent of the skills and learning environment created by the debriefer [32]. One of the investigators works at the Centre for Medical Simulation and is trained as a facilitator in debriefing sessions. The debriefers are known to the trainees. We believe that this contributed positively to create a non-hostile debriefing environment.

We recognize that this study has some limitations. First, it is a single-center study, and only assessed 7 physicians and 3 paramedics. Secondly, we included only anesthesiologists working in a P-EMS system with a homogenous set of skills and the results might therefore not be generalized to physicians from other specialties. However, the study is relevant to services such as in Scandinavia, where mainly anesthesiologists participates in the physician-manned P-EMS. Thirdly, the simulation was done on mannequins, and although the high-fidelity simulation mimicked the prehospital setting, it may not translate directly to the real prehospital environment. Fourth, this is a scenario where all participants are prepared specifically for testing the REBOA procedure and where all participants knew the indications well. Finally, the objective assessment chart had to be developed for this study, meaning that it has yet to be validated.

Strengths of this study is that it is specifically designed for a team competent in the Seldinger technique, thereby, relevant for the personnel who will perform REBOA in real life settings. We evaluated both technical and communication skills, as well as team work. The OSAPRA scoring chart is constructed in a systematic manner, based on input from physicians with a wide range of expertise.

REBOA may be an important modality for out-of-hospital ACLS. This is supported by animal studies on physiology during CPR. However, it is not known if REBOA will give benefit on human ACLS. An answer to this question can only be given by a comparative study of REBOA plus standard care versus standard care alone. However, it is reasonable to develop and perform an educational program and to test in-field feasibility of REBOA in the prehospital setting before initiating a comparative study. This clinical feasibility study is currently in progress (ClinicalTrials.gov Identifier NCT03534011).

**Conclusions**

This four-step approach to educate, train and implement the REBOA technique in a prehospital working team provides adequate competence in a simulated setting. This training is a first step before the start of a planned feasibility trial of REBOA for OHCA. We recommend the use of a systematic training program and the OSAPRA score to guide and improve training. In a simulated prehospital setting the teams used 8,5 minutes to establish a REBOA-catheter. This indicates that the procedure does not add significant time to the resuscitation time prehospital. Based on the feedback from the participants and the observers we conclude that the procedure does not interfere with the quality of the ACLS given simultaneously.



**Declarations**

**Etichs approval and consent to participate:** This study was approved by the Regional Committee for Medical and Health Research Ethics (reference 2017/2482/REKmidt).

**Consent for publication:** Not applicable

**Availability of data and material:** The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Competing interests**: One of the authors (ES) has stock ownership and a board position in Reboa Medical AS. The other authors declare that they have no competing interests.

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**Authors' contributions**: JRB and TL designed the study, interpreted and analyzed the data. JRB drafted the manuscript and prepared the figures/tables. ES, AJK and PK contributed to the design of the study and revised the manuscript. TS, CK and MS contributed on developing the dummy training model. All authors read and approved the final manuscript.

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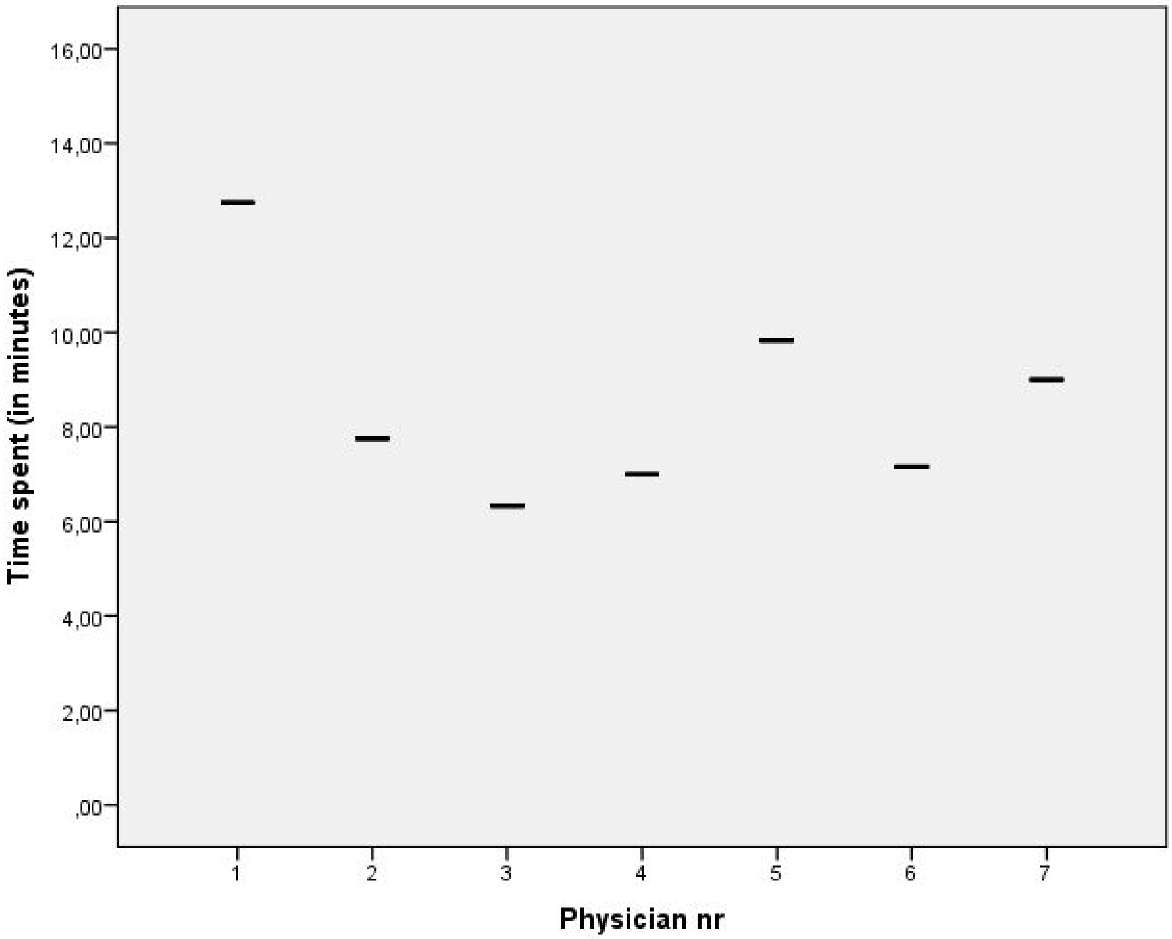
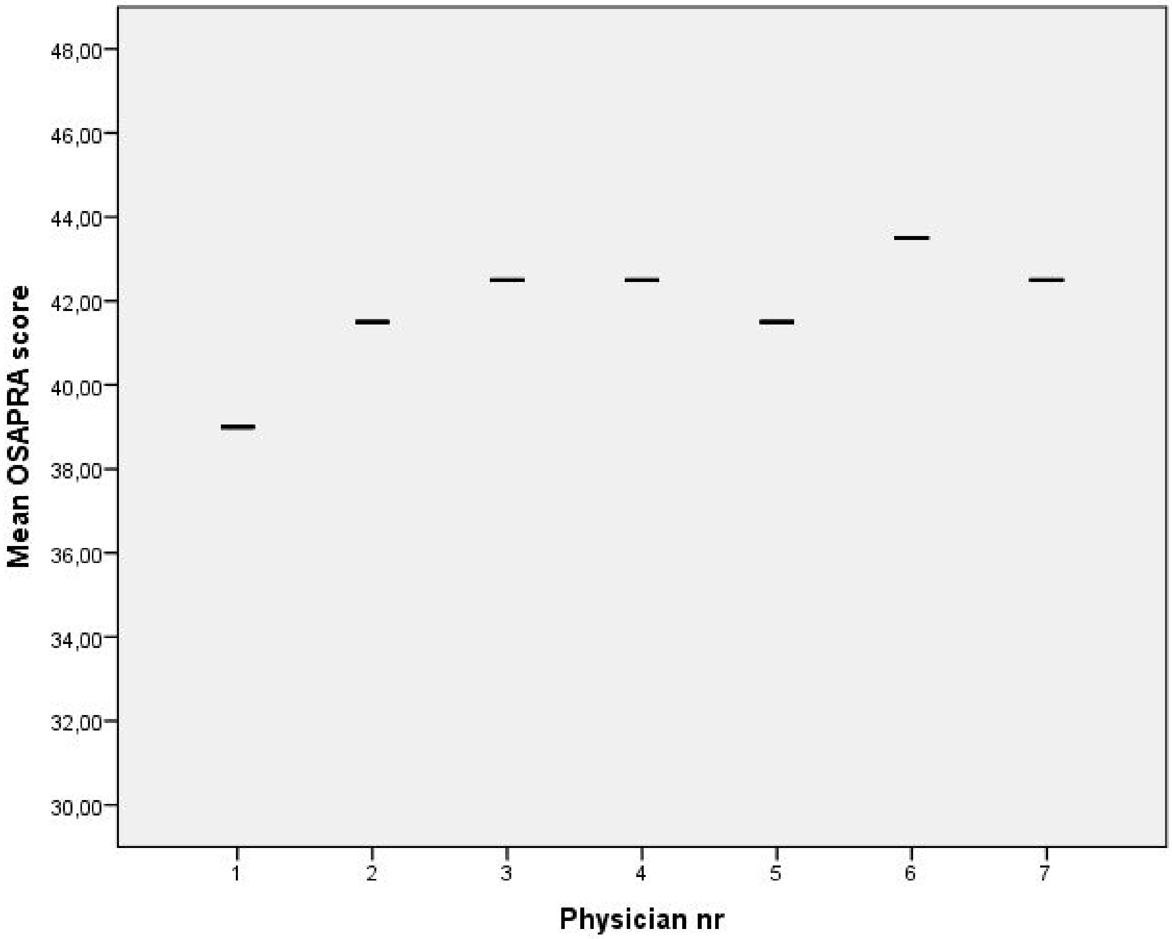

16,00
14,00
12,00
10,00
8,00
6,00
4,00
2,00
,00
Time spent (in minutes)
1
2
3
4
5
6
7
Physician nr


Mean OSAPRA score
48,00
46,00
44,00
42,00
40,00
38,00
36,00
34,00
32,00
30,00
1
2
3
4
5
6
7
Physician nr

# PROCEDURE FOR INSERTION OF REBOA FOR OHCA

Abort procedure if technical problems like:

- -severe difficulties in ultrasound (US) visualization of the artery or cannulation
- -resistance when inserting guidewire, introducer or catheter
- -severe bleeding
- -time consuming procedure

| PHYSICIAN | PARAMEDIC |
|---|---|
| **1.** Cut clothes from knee to groin | **1.** Open kit – unpack – place sterile gloves for physician |
| **2.** Examine with US – store image | **2.** Place introducer and balloon-catheter on sterile cloth |
| **3.** Note EtCO2 | **3.** Prepare NaCl and Chlorhexidine – close to physician |
| **4.** Fill NaCl in wash tray | **4.** Put on sterile gloves |
| **5.** Apply Chlorhexidine on compresses | **5.** Aspirate 15 ml NaCl from wash tray in 20 ml syringe |
| **6.** Wash selected area with forceps and compresses | **6.** Hand physician forceps – place compresses on sterile cloth |
| **7.** Fill gel into the US-cover – place it on the US-probe | **7.** Apply sterile drape |
| **8.** Apply US-gel on the thigh | **8.** Prepare US-cover |
| **9.** US-guided cannulation of a. femoralis | **9.** Apply elastic band – place probe on the sterile drape |
| **10.** Insert guidewire into cannulation needle, 60 cm | **10.** Prepare needle with 5 ml syringe |
| **11.** Remove needle – make skin incision with scalpel | **11.** Ready guidewire |
| **12.** Record US-video of guidewire in a. femoralis | **12.** Hand physician soft end of guidewire, insert to 60 cm |
| **13.** Insert introducer – remove dilatator | **13.** Hand scalpel to physician |
| **14.** Insert balloon-catheter, 50 cm | **14.** Mount introducer and dilatator onto guidewire |
| **15.** Check pulse - LEFT a. radialis | **15.** Control the guidewire |
| **16.** Fill balloon with 15 ml NaCl | **16.** Ready balloon-catheter |
| **17.** Check pulse in LEFT a. radialis | **17.** Put stopcock on blue line |
| **18.** Note time for balloon inflation and EtCO2 | **18.** Put plug on the black line |
| **19.** Suture and fixate | **19.** Hand physician 20 ml syringe with 15 ml NaCl |
| **20.** Place adhesive cover over REBOA-equipment | **20.** Ready suture – needle-holder – scalpel |
| **21.** Secure guidewire with forceps | **21.** Cut suture |
| | **22.** Ready adhesive cover |
| | **23.** Cut and remove sterile drape |

## Objective Structural Assessment of Prehospital REBOA Application - OSAPRA

**Trainee:** **Evaluator:**

### Indication for REBOA

| | | ***Score:*** |
|---|---|---|
| Obtains relevant medical history and physiological values | 0: Does not obtain any information | |
| | 2: Obtains sufficient information, partial completion of checklist | |
| | 4: Obtains relevant information and completes checklist | |

### Preparations for the procedure

| | | |
|---|---|---|
| Informs crew about the decision | 0: Does not inform crew at all | |
| | 2: Gives sufficient information | |
| | 4: Informs in a relevant and precise way | |

| | | |
|---|---|---|
| Prepares the patient | 0: Does not prepare patient for the procedure at all | |
| | 2: Prepares the patient sufficiently | |
| | 4: Prepares the patient with desinfectant, sterile cloth and uses ultrasound probe cover | |

### Performing the procedure

| | | |
|---|---|---|
| Proficiency in ultrasound imaging | 0: Shows no skill in identifying vessels and structures | |
| | 2: Shows adequate skills in identifying vessels and structures | |
| | 4: Shows ample skills in identifying vessels and structures | |

| | | |
|---|---|---|
| Intraarterial cannulation | 0: Does not use needle-tip-tracking to cannulate | |
| | 2: Uses some needle-tip-tracking | |
| | 4: Display ample skills in needle-tip-tracking and cannulation | |

| | | |
|---|---|---|
| Inserting guidewire | 0: Does not stabilize and angle the needle when inserting wire and does no measurement of guidewire length | |
| | 2: Handles the needle suficiently when inserting the wire and handles guidewire somewhat skilled | |
| | 4: Handles the needle proficiently when inserting the wire and uses correct insertion length with impecable handling of wire | |

| | | |
|---|---|---|
| Inserting introducer | 0: Does not make skin incision and handles the introducer poorly | |
| | 2: Makes skin incision and handles the introducer sufficiently | |
| | 4: Makes skin incision and handles the introducer proficiently | |

| | | |
|---|---|---|
| Inserting the REBOA | 0: Poor handling of catheter | |
| | 2: Sufficient handling of the catheter and placementh of length | |
| | 4: Shows ample skills in handling catheter and correct length | |

| | | |
|---|---|---|
| Fixation | 0: No fixation of catheter | |
| | 2: Fixation with dressing/tape or suture | |
| | 4: Fixation with dressing/tape and suture | |

***Turn paper***

**After ROSC**

| | | |
|---|---|---|
| Deflation of the balloon | 0: Does not deflate the balloon at all | |
| | 2: Deflates the balloon appropriately when achieved ROSC | |
| | 4: Deflates the balloon with perfect timing at ROSC | |

**Coorporation with assistant**

| | | |
|---|---|---|
| Communication | 0: Does not communicate with the assistant at all | |
| | 2: Communicates sufficiently with the assistant | |
| | 4: Communicates in a clear and proficient way | |

| | | |
|---|---|---|
| Use of assistant | 0: Does not make use of assistant at all | |
| | 2: Uses assistant in a sufficient way | |
| | 4: Uses assistant proficiently and optimally | |

***Total score:*** ______

of total 48

**Time**

| | |
|---|---|
| Time spent from start REBOA procedure to occlusion of aorta | min |

BMJ Open

# Resuscitative Balloon Occlusion of the Aorta (REBOA) in non-traumatic out of hospital cardiac arrest – evaluation of an educational program

| | |
|---|---|
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| | |

# Resuscitative Balloon Occlusion of the Aorta (REBOA) in non-traumatic out of hospital cardiac arrest – evaluation of an educational program

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## Abstract

BACKGROUND: Out of hospital cardiac arrest is a critical incident with a high mortality rate. Augmentation of the circulation during cardio-pulmonal resuscitation (CPR) might be beneficial. Use of resuscitative endovascular balloon occlusion of the aorta (REBOA) redistribute cardiac output to the organs proximal to the occlusion. Preclinical data supports that patients in non-traumatic cardiac arrest might benefit from REBOA in the thoracic level during CPR. This study describes a training program to implement the REBOA procedure to a prehospital working team, in preparation to a planned clinical study.

METHODS: We developed a team-based REBOA training program involving the physicians and paramedics working on the National Air Ambulance helicopter base in Trondheim, Norway. The program consists of a four-step approach to educate, train and implement the REBOA procedure in a simulated prehospital setting. An objective structured assessment of prehospital REBOA application (OSAPRA) scoring chart and a special designed simulation mannequin was made for this study.

RESULTS: 7 physicians and 3 paramedics participated. The time needed to perform the REBOA procedure was 8,5 (6,3 – 12,7) min. The corresponding time from arrival at scene to balloon inflation was 12,0 (8,8 – 15) min. The total objective assessment scores of the candidates' competency was 41,8 (39 – 43,5) points out of 48. The advanced cardiovascular life support (ACLS) remained at standard quality, regardless of the simultaneous REBOA procedure.

CONCLUSION: This four-step approach to educate, train and implement the REBOA procedure to a prehospital working team ensures adequate competence in a simulated OHCA setting. The use of a structured training program and objective assessment of skills is recommended before utilizing the procedure in a clinical setting. In a simulated setting the procedure does not add significant time to the prehospital resuscitation time nor does the procedure interfere with the quality of the ACLS.


## Strengths and limitations of this study

- This study provides insight on the novel use of REBOA on out of hospital cardiac arrest patients.

- It is the first study to describe an extensive educational program for implementing this procedure
- It presents a new objective scoring chart for the REBOA procedure
- It is a single-center study on anesthesiologists, limiting the generalizability of the data.
- Although it is most relevant for physician manned prehospital services, it is also informative for treatment of in-hospital cardiac arrest.

## Background

Out of hospital cardiac arrest (OHCA) is a critical incident with a high mortality rate [1]. For non-traumatic cardiac arrest (CA) the most frequent etiology is cardiac disease [2, 3], with deaths related to failure to achieve return of spontaneous circulation (ROSC), circulatory failure after ROSC or anoxic brain damage [4]. During cardio-pulmonal resuscitation (CPR) the cardiac output is usually not sufficient to maintain consciousness and the lack of oxygen delivery can result in irreversible damage to vital organs [1]. Augmentation of the circulation and hence oxygen delivery to vital organs such as the brain and heart during CPR is therefore beneficial.

Balloon occlusion of the aorta was introduced in the Korean War in 1954 as a means to stabilize soldiers with intraabdominal haemorrhages [5]. After this, resuscitative endovascular balloon occlusion of the aorta (REBOA) has been employed in patients in haemorrhagic shock or CA secondary to trauma. Continuous occlusion of the aorta with REBOA gives a redistribution of cardiac output to the organs proximal to the occlusion including the brain and heart [6] (Figure 1).

*Figure 1. Aortic zone 1 occlusion*

Several animal studies demonstrate that REBOA during CPR increase both coronary artery blood flow and coronary perfusion pressure and increase the rates of ROSC [7–14]. Aortic occlusion during CPR also gives clinically relevant increased carotid artery blood flow [10, 15], cerebral arterial blood flow [8, 9, 15–17] and cerebral perfusion pressure [8, 9, 15, 18]. Based upon these preclinical data patients in non-traumatic CA might benefit from REBOA in the thoracic level during CPR.

There are no systematic human studies on the use of REBOA for non-traumatic CA. To our knowledge only three case reports are published, of which two patients were considered to have a positive effect of REBOA [19–21]. One explanation for that REBOA is not introduced for OHCA is the feasibility of REBOA insertion in the prehospital setting. However, technological advances in the REBOA technique now allows for fluoroscopy-free aortic occlusion [22] and REBOA is at present used by numerous prehospital services, both civilian and military on trauma patients [23].

The Norwegian physician staffed prehospital emergency medical services (P-EMS) include anaesthesiologists [24]. These physicians will regularly be part of the resuscitation team at OHCA. All anaesthesiologists are skilled in establishing central vascular lines using the Seldinger technique and the use of ultrasound. However, the implementation of a new procedure such as REBOA requires special training before implemented in clinical practice. An educational program was therefore designed to educate, train and implement the REBOA technique to prehospital personnel. In this report, we describe the organization of a team-based REBOA training program and the evaluation of REBOA competencies in a high-fidelity simulation scenario, in preparation for a clinical feasibility study on REBOA in OHCA.

## Methods

### Patients and Public Involvement

No patients or public were involved in this study.

### Participants

The physicians and paramedics involved in this study work at the P-EMS base in Trondheim, Norway. The P-EMS has a catchment population of about 700,000 and usually transfer patients with OHCA to one tertiary university hospital (St. Olavs Hospital). The service dispose both a helicopter and a rapid response car. All physicians are board certified qualified anesthesiologist with prehospital work experience from 4 to 18 years. The paramedics have from 11 to 34 years work experience in the service. Seven physicians and 3 paramedics participated.

**REBOA procedure**

Aortic zones are divided in three zones, I, II, and III, spanning from proximal to distal. Zone I is the descending thoracic aorta between the origin of the left subclavian and celiac arteries. REBOA during CA is placed in zone I, for optimal haemodynamic effect [25]. The insertion technique of REBOA is based on identification of the femoral artery by ultrasound, insertion of the REBOA catheter over a guidewire and placement based upon length of catheter from the insertion. The balloon is deflated when the team recognize ROSC. The REBOA Medical catheter use a guidewire for insertion of the balloon catheter and was chosen as this is the catheter currently marketed in Norway and is in use at our hospital. A detailed outline of the procedure is described in appendix 1.

**Educational program**

The educational program is performed in defined steps and is a combined theoretical and practical training program. It is based upon validated educational models for skill training of other procedures performed by physicians from a variety of specialties [26–28]. The educational program is divided in a theoretical part, basic skill training, training in the interventional radiology department and high-fidelity simulation.

**Part 1 - Theoretical part**

The didactic theoretical part of this study is an introduction to the concept of REBOA, as well as placement technique and the necessary equipment, given to both physicians and paramedics. The educational content of this part is a Microsoft PowerPoint presentation and a Q&A discussion.

**Part 2 - Basic skill training**

The physicians and paramedics trained repeatedly on a simulation mannequin. This mannequin was designed specifically for this use, in collaboration with engineers at Norwegian University of Science and Technology (NTNU). The cannulation site is a block made of a mixture of hydrocarbon gel and silicone rubber, measuring 10 x 20 x 6 cm. Two compressible silicone rubber tubes (inner diameter 7 and 12 mm), representing the femoral artery and vein, was molded into the block at a depth of approximately 10 mm. The cannulation site was developed with the capacity of both being replaceable and to withstand several cannulations without leakage or deterioration of the ultrasound image quality. The arterial lumen was of 1 m length and expanded to 3 cm in diameter, allowing placement of the introducer (Super Arrow-Flex, Teleflex, 7 Fr, 45 cm length), guidewire and balloon catheter (REBOA Medical, 7 Fr, 20 mm diameter, 30 mm occlusion length). The arterial tubing was not designed to give a realistic tactile feedback. This training ensured knowledge of the equipment, correct technique and correct placement of the REBOA catheter. It also allowed the trainees to repeat the procedure as many times as necessary to obtain the proper skill and confidence in performing the procedure. The training was observed by the first author, available for questions and/or guidance.

**Part 3 - Interventional radiology department**

The physicians attended one day at the interventional laboratory, St. Olavs Hospital. Similar guidewires, introducers and catheters as used in REBOA are in daily use at this laboratory. The physician participated in inserting the equipment in patients scheduled for angiography under guidance and supervision of an experienced interventional radiologist. Vascular access was achieved using ultrasound guidance. After training each operator was approved for the REBOA procedure by a consultant interventional radiologist.

**Part 4 - High fidelity simulation**

This part was held in the Centre for Medical Simulation, St. Olavs Hospital. The facility simulated a prehospital setting and was equipped with sound- and video-recording and a one-way mirror window. Video sequences were used in the debriefing session.

The scenario started with establishing advanced cardiovascular life support (ACLS) according to current guidelines from The Norwegian Resuscitation Council [29]. Ambulance personnel and/or medical students trained in ACLS participated, which is representative of the personnel resources usually available at scene. After endotracheal intubation, establishing manual chest compression and intravenous access on the upper body, the decision to insert a REBOA-catheter was made. The resuscitation mannequin used (Resusci Anne First Aid, Laerdal Medical, Norway) is not designed for use of a mechanically chest compression machine, therefore only manual chest compressions were performed (Figure 2). The ultrasound guided femoral artery access was performed on the designed cannulation block, integrated into the resuscitation mannequin.

*Figure 2. High fidelity simulation with REBOA application during ACLS.*

All teams where given the same case; a 59-year-old man with known hypertension, monotherapy antihypertensive treatment, suffering from a cardiac arrest at his home, wife present and by-stander CPR of good quality until the ambulance crew arrived. Initial rhythm was ventricular fibrillation (VF) and this VF was refractory regardless of other treatment than REBOA. ROSC was simulated 1 minute after balloon occlusion. The scenario was aborted after the team recognized ROSC and started to prepare for departure to hospital.

**Assessment of performance**

Global rating scale (GRS) is an assessment tool based on different aspect of quality in operative performance, adapted from a validated scoring system [30]. It is a quantitative marker of performance and is not specific to the REBOA procedure and may apply to other endovascular or technical procedures. It is shown that procedure specific rating scales can be used to assess trainee's competence in endovascular procedures [31] or other bedside procedures [26]. Since a GRS for a prehospital REBOA procedure does not exist, an Objective Structured Assessment of Prehospital REBOA Application (OSAPRA) chart, modified for the REBOA procedure, was developed (Figure 3). The OSAPRA consist of 12 5-points categorical scores each anchored 0 – 4. Cut scores for adequate performance had to be determined without previous empirical data. Based on what was considered as the minimum level of performance, the investigators agreed upon a cut score of 30 of a total of 48 points on the OSAPRA. Each assessment was performed based upon video recording and done independently by two observers. If major discrepancies between the observer ratings occurred, a third observer performed an independently assessment, then the observers discussed until agreement.

*Figure 3. Objective Structured Assessment of Prehospital REBOA Application chart.*

## Debriefing

After every session, a semi-structured debriefing was held, led by the two observers. The use of debriefing after a simulation event is an important tool for learning [32] and can be used to develop and implement a new procedure [33]. All members of the resuscitation team participated in this open discussion. The debriefers ensured that following questions were answered: Was the physician able to maintain in control of the resuscitation? Did the patient receive standard care? Did the procedure interfere with the resuscitation? Did the resuscitation interfere with the procedure? Did the two teams, ambulance crew and P-EMS crew, cooperate well? Was this training program feasible for implementing this new procedure?

## Statistics

All data is descriptive and given as absolute numbers. Due to the descriptive nature of the study no formal sample testing was performed.

## Results

### Completion of the training program

The theoretical education and mannequin training were completed within two days, with half of the crew (physicians and paramedics) present each day. This ensured a common understanding of the theoretical background and purpose of the intervention, as well as building a consensus on logistics and work pattern. In addition to this training session a mannequin was installed at the helicopter base, enabling the crew to practice the procedure.

The cannulation block made for training was well appraised. The tactile feedback, needle puncturing and inserting of guidewire, introducer and balloon sheaths was of life-like quality. The ultrasound quality was also adequate, hence reflecting a realistic situation. Each training block tolerated more than 20 punctures.

The patient cannulation in the radiological department was completed over a period of 3 weeks. All 7 physicians were approved for competency by the consulting interventional radiologist.

The high-fidelity simulations were completed over a period of 4 days, with one or two physicians participating each day. One of the paramedics attended two days.

**Time for REBOA procedure at simulation**

The time needed to perform the REBOA procedure was 8,5 (6,3 – 12,7, SD 2,2) min (Figure 4). The time interval started when the physician called procedural start and stopped when the balloon was inflated. The corresponding time from arrival at scene to balloon inflation was 12,0 (8,8 – 15, SD 2,1) min.

*Figure 4. Time (minutes) used to perform the procedure for the 7 candidates.*

**Competency assessment of REBOA procedure in simulation**

The total objective assessment scores of the candidates' competency was 41,8 (39 – 43,5, SD 1,4) points out of 48 (Figure 5). All scores are mean values from the two observers. No major discrepancies in grading of the candidates occurred between the observers.

*Figure 5. OSAPRA-scores for the 7 candidates*

**Debriefing after simulation**

All resuscitation teams regarded the ACLS to be of standard quality. None of the teams felt that neither the REBOA procedure nor the ACLS interfered with each other negatively. The team leaders (physicians) all considered themselves to "be on top of the situation", even though they concentrated on performing a new specialized procedure. Another factor that were emphasized is that the paramedics are not used to sterile procedures and in this specific procedure they have a crucial role in handling equipment to the physicians. The participants considered this four-step training to implement the REBOA technique to be adequate and recommended before use in a clinical setting.

**Discussion**

This study showed that a team based four-step educational program resulted in adequate performance of a REBOA procedure in a simulated OHCA setting.

This educational program's stepwise combination of theory, training on mannequins and patients and the use of high-fidelity simulation provides the trainees with adequate competency in a simulated model. The time needed to establish a REBOA catheter was approximately 8,5 minutes. Based on the feedback from the participants and the observers we observed that the procedure did not interfere with the quality of the ACLS given simultaneously. This indicates that the procedure does not add significant time to the prehospital resuscitation time and will not interact negatively on established care.

The use of ultrasound is mandatory. A landmark-oriented approach to femoral arterial cannulation is difficult in patients with low blood pressure or no palpable femoral pulse, which is the case in 40 % of patients receiving CPR [34]. Ultrasound guidance for femoral artery catheterization is associated with 49 % reduction in overall complications and increases the likelihood of first-attempt success [35]. Several studies describes how to measure or predict the length from the common femoral arterial puncture site to Zone 1 [36–38]. Detailed calculations, regardless of simple input parameters, are not likely to be performed in a prehospital setting. Based on the experiences from the catheterization lab at St. Olavs Hospital, we used a fixed length of guidewire and balloon catheter placement. The placement was also controlled with a present pulse in the left radial artery suggesting balloon inflation below the left subclavian artery. The descending aorta is approximately 25 mm in width in the age span of patients eligible for inclusion [39, 40]. To minimize the risk of complications such as aortic rupture [22] or local complications, 7Fr equipment and a 20 mm balloon is used. Hence, some patients will potentially have subtotal aortic occlusion. Given an occlusion length of 30 mm, the great increase in resistance to blood flow will provide the same hemodynamic effect and limit the risk of aortic injury. Thus, for REBOA done in the prehospital setting there must be a consideration for partial aortic occlusions versus to avoid risk of aortic injury.

An objective measurement of skills is difficult. Checklists are easy to use, but to evaluate clinical skills, studies suggest that GRS is a more dependable measure [26, 41–43]. Cut scores are often used to assess performance and the selection of a cut score risk to be biased by evaluators opinions. There are recommendations for how to decide cut scores or define adequate performance [44–46]. However, a GRS for a prehospital REBOA procedure does not exist and cut scores to the OSAPRA score had to be determined without previous empirical data. A possible method to set the cut score is the Angoff method [47], in which a group of experts establishes the cut score based on a fictitious "borderline" candidate. Experts present a description of a performance that they believe is on the borderline between competent and incompetent, and the cut score is set based on the score of this performance. Borderline cases can also be identified by that the raters record "red flag" performances, using a global impression. The reasons to identify a "red flag" performance for interventional procedures are often significant breaches of sterility or performances leading to damage to important structures or organs [26]. We believe that a combination of cut scores and an overall global impression on safety and competence can be used as foundation to deem adequate competency.

Practice in an interventional radiology lab can be difficult to perform in places that lack this service or where hospital or inter-department regulations are strict. We propose that the REBOA procedure then may be learned at specialized courses with a structured educational program, for instance like the one described here.

Applying high-fidelity simulation to an educational program provides a powerful platform for evaluating technical skills as well as team work and communication. In addition to the actual training we consider the debriefing sessions as important for the learning effect. The debriefers role in the debriefing session is important and difficult, and the learning effect of such a session is dependent of the skills and learning environment created by the debriefer [32]. One of the investigators works at the Centre for Medical Simulation and is trained as a facilitator in debriefing sessions. The debriefers are known to the trainees. We believe that this contributed positively to create a non-hostile debriefing environment.

It must be recognized that REBOA placement will not always be successful. Therefore, a part of the training must be to abort the procedure if difficult or if it interferes with performance of standard CPR. There will also be operational circumstances such as cold weather or environmental hazard where REBOA should not be initiated. This study does not answer how REBOA can be achieved during real life field operations. Moreover, the frequency of REBOA complications can be different in a prehospital setting and clinical studies are needed to observe if REBOA is feasible in a prehospital setting during CA and if complications associated with REBOA balance the potential benefit from REBOA. We also emphasize that the concept of REBOA during cardiac arrest is in its infancy and several issues related to what is the better technique must be developed.

We recognize that this study has some limitations. First, it is a single-center study, and only assessed 7 physicians and 3 paramedics. Secondly, we included only anesthesiologists working in a P-EMS system with a homogenous set of skills and the results might therefore not be generalized to physicians from other specialties. However, the study is relevant to services such as in Scandinavia, where mainly anesthesiologists participates in the physician-manned P-EMS. Thirdly, the simulation was done on mannequins, and although the high-fidelity simulation mimicked the prehospital setting, it may not translate directly to the real prehospital environment. Fourth, this is a scenario where all participants are prepared specifically for testing the REBOA procedure and where all participants knew the indications well. Finally, the objective assessment chart had to be developed for this study, meaning that it has yet to be validated.

Strengths of this study is that it is specifically designed for a team competent in the Seldinger technique, thereby, relevant for the personnel who will perform REBOA in real life settings. We evaluated both technical and communication skills, as well as team work. The OSAPRA scoring chart is constructed in a systematic manner, based on input from physicians with a wide range of expertise.

REBOA may be an important modality for out-of-hospital ACLS. This is supported by animal studies on physiology during CPR. However, it is not known if REBOA will give benefit on human ACLS. An answer to this question can only be given by a comparative study of REBOA plus standard care versus standard care alone. However, it is reasonable to develop and perform an educational program and to test in-field feasibility of REBOA in the prehospital setting before initiating a comparative study. This clinical feasibility study is currently in progress (ClinicalTrials.gov Identifier NCT03534011).

**Conclusions**

This four-step approach to educate, train and implement the REBOA technique in a prehospital working team provides adequate competence in a simulated setting. This training is a first step before the start of a planned feasibility trial of REBOA for OHCA. We recommend the use of a systematic training program and the OSAPRA score to guide and improve training. In a simulated prehospital setting the teams used 8,5 minutes to establish a REBOA-catheter. This indicates that the procedure does not add significant time to the resuscitation time prehospital. Based on the feedback from the participants and the observers we conclude that the procedure does not interfere with the quality of the ACLS given simultaneously.

**Declarations**

**Ethics approval and consent to participate:** This study was approved by the Regional Committee for Medical and Health Research Ethics (reference 2017/2482/REKmidt).

**Consent for publication:** No patients or public were involved in the study. The participants gave approval for publication and the participants featured in figure 2 gave written consent for use of the image.

**Availability of data and material:** The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Competing interests**: One of the authors (ES) has stock ownership and a board position in Reboa Medical AS. The other authors declare that they have no competing interests.

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**Authors' contributions**: JRB and TL designed the study, interpreted and analyzed the data. JRB drafted the manuscript and prepared the figures/tables. ES, AJK and PK contributed to the design of the study and revised the manuscript. TS, CK and MS contributed on developing the simulation mannequin. All authors read and approved the final manuscript.

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**Figure legends**

*Figure 1. Aortic zone 1 occlusion*

*Figure 2. High fidelity simulation with REBOA application during ACLS.*

*Figure 3. Objective Structured Assessment of Prehospital REBOA Application chart.*

*Figure 4. Time (minutes) used to perform the procedure for the 7 candidates.*

*Figure 5. OSAPRA-scores for the 7 candidates*

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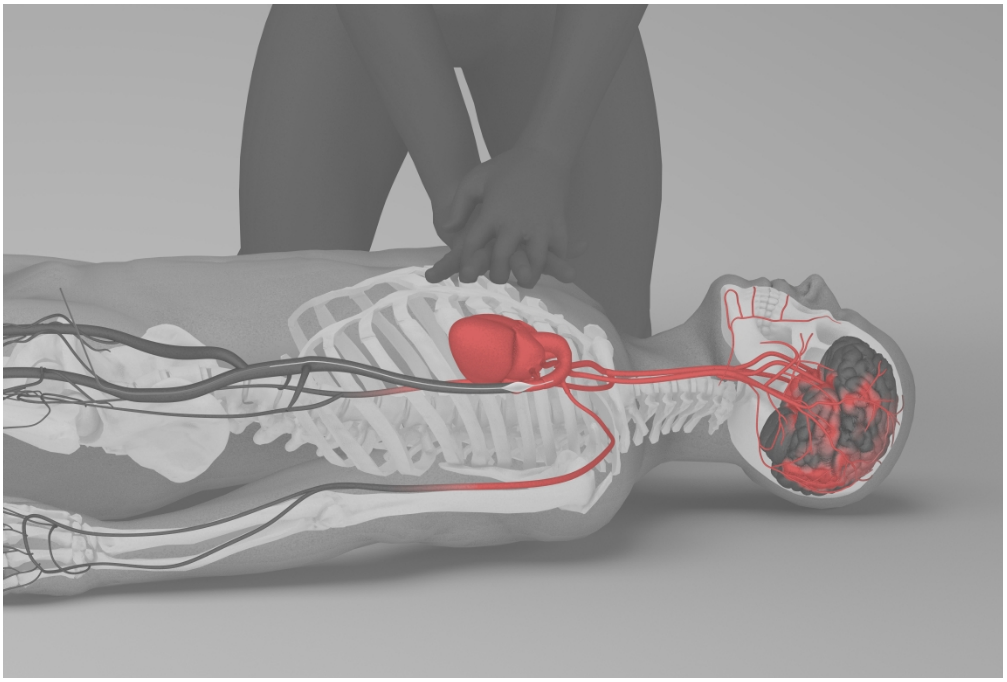


Aortic zone 1 occlusion

1800x1215mm (72 x 72 DPI)


High fidelity simulation with REBOA application during ACLS

169x254mm (300 x 300 DPI)

## Objective Structural Assessment of Prehospital REBOA Application - OSAPRA

**Trainee:** **Evaluator:**

### Indication for REBOA

| | | ***Score:*** |
|---|---|---|
| Obtains relevant medical history and physiological values | 0: Does not obtain any information | |
| | 2: Obtains sufficient information, partial completion of checklist | |
| | 4: Obtains relevant information and completes checklist | |

### Preparations for the procedure

| | | |
|---|---|---|
| Informs crew about the decision | 0: Does not inform crew at all | |
| | 2: Gives sufficient information | |
| | 4: Informs in a relevant and precise way | |

| | | |
|---|---|---|
| Prepares the patient | 0: Does not prepare patient for the procedure at all | |
| | 2: Prepares the patient sufficiently | |
| | 4: Prepares the patient with desinfectant, sterile cloth and uses ultrasound probe cover | |

### Performing the procedure

| | | |
|---|---|---|
| Proficiency in ultrasound imaging | 0: Shows no skill in identifying vessels and structures | |
| | 2: Shows adequate skills in identifying vessels and structures | |
| | 4: Shows ample skills in identifying vessels and structures | |

| | | |
|---|---|---|
| Intraarterial cannulation | 0: Does not use needle-tip-tracking to cannulate | |
| | 2: Uses some needle-tip-tracking | |
| | 4: Display ample skills in needle-tip-tracking and cannulation | |

| | | |
|---|---|---|
| Inserting guidewire | 0: Does not stabilize and angle the needle when inserting wire and does no measurement of guidewire length | |
| | 2: Handles the needle suficiently when inserting the wire and handles guidewire somewhat skilled | |
| | 4: Handles the needle proficiently when inserting the wire and uses correct insertion length with impecable handling of wire | |

| | | |
|---|---|---|
| Inserting introducer | 0: Does not make skin incision and handles the introducer poorly | |
| | 2: Makes skin incision and handles the introducer sufficiently | |
| | 4: Makes skin incision and handles the introducer proficiently | |

| | | |
|---|---|---|
| Inserting the REBOA | 0: Poor handling of catheter | |
| | 2: Sufficient handling of the catheter and placementh of length | |
| | 4: Shows ample skills in handling catheter and correct length | |

| | | |
|---|---|---|
| Fixation | 0: No fixation of catheter | |
| | 2: Fixation with dressing/tape or suture | |
| | 4: Fixation with dressing/tape and suture | |

***Turn paper***

**After ROSC**

| | | |
|---|---|---|
| Deflation of the balloon | 0: Does not deflate the balloon at all | |
| | 2: Deflates the balloon appropriately when achieved ROSC | |
| | 4: Deflates the balloon with perfect timing at ROSC | |

**Coorporation with assistant**

| | | |
|---|---|---|
| Communication | 0: Does not communicate with the assistant at all | |
| | 2: Communicates sufficiently with the assistant | |
| | 4: Communicates in a clear and proficient way | |

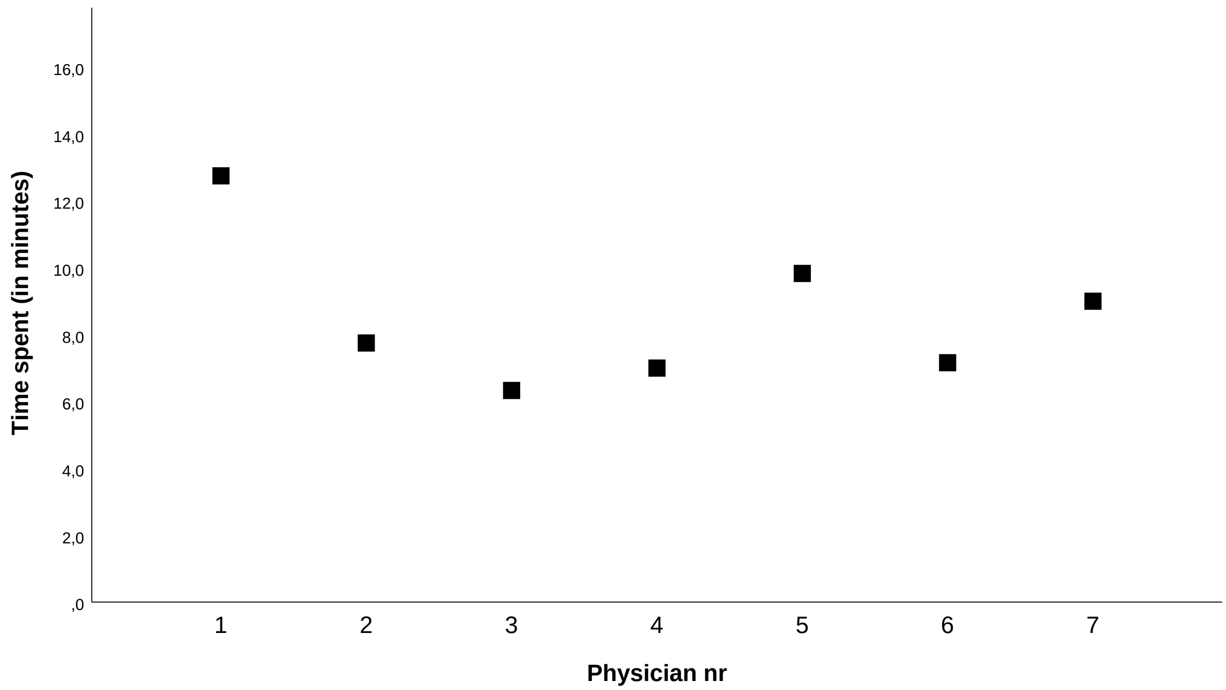
| | | |
|---|---|---|
| Use of assistant | 0: Does not make use of assistant at all | |
| | 2: Uses assistant in a sufficient way | |
| | 4: Uses assistant proficiently and optimally | |

***Total score:*** ________

of total 48

**Time**

| | |
|---|---|
| Time spent from start REBOA procedure to occlusion of aorta | min |


Time spent (in minutes)
16,0
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12,0
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1
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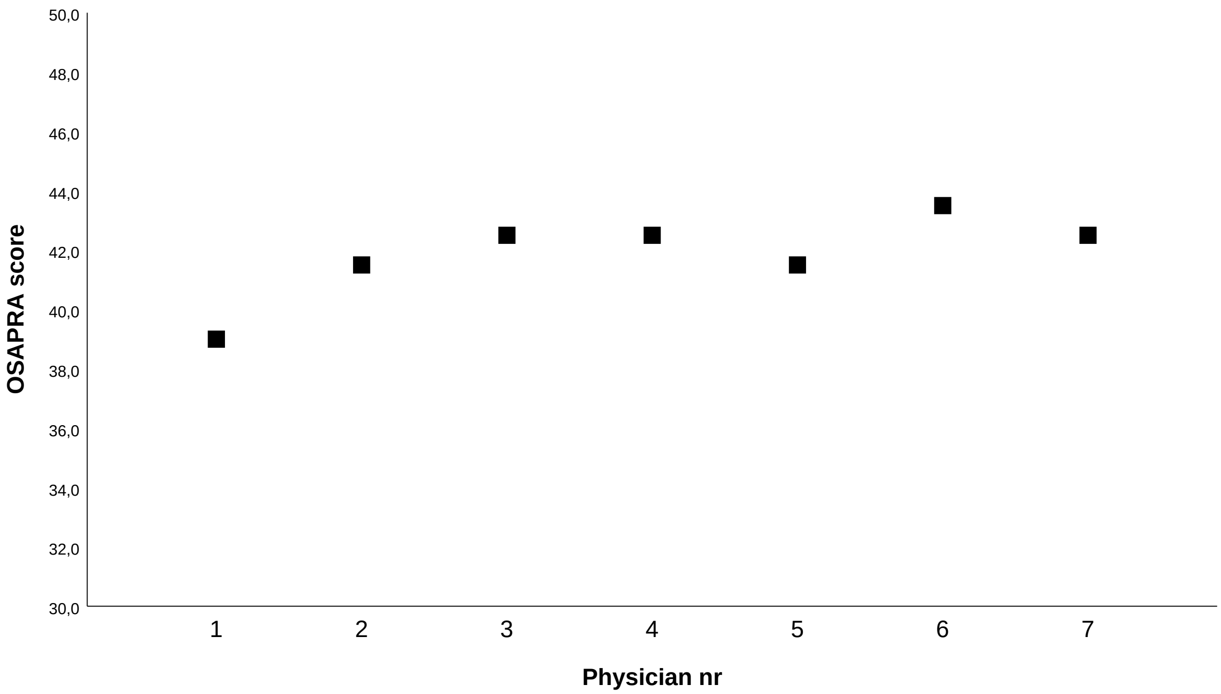
5
6
7
Physician nr

Page 1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40,0
38,0
36,0
34,0
32,0
30,0
OSAPRA score
1
2
3
4
5
6
7
Physician nr

Page 1

# PROCEDURE FOR INSERTION OF REBOA FOR OHCA

Abort procedure if technical problems like:

- -severe difficulties in ultrasound (US) visualization of the artery or cannulation
- -resistance when inserting guidewire, introducer or catheter
- -severe bleeding
- -time consuming procedure

| PHYSICIAN | PARAMEDIC |
|---|---|
| **1.** Cut clothes from knee to groin | **1.** Open kit – unpack – place sterile gloves for physician |
| **2.** Examine with US – store image | **2.** Place introducer and balloon-catheter on sterile cloth |
| **3.** Note EtCO2 | **3.** Prepare NaCl and Chlorhexidine – close to physician |
| **4.** Fill NaCl in wash tray | **4.** Put on sterile gloves |
| **5.** Apply Chlorhexidine on compresses | **5.** Aspirate 15 ml NaCl from wash tray in 20 ml syringe |
| **6.** Wash selected area with forceps and compresses | **6.** Hand physician forceps – place compresses on sterile cloth |
| **7.** Fill gel into the US-cover – place it on the US-probe | **7.** Apply sterile drape |
| **8.** Apply US-gel on the thigh | **8.** Prepare US-cover |
| **9.** US-guided cannulation of a. femoralis | **9.** Apply elastic band – place probe on the sterile drape |
| **10.** Insert guidewire into cannulation needle, 60 cm | **10.** Prepare needle with 5 ml syringe |
| **11.** Remove needle – make skin incision with scalpel | **11.** Ready guidewire |
| **12.** Record US-video of guidewire in a. femoralis | **12.** Hand physician soft end of guidewire, insert to 60 cm |
| **13.** Insert introducer – remove dilatator | **13.** Hand scalpel to physician |
| **14.** Insert balloon-catheter, 50 cm | **14.** Mount introducer and dilatator onto guidewire |
| **15.** Check pulse - LEFT a. radialis | **15.** Control the guidewire |
| **16.** Fill balloon with 15 ml NaCl, less if resistance | **16.** Ready balloon-catheter |
| **17.** Check pulse in LEFT a. radialis | **17.** Put stopcock on blue line |
| **18.** Note time for balloon inflation and EtCO2 | **18.** Put plug on the black line |
| **19.** Suture and fixate | **19.** Hand physician 20 ml syringe with 15 ml NaCl |
| **20.** Place adhesive cover over REBOA-equipment | **20.** Ready suture – needle-holder – scalpel |
| **21.** Secure guidewire with forceps | **21.** Cut suture |
| | **22.** Ready adhesive cover |
| | **23.** Cut and remove sterile drape |

BMJ Open

# Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in non-traumatic out of hospital cardiac arrest – evaluation of an educational program



| | |
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| | |
|---|---|
| <b>Primary Subject Heading</b>: | Emergency medicine |
| Secondary Subject Heading: | Medical education and training, Emergency medicine |
| Keywords: | Adult intensive & critical care < ANAESTHETICS, CARDIOLOGY, ACCIDENT & EMERGENCY MEDICINE |
| | |

# Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in non-traumatic out of hospital cardiac arrest – evaluation of an educational program

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**Abstract**

BACKGROUND: Out of hospital cardiac arrest is a critical incident with a high mortality rate. Augmentation of the circulation during cardiopulmonary resuscitation (CPR) might be beneficial. Use of resuscitative endovascular balloon occlusion of the aorta (REBOA) redistribute cardiac output to the organs proximal to the occlusion. Preclinical data supports that patients in non-traumatic cardiac arrest might benefit from REBOA in the thoracic level during CPR. This study describes a training program to implement the REBOA procedure to a prehospital working team, in preparation to a planned clinical study.

METHODS: We developed a team-based REBOA training program involving the physicians and paramedics working on the National Air Ambulance helicopter base in Trondheim, Norway. The program consists of a four-step approach to educate, train and implement the REBOA procedure in a simulated prehospital setting. An objective structured assessment of prehospital REBOA application (OSAPRA) scoring chart and a special designed simulation mannequin was made for this study.

RESULTS: 7 physicians and 3 paramedics participated. The time needed to perform the REBOA procedure was 8,5 (6,3 – 12,7) min. The corresponding time from arrival at scene to balloon inflation was 12,0 (8,8 – 15) min. The total objective assessment scores of the candidates' competency was 41,8 (39 – 43,5) points out of 48. The advanced cardiovascular life support (ACLS) remained at standard quality, regardless of the simultaneous REBOA procedure.

CONCLUSION: This four-step approach to educate, train and implement the REBOA procedure to a prehospital working team ensures adequate competence in a simulated OHCA setting. The use of a structured training program and objective assessment of skills is recommended before utilizing the procedure in a clinical setting. In a simulated setting the procedure does not add significant time to the prehospital resuscitation time nor does the procedure interfere with the quality of the ACLS.

**Strengths and limitations of this study**

- This study provides insight on the novel use of REBOA on out of hospital cardiac arrest patients.

- It is the first study to describe an extensive educational program for implementing this procedure
- It presents a new objective scoring chart for the REBOA procedure
- It is a single-center study on anesthesiologists, limiting the generalizability of the data.
- Although it is most relevant for physician manned prehospital services, it is also informative for treatment of in-hospital cardiac arrest.

## Background

Out of hospital cardiac arrest (OHCA) is a critical incident with a high mortality rate [1]. For non-traumatic cardiac arrest (CA) the most frequent etiology is cardiac disease [2, 3], with deaths related to failure to achieve return of spontaneous circulation (ROSC), circulatory failure after ROSC or anoxic brain damage [4]. During cardiopulmonary resuscitation (CPR) the cardiac output is usually not sufficient to maintain consciousness and the lack of oxygen delivery can result in irreversible damage to vital organs [1]. Augmentation of the circulation and hence oxygen delivery to vital organs such as the brain and heart during CPR is therefore beneficial.

Balloon occlusion of the aorta was introduced in the Korean War in 1954 as a means to stabilize soldiers with intraabdominal haemorrhages [5]. After this, resuscitative endovascular balloon occlusion of the aorta (REBOA) has been employed in patients in haemorrhagic shock or CA secondary to trauma. Continuous occlusion of the aorta with REBOA gives a redistribution of cardiac output to the organs proximal to the occlusion including the brain and heart [6] (Figure 1).

*Figure 1. Aortic zone 1 occlusion*

Several animal studies demonstrate that REBOA during CPR increase both coronary artery blood flow and coronary perfusion pressure and increase the rates of ROSC [7–14]. Aortic occlusion during CPR also gives clinically relevant increased carotid artery blood flow [10, 15], cerebral arterial blood flow [8, 9, 15–17] and cerebral perfusion pressure [8, 9, 15, 18]. Based upon these preclinical data patients in non-traumatic CA might benefit from REBOA in the thoracic level during CPR.

There are no systematic human studies on the use of REBOA for non-traumatic CA. To our knowledge only three case reports are published, of which two patients were considered to have a positive effect of REBOA [19–21]. One explanation for that REBOA is not introduced for OHCA is the feasibility of REBOA insertion in the prehospital setting. However, technological advances in the REBOA technique now allows for fluoroscopy-free aortic occlusion [22] and REBOA is at present used by numerous prehospital services, both civilian and military on trauma patients [23].

The Norwegian physician staffed prehospital emergency medical services (P-EMS) include anaesthesiologists [24]. These physicians will regularly be part of the resuscitation team at OHCA. All anaesthesiologists are skilled in establishing central vascular lines using the Seldinger technique and the use of ultrasound. However, the implementation of a new procedure such as REBOA requires special training before implemented in clinical practice. An educational program was therefore designed to educate, train and implement the REBOA technique to prehospital personnel. In this report, we describe the organization of a team-based REBOA training program and the evaluation of REBOA competencies in a high-fidelity simulation scenario, in preparation for a clinical feasibility study on REBOA in OHCA.

**Methods**

**Patients and Public Involvement**

No patients or public were involved in this study.

**Participants**

The physicians and paramedics involved in this study work at the P-EMS base in Trondheim, Norway. The P-EMS has a catchment population of about 700,000 and usually transfer patients with OHCA to one tertiary university hospital (St. Olavs Hospital). The service dispose both a helicopter and a rapid response car. All physicians are board certified qualified anesthesiologist with prehospital work experience from 4 to 18 years. The paramedics have from 11 to 34 years work experience in the service. Seven physicians and 3 paramedics participated.

**REBOA procedure**

Aortic zones are divided in three zones, I, II, and III, spanning from proximal to distal. Zone I is the descending thoracic aorta between the origin of the left subclavian and celiac arteries. REBOA during CA is placed in zone I, for optimal haemodynamic effect [25]. The insertion technique of REBOA is based on identification of the femoral artery by ultrasound, insertion of the REBOA catheter over a guidewire and placement based upon length of catheter from the insertion (50 cm in all patients). The balloon is deflated when the team recognize ROSC. It is reported that guidewire-free platforms can reduce procedure time [26]. The REBOA Medical catheter use a guidewire for insertion of the balloon catheter and was chosen as this is the catheter currently marketed in Norway and is in use at our hospital. A detailed outline of the procedure is described in appendix 1.

**Educational program**

The educational program is performed in defined steps and is a combined theoretical and practical training program. It is based upon validated educational models for skill training of other procedures performed by physicians from a variety of specialties [27–29]. The educational program is divided in a theoretical part, basic skill training, training in the interventional radiology department and high-fidelity simulation.

**Part 1 - Theoretical part**

The didactic theoretical part of this study is an introduction to the concept of REBOA, as well as placement technique and the necessary equipment, given to both physicians and paramedics. The educational content of this part is a Microsoft PowerPoint presentation and a Q&A discussion.

**Part 2 - Basic skill training**

The physicians and paramedics trained repeatedly on a simulation mannequin. This mannequin was designed specifically for this use, in collaboration with engineers at Norwegian University of Science and Technology (NTNU). The cannulation site is a block made of a mixture of hydrocarbon gel and silicone rubber, measuring 10 x 20 x 6 cm. Two compressible silicone rubber tubes (inner diameter 7 and 12 mm), representing the femoral artery and vein, was molded into the block at a depth of approximately 10 mm. The cannulation site was developed with the capacity of both being replaceable and to withstand several cannulations without leakage or deterioration of the ultrasound image quality. The arterial lumen was of 1 m length and expanded to 3 cm in diameter, allowing placement of the introducer (Super Arrow-Flex, Teleflex, 7 Fr, 45 cm length), guidewire and balloon catheter (REBOA Medical, 7 Fr, 20 mm diameter, 30 mm occlusion length). The arterial tubing was not designed to give a realistic tactile feedback. This training ensured knowledge of the equipment, correct technique and correct placement of the REBOA catheter. It also allowed the trainees to repeat the procedure as many times as necessary to obtain the proper skill and confidence in performing the procedure. The training was observed by the first author, available for questions and/or guidance.

**Part 3 - Interventional radiology department**

The physicians attended one day at the interventional laboratory, St. Olavs Hospital. Similar guidewires, introducers and catheters as used in REBOA are in daily use at this laboratory. The physician participated in inserting the equipment in patients scheduled for angiography under guidance and supervision of an experienced interventional radiologist. Vascular access was achieved using ultrasound guidance. After training each operator was approved for the REBOA procedure by a consultant interventional radiologist.

**Part 4 - High fidelity simulation**

This part was held in the Centre for Medical Simulation, St. Olavs Hospital. The facility simulated a prehospital setting and was equipped with sound- and video-recording and a one-way mirror window. Video sequences were used in the debriefing session.

The scenario started with establishing advanced cardiovascular life support (ACLS) according to current guidelines from The Norwegian Resuscitation Council [30]. Ambulance personnel and/or medical students trained in ACLS participated, which is representative of the personnel resources usually available at scene. After endotracheal intubation, establishing manual chest compression and intravenous access on the upper body, the decision to insert a REBOA-catheter was made. The resuscitation mannequin used (Resusci Anne First Aid, Laerdal Medical, Norway) is not designed for use of a mechanically chest compression machine, therefore only manual chest compressions were performed (Figure 2). The ultrasound guided femoral artery access was performed on the designed cannulation block, integrated into the resuscitation mannequin.

*Figure 2. High fidelity simulation with REBOA application during ACLS.*

All teams where given the same case; a 59-year-old man with known hypertension, monotherapy antihypertensive treatment, suffering from a cardiac arrest at his home, wife present and by-stander CPR of good quality until the ambulance crew arrived. Initial rhythm was ventricular fibrillation (VF) and this VF was refractory regardless of other treatment than REBOA. ROSC was simulated 1 minute after balloon occlusion. The scenario was aborted after the team recognized ROSC and started to prepare for departure to hospital.

**Assessment of performance**

Global rating scale (GRS) is an assessment tool based on different aspect of quality in operative performance, adapted from a validated scoring system [31]. It is a quantitative marker of performance and is not specific to the REBOA procedure and may apply to other endovascular or technical procedures. It is shown that procedure specific rating scales can be used to assess trainee's competence in endovascular procedures [32] or other bedside procedures [27]. Since a GRS for a prehospital REBOA procedure does not exist, an Objective Structured Assessment of Prehospital REBOA Application (OSAPRA) chart, modified for the REBOA procedure, was developed (Figure 3). The OSAPRA consist of 12 5-points categorical scores each anchored 0 – 4. Cut scores for adequate performance had to be determined without previous empirical data. Based on what was considered as the minimum level of performance, the investigators agreed upon a cut score of 30 of a total of 48 points on the OSAPRA. Each assessment was performed based upon video recording and done independently by two observers. If major discrepancies between the observer ratings occurred, a third observer performed an independently assessment, then the observers discussed until agreement.

*Figure 3. Objective Structured Assessment of Prehospital REBOA Application chart.*

**Debriefing**

After every session, a semi-structured debriefing was held, led by the two observers. The use of debriefing after a simulation event is an important tool for learning [33] and can be used to develop and implement a new procedure [34]. All members of the resuscitation team participated in this open discussion. The debriefers ensured that following questions were answered: Was the physician able to maintain in control of the resuscitation? Did the patient receive standard care? Did the procedure interfere with the resuscitation? Did the resuscitation interfere with the procedure? Did the two teams, ambulance crew and P-EMS crew, cooperate well? Was this training program feasible for implementing this new procedure?

**Statistics**

All data is descriptive and given as absolute numbers. Due to the descriptive nature of the study no formal sample testing was performed.

**Results**

**Completion of the training program**

The theoretical education and mannequin training were completed within two days, with half of the crew (physicians and paramedics) present each day. This ensured a common understanding of the theoretical background and purpose of the intervention, as well as building a consensus on logistics and work pattern. In addition to this training session a mannequin was installed at the helicopter base, enabling the crew to practice the procedure.

The cannulation block made for training was well appraised. The tactile feedback, needle puncturing and inserting of guidewire, introducer and balloon sheaths was of life-like quality. The ultrasound quality was also adequate, hence reflecting a realistic situation. Each training block tolerated more than 20 punctures.

The patient cannulation in the radiological department was completed over a period of 3 weeks. All 7 physicians were approved for competency by the consulting interventional radiologist.

The high-fidelity simulations were completed over a period of 4 days, with one or two physicians participating each day. One of the paramedics attended two days.

**Time for REBOA procedure at simulation**

The time needed to perform the REBOA procedure was 8,5 (6,3 – 12,7, SD 2,2) min (Figure 4). The time interval started when the physician called procedural start and stopped when the balloon was inflated. The corresponding time from arrival at scene to balloon inflation was 12,0 (8,8 – 15, SD 2,1) min.

*Figure 4. Time (minutes) used to perform the procedure for the 7 candidates.*

**Competency assessment of REBOA procedure in simulation**

The total objective assessment scores of the candidates' competency was 41,8 (39 – 43,5, SD 1,4) points out of 48 (Figure 5). All scores are mean values from the two observers. No major discrepancies in grading of the candidates occurred between the observers.

*Figure 5. OSAPRA-scores for the 7 candidates*

**Debriefing after simulation**

All resuscitation teams regarded the ACLS to be of standard quality. None of the teams felt that neither the REBOA procedure nor the ACLS interfered with each other negatively. The team leaders (physicians) all considered themselves to "be on top of the situation", even though they concentrated on performing a new specialized procedure. Another factor that were emphasized is that the paramedics are not used to sterile procedures and in this specific procedure they have a crucial role in handling equipment to the physicians. The participants considered this four-step training to implement the REBOA technique to be adequate and recommended before use in a clinical setting.

**Discussion**

This study showed that a team based four-step educational program resulted in adequate performance of a REBOA procedure in a simulated OHCA setting.

This educational program's stepwise combination of theory, training on mannequins and patients and the use of high-fidelity simulation provides the trainees with adequate competency in a simulated model. The time needed to establish a REBOA catheter was approximately 8,5 minutes. Based on the feedback from the participants and the observers we observed that the procedure did not interfere with the quality of the ACLS given simultaneously. This indicates that the procedure does not add significant time to the prehospital resuscitation time and will not interact negatively on established care.

The use of ultrasound is mandatory. A landmark-oriented approach to femoral arterial cannulation is difficult in patients with low blood pressure or no palpable femoral pulse, which is the case in 40 % of patients receiving CPR [35]. Ultrasound guidance for femoral artery catheterization is associated with 49 % reduction in overall complications and increases the likelihood of first-attempt success [36]. Several studies describes how to measure or predict the length from the common femoral arterial puncture site to Zone 1 [37–39]. Detailed calculations, regardless of simple input parameters, are not likely to be performed in a prehospital setting. Based on the experiences from the catheterization lab at St. Olavs Hospital, we used a fixed length of guidewire and balloon catheter placement. The placement was also controlled with a present pulse in the left radial artery suggesting balloon inflation below the left subclavian artery. The descending aorta is approximately 25 mm in width in the age span of patients eligible for inclusion [40, 41]. To minimize the risk of complications such as aortic rupture [22] or local complications, 7Fr equipment and a 20 mm balloon is used. Hence, some patients will potentially have subtotal aortic occlusion. Given an occlusion length of 30 mm, the great increase in resistance to blood flow will provide the same hemodynamic effect and limit the risk of aortic injury. Thus, for REBOA done in the prehospital setting there must be a consideration for partial aortic occlusions versus to avoid risk of aortic injury.

An objective measurement of skills is difficult. Checklists are easy to use, but to evaluate clinical skills, studies suggest that GRS is a more dependable measure [27, 42–44]. Cut scores are often used to assess performance and the selection of a cut score risk to be biased by evaluators opinions. There are recommendations for how to decide cut scores or define adequate performance [45–47]. However, a GRS for a prehospital REBOA procedure does not exist and cut scores to the OSAPRA score had to be determined without previous empirical data. A possible method to set the cut score is the Angoff method [48], in which a group of experts establishes the cut score based on a fictitious "borderline" candidate. Experts present a description of a performance that they believe is on the borderline between competent and incompetent, and the cut score is set based on the score of this performance. Borderline cases can also be identified by that the raters record "red flag" performances, using a global impression. The reasons to identify a "red flag" performance for interventional procedures are often significant breaches of sterility or performances leading to damage to important structures or organs [27]. We believe that a combination of cut scores and an overall global impression on safety and competence can be used as foundation to deem adequate competency.

Practice in an interventional radiology lab can be difficult to perform in places that lack this service or where hospital or inter-department regulations are strict. We propose that the REBOA procedure then may be learned at specialized courses with a structured educational program, for instance like the one described here.

Applying high-fidelity simulation to an educational program provides a powerful platform for evaluating technical skills as well as team work and communication. In addition to the actual training we consider the debriefing sessions as important for the learning effect. The debriefers role in the debriefing session is important and difficult, and the learning effect of such a session is dependent of the skills and learning environment created by the debriefer [33]. One of the investigators works at the Centre for Medical Simulation and is trained as a facilitator in debriefing sessions. The debriefers are known to the trainees. We believe that this contributed positively to create a non-hostile debriefing environment.

It must be recognized that REBOA placement will not always be successful. Therefore, a part of the training must be to abort the procedure if difficult or if it interferes with performance of standard CPR. There will also be operational circumstances such as cold weather or environmental hazard where REBOA should not be initiated. This study does not answer how REBOA can be achieved during real life field operations. Moreover, the frequency of REBOA complications can be different in a prehospital setting and clinical studies are needed to observe if REBOA is feasible in a prehospital setting during CA and if complications associated with REBOA balance the potential benefit from REBOA. We also emphasize that the concept of REBOA during cardiac arrest is in its infancy and several issues related to what is the better technique must be developed.

We recognize that this study has some limitations. First, it is a single-center study, and only assessed 7 physicians and 3 paramedics. Secondly, we included only anesthesiologists working in a P-EMS system with a homogenous set of skills and the results might therefore not be generalized to physicians from other specialties. However, the study is relevant to services such as in Scandinavia, where mainly anesthesiologists participates in the physician-manned P-EMS. Thirdly, the simulation was done on mannequins, and although the high-fidelity simulation mimicked the prehospital setting, it may not translate directly to the real prehospital environment. Fourth, this is a scenario where all participants are prepared specifically for testing the REBOA procedure and where all participants knew the indications well. Finally, the objective assessment chart had to be developed for this study, meaning that it has yet to be validated.

Strengths of this study is that it is specifically designed for a team competent in the Seldinger technique, thereby, relevant for the personnel who will perform REBOA in real life settings. We evaluated both technical and communication skills, as well as team work. The OSAPRA scoring chart is constructed in a systematic manner, based on input from physicians with a wide range of expertise.

REBOA may be an important modality for out-of-hospital ACLS. This is supported by animal studies on physiology during CPR. However, it is not known if REBOA will give benefit on human ACLS. An answer to this question can only be given by a comparative study of REBOA plus standard care versus standard care alone. However, it is reasonable to develop and perform an educational program and to test in-field feasibility of REBOA in the prehospital setting before initiating a comparative study. This clinical feasibility study is currently in progress (ClinicalTrials.gov Identifier NCT03534011).

**Conclusions**

This four-step approach to educate, train and implement the REBOA technique in a prehospital working team provides adequate competence in a simulated setting. This training is a first step before the start of a planned feasibility trial of REBOA for OHCA. We recommend the use of a systematic training program and the OSAPRA score to guide and improve training. In a simulated prehospital setting the teams used 8,5 minutes to establish a REBOA-catheter. This indicates that the procedure does not add significant time to the resuscitation time prehospital. Based on the feedback from the participants and the observers we conclude that the procedure does not interfere with the quality of the ACLS given simultaneously.

## Declarations

**Ethics approval and consent to participate:** This study was approved by the Regional Committee for Medical and Health Research Ethics (reference 2017/2482/REKmidt).

**Consent for publication:** No patients or public were involved in the study. The participants gave approval for publication and the participants featured in figure 2 gave written consent for use of the image.

**Availability of data and material:** The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Competing interests**: One of the authors (ES) has stock ownership and a board position in Reboa Medical AS. The other authors declare that they have no competing interests.

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**Authors' contributions**: JRB and TL designed the study, interpreted and analyzed the data. JRB drafted the manuscript and prepared the figures/tables. ES, AJK and PK contributed to the design of the study and revised the manuscript. TS, CK and MS contributed on developing the simulation mannequin. All authors read and approved the final manuscript.

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## Figure legends

*Figure 1. Aortic zone 1 occlusion*

*Figure 2. High fidelity simulation with REBOA application during ACLS.*

*Figure 3. Objective Structured Assessment of Prehospital REBOA Application chart.*

*Figure 4. Time (minutes) used to perform the procedure for the 7 candidates.*

*Figure 5. OSAPRA-scores for the 7 candidates*

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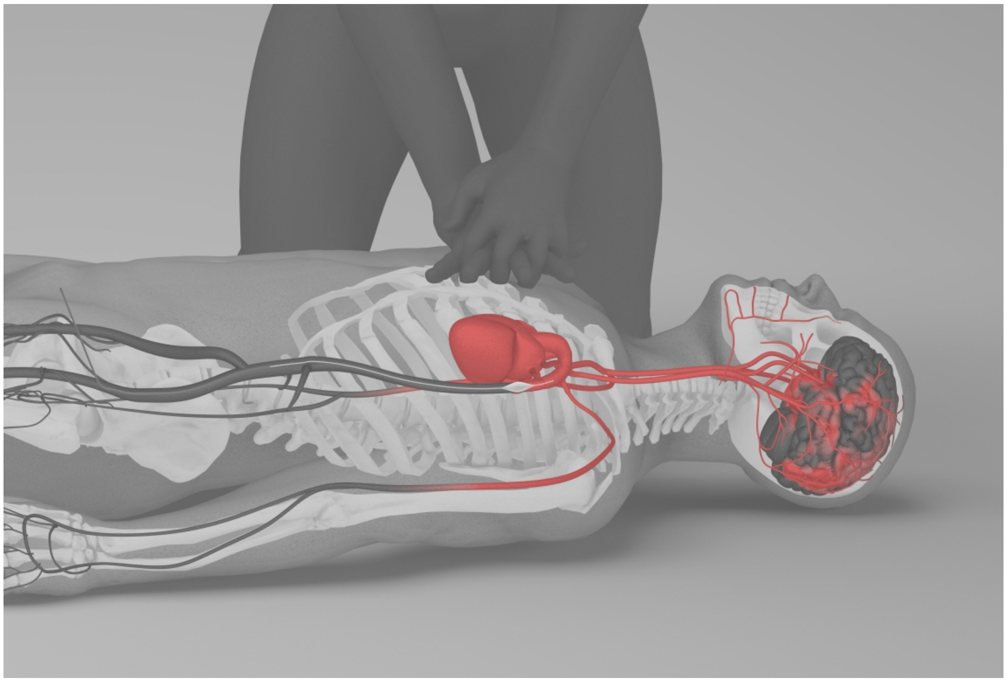


Aortic zone 1 occlusion

1800x1215mm (72 x 72 DPI)

High fidelity simulation with REBOA application during ACLS

169x254mm (300 x 300 DPI)

**Objective Structural Assessment of Prehospital REBOA Application - OSAPRA**

**Trainee:** **Evaluator:**

**Indication for REBOA**

| | | ***Score:*** |
|---|---|---|
| Obtains relevant medical history and physiological values | 0: Does not obtain any information | |
| | 2: Obtains sufficient information, partial completion of checklist | |
| | 4: Obtains relevant information and completes checklist | |

**Preparations for the procedure**

| | | |
|---|---|---|
| Informs crew about the decision | 0: Does not inform crew at all | |
| | 2: Gives sufficient information | |
| | 4: Informs in a relevant and precise way | |

| | | |
|---|---|---|
| Prepares the patient | 0: Does not prepare patient for the procedure at all | |
| | 2: Prepares the patient sufficiently | |
| | 4: Prepares the patient with desinfectant, sterile cloth and uses ultrasound probe cover | |

**Performing the procedure**

| | | |
|---|---|---|
| Proficiency in ultrasound imaging | 0: Shows no skill in identifying vessels and structures | |
| | 2: Shows adequate skills in identifying vessels and structures | |
| | 4: Shows ample skills in identifying vessels and structures | |

| | | |
|---|---|---|
| Intraarterial cannulation | 0: Does not use needle-tip-tracking to cannulate | |
| | 2: Uses some needle-tip-tracking | |
| | 4: Display ample skills in needle-tip-tracking and cannulation | |

| | | |
|---|---|---|
| Inserting guidewire | 0: Does not stabilize and angle the needle when inserting wire and does no measurement of guidewire length | |
| | 2: Handles the needle suficiently when inserting the wire and handles guidewire somewhat skilled | |
| | 4: Handles the needle proficiently when inserting the wire and uses correct insertion length with impecable handling of wire | |

| | | |
|---|---|---|
| Inserting introducer | 0: Does not make skin incision and handles the introducer poorly | |
| | 2: Makes skin incision and handles the introducer sufficiently | |
| | 4: Makes skin incision and handles the introducer proficiently | |

| | | |
|---|---|---|
| Inserting the REBOA | 0: Poor handling of catheter | |
| | 2: Sufficient handling of the catheter and placementh of length | |
| | 4: Shows ample skills in handling catheter and correct length | |

| | | |
|---|---|---|
| Fixation | 0: No fixation of catheter | |
| | 2: Fixation with dressing/tape or suture | |
| | 4: Fixation with dressing/tape and suture | |

***Turn paper***

**After ROSC**

| | | |
|---|---|---|
| Deflation of the balloon | 0: Does not deflate the balloon at all | |
| | 2: Deflates the balloon appropriately when achieved ROSC | |
| | 4: Deflates the balloon with perfect timing at ROSC | |

**Coorporation with assistant**

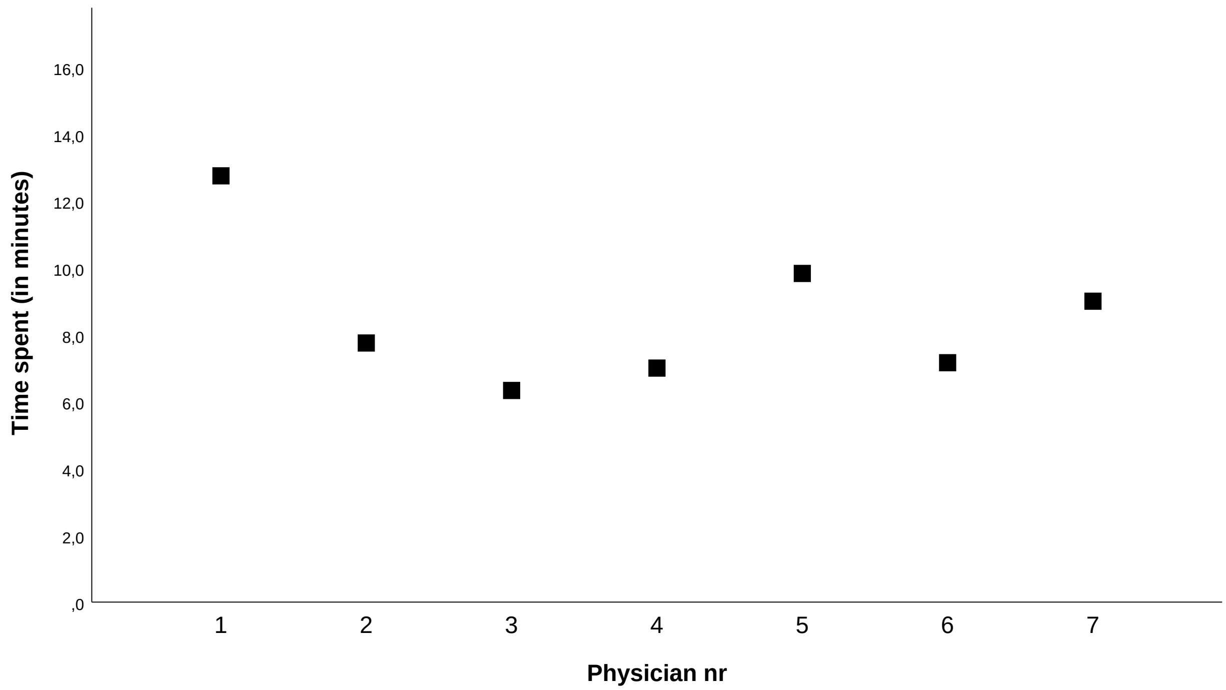
| | | |
|---|---|---|
| Communication | 0: Does not communicate with the assistant at all | |
| | 2: Communicates sufficiently with the assistant | |
| | 4: Communicates in a clear and proficient way | |

| | | |
|---|---|---|
| Use of assistant | 0: Does not make use of assistant at all | |
| | 2: Uses assistant in a sufficient way | |
| | 4: Uses assistant proficiently and optimally | |

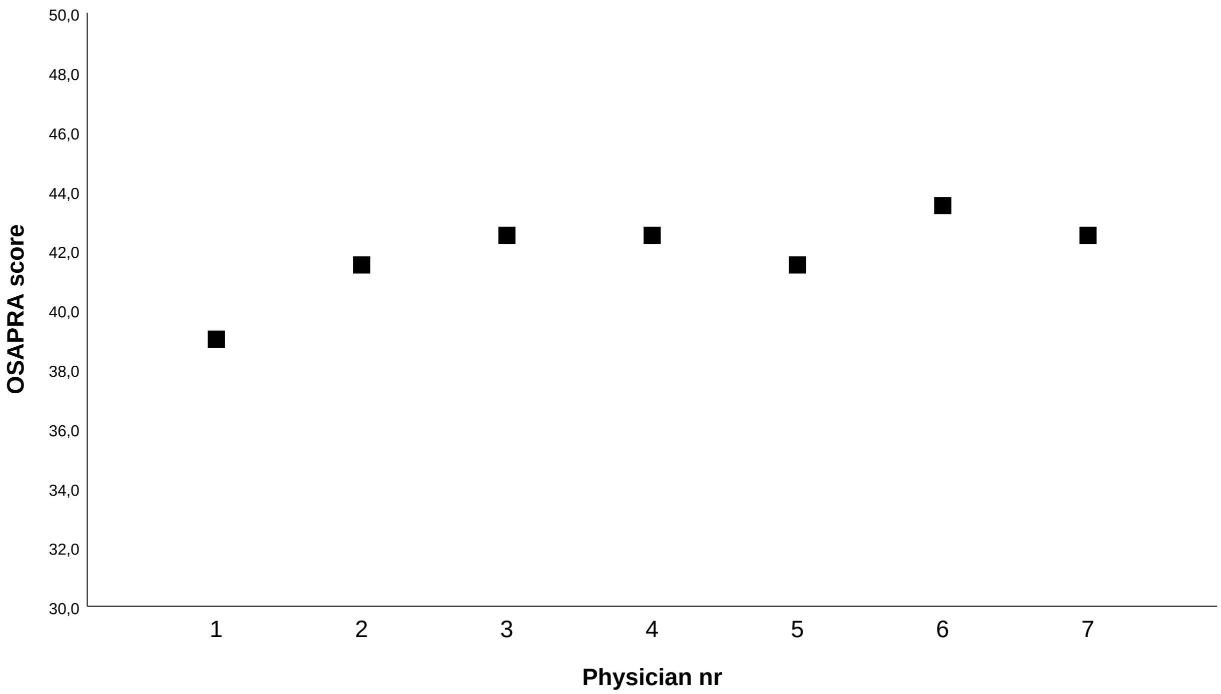
***Total score:*** ______
of total 48

**Time**

| | |
|---|---|
| Time spent from start REBOA procedure to occlusion of aorta | min |


Time spent (in minutes)
16,0
14,0
12,0
10,0
8,0
6,0
4,0
2,0
,0
1
2
3
4
5
6
7
Physician nr

Page 1


50,0
48,0
46,0
44,0
42,0
40,0
38,0
36,0
34,0
32,0
30,0
OSAPRA score
1
2
3
4
5
6
7
Physician nr



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# PROCEDURE FOR INSERTION OF REBOA FOR OHCA

Abort procedure if technical problems like:

-severe difficulties in ultrasound (US) visualization of the artery or cannulation
-resistance when inserting guidewire, introducer or catheter
-severe bleeding
-time consuming procedure

| PHYSICIAN | PARAMEDIC |
|---|---|
| **1.** Cut clothes from knee to groin | **1.** Open kit – unpack – place sterile gloves for physician |
| **2.** Examine with US – store image | **2.** Place introducer and balloon-catheter on sterile cloth |
| **3.** Note EtCO2 | **3.** Prepare NaCl and Chlorhexidine – close to physician |
| **4.** Fill NaCl in wash tray | **4.** Put on sterile gloves |
| **5.** Apply Chlorhexidine on compresses | **5.** Aspirate 15 ml NaCl from wash tray in 20 ml syringe |
| **6.** Wash selected area with forceps and compresses | **6.** Hand physician forceps – place compresses on sterile cloth |
| **7.** Fill gel into the US-cover – place it on the US-probe | **7.** Apply sterile drape |
| **8.** Apply US-gel on the thigh | **8.** Prepare US-cover |
| **9.** US-guided cannulation of a. femoralis | **9.** Apply elastic band – place probe on the sterile drape |
| **10.** Insert guidewire into cannulation needle, 60 cm | **10.** Prepare needle with 5 ml syringe |
| **11.** Remove needle – make skin incision with scalpel | **11.** Ready guidewire |
| **12.** Record US-video of guidewire in a. femoralis | **12.** Hand physician soft end of guidewire, insert to 60 cm |
| **13.** Insert introducer – remove dilatator | **13.** Hand scalpel to physician |
| **14.** Insert balloon-catheter, 50 cm | **14.** Mount introducer and dilatator onto guidewire |
| **15.** Check pulse - LEFT a. radialis | **15.** Control the guidewire |
| **16.** Fill balloon with 15 ml NaCl, less if resistance | **16.** Ready balloon-catheter |
| **17.** Check pulse in LEFT a. radialis | **17.** Put stopcock on blue line |
| **18.** Note time for balloon inflation and EtCO2 | **18.** Put plug on the black line |
| **19.** Suture and fixate | **19.** Hand physician 20 ml syringe with 15 ml NaCl |
| **20.** Place adhesive cover over REBOA-equipment | **20.** Ready suture – needle-holder – scalpel |
| **21.** Secure guidewire with forceps | **21.** Cut suture |
| | **22.** Ready adhesive cover |
| | **23.** Cut and remove sterile drape |