Original Article

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REBOA in Bleeding and Cardiac Arrest in Pre-Hospital Care by Helicopter Emergency Medical Service: The RIBCAP-HEMS Project

Presentation of a possible care concept to incorporate REBOA in pre-hospital care

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Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) plays an important role in the most severe trauma and medical patients with cardiac arrest. Its use in pre-hospital emergency medicine in Germany does not yet regularly occur, and the vast majority of rapid response vehicles are not equipped with REBOA devices. In this article we will describe the introduction of REBOA for bleeding patients, as well as an adjunct for refractory out-of-hospital cardiac arrest (OHCA), in a German helicopter emergency medical service (HEMS).
Methods: The DRF-Luftrettung HEMS base in Halle (Saale) Germany has incorporated REBOA in pre-hospital emergency medicine and will accompany this introduction with a feasibility study. We will describe the implementation of REBOA and the results of the training course. The training consists of theoretical and practical issues within different case scenarios. This was carried out before introducing REBOA into pre-hospital emergency medicine. Using a pre- and post-course exam and a self-assessment questionnaire the theoretical and practical knowledge and the performance of the critical care teams were determined.
Results: The results of the pre-course exam in comparison with the post-course exam improved from 82% to 96%. Based on the self-assessment questionnaires, all participants felt a relevant improvement of their theoretical and practical knowledge. All physicians successfully performed REBOA under ongoing cardiopulmonary resuscitation in manikin simulators.
Conclusions: The results from the training course indicate that there was a significant improvement of the theoretical and practical knowledge, as well as the performance of REBOA. The on-going feasibility study will show if it is worth introducing REBOA in a civilian HEMS for the patients in extremis.

Keywords: *Bleeding; Cardiac Arrest; REBOA; Pre-Hospital Emergency Medicine; Helicopter Emergency Medical Service*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) was originally conceived to manage non-compressible torso haemorrhage (NCTH). However, the indications are now that the use of REBOA have come to address a broad array of morbidities in the hospital and pre-hospital settings. REBOA is an endovascular procedure established in some of the German major trauma centres (MTCs) for temporary bleeding control of NCTH after trauma and in non-traumatic bleeding cases, as well as in some medical issues for cardiopulmonary resuscitation (CPR). Therefore, REBOA is part of the endovascular resuscitation and trauma management (EVTM), and plays an important role for the most severe trauma and medical patients [1]. If REBOA is just limited to traumatic NCTH, the pre-hospital number of potential patients is very low [2]. Beside traumatic NCTH, REBOA has the potential to be beneficial in the hospital and in the pre-hospital settings, including non-traumatic haemorrhage such as gastrointestinal bleeding (GIB), post-partum haemorrhage (PPH) or out-of-hospital cardiac arrest (OHCA). In Germany, the pre-hospital use of REBOA does not yet exist on a regular basis, and the vast majority of rapid response vehicles or rescue helicopters are not equipped with REBOA devices. In recent years, invasive life-saving measures, such as extracorporeal membrane oxygenation (ECMO), extracorporeal cardiopulmonary resuscitation (eCPR) or resuscitative thoracotomy, have become increasingly important in pre-hospital emergency care. Due to its less invasive and endovascular nature, REBOA could close an important gap with its range of applications as part of the EVTM concept. Theoretically, an early REBOA attempt before or just in time of catastrophic deterioration of the patient may be most beneficial. This implies that some patients may already require REBOA in the pre-hospital emergency care environment. Therefore, bringing REBOA to the scene would be a step forward in adding therapeutic options in the early treatment of critically ill patients, as has already been done by the London Air Ambulance, the Norwegian Air Ambulance helicopter emergency medical service (HEMS) base of Trondheim and the Bologna HEMS [3].

With the given indications, REBOA has the potential to be employed by specialised critical care teams on a regular basis to save lives in:

- Bleeding control in trauma patients with catastrophic haemorrhage below the diaphragm;
- Bleeding control in non-traumatic catastrophic haemorrhage below the diaphragm;
- Adjunct in OHCA in selected cases for circulatory support.

Beside the use of REBOA on the scene, the device can also be used as a safety net to enable transfer of very sick bleeding patients from local centres to level 1 trauma centres [4].

In this article we will describe the conditions, the theoretical and practical training needed to implement pre-hospital REBOA for bleeding and cardiac arrest in a HEMS, as well as the important issues revealed during the practical training.

METHODS

In the federal state of Saxony-Anhalt, Germany, all HEMS physicians of the DRF-Luftrettung (German Air Rescue) are specialised in anaesthesiology and intensive care medicine. As part of the pre-hospital critical care teams, they are highly qualified specialists in emergency medicine. Establishing access to the common femoral artery (CFA) is a basic requirement for the REBOA procedure, this is done by the HEMS physicians on a regular basis during their work as physicians in hospitals. Because of the fact that pre-hospital blood or plasma is not available in Saxony-Anhalt, ‘stop the bleeding’ is key in the bleeding patients’ cohort. Therefore, in addition to standard care, REBOA is the only option to get an extremely exsanguinated patient alive to a hospital.

The RIBCAP-HEMS project of the DRF-Luftrettung in cooperation with the MTC ‘Bergmannstrost’ and the University Hospital of Halle (Saale) brings REBOA to the most unwell patients. To ensure sufficient hospital care all trauma patients will be transported to the MTC, which has been using REBOA in the emergency room (ER) over the past 6 years. Patients with OHCA and return of spontaneous circulation (ROSC) after REBOA employment will be transported to the local university hospital. Due to the fact that currently REBOA is rarely used in the cardiology department of the mentioned university hospital, we involved the hospital staff in the REBOA course as mentioned below. Furthermore, many patients with ROSC after OHCA are candidates for percutaneous coronary intervention (PCI), and therefore the performed CFA access can be used for PCI or if necessary for ECMO.

REBOA Training Course Prior to Implementation

Before introducing REBOA into pre-hospital emergency medical services, a preparation phase was needed. The course consisted of:

- Self-study of the Prytime Medical learning module for ER-REBOA-Plus;
- Self-study of five important review papers regarding the topic [5–9];
- Pre-course test for evaluation of the self-study results;
- Theoretical lecture regarding the use of REBOA in trauma including the indications, contraindications and potential undesirable side effects;
- Theoretical lecture regarding the use of REBOA in OHCA including the indications, contraindications, eCPR and potential undesirable side effects;

Figure 1 The access and resuscitative endovascular balloon occlusion of the aorta (REBOA) technique instructor (ARTI), a purpose built REBOA training simulator (Prytime Medical, Boerne, TX, USA) used for preparing and training of the pre-hospital critical care teams.

Figure 2 Resuscitative endovascular balloon occlusion of the aorta (REBOA) flight bag containing all necessary equipment (convenience kit, sterile gloves, ER-REBOA-Plus catheter, two pressure transducers and a cuff).

- Time management and the correct mode of transportation to the proper destination for the right patient;
- Familiarisation with the equipment (ER-REBOA-Plus catheter and the access and REBOA technique instructor (ARTI) simulator, see Figure 1), verify the ultrasound skills, specifically to be able to identify the common femoral vessels and to perform ultrasound-guided insertion (using the GE Vscan portable ultrasound device) of the access needle in a hypovolemic patient or in a patient undergoing CPR and using REBOA under controlled in-house conditions;
- Theoretical presentations, with relevant case examples, on issues regarding the appropriate use of REBOA such as when, where, in whom and how to perform the procedure, pitfalls, and complications;
- Practical team training of different case scenarios at the helicopter base under cold environmental conditions;
- Final exam.

To evaluate the effectiveness of the course, the participants got a pre-questionnaire regarding the self-assessment of theoretical and practical knowledge regarding REBOA. A day after the training, a post-questionnaire containing the same questions was completed. A six-point Likert scale was used in the questionnaires. To assess the gain in theoretical knowledge, the results of the pre-course exam and post-course exam were compared.

Figure 3 Helicopters of the DRF-Luftrettung helicopter emergency medical service (HEMS) base in Halle (Saale). In the foreground the CHX 85, an H 135 Airbus helicopter, operated during daytime, and in the background the CHX 84, an H 145 Airbus helicopter, operated 24/7.

REBOA Equipment

The aircraft of the DRF-Luftrettung's HEMS base in Halle (Germany) are equipped with the ER-REBOA-Plus catheter, the appropriate convenience kit (REBOA Catheter Convenience Set, Prytime Medical, Boerne, TX, USA) and a portable ultrasound device (GE Vscan). All the equipment including the catheter and the access kit with all additional material needed to employ REBOA successfully (see Figure 2) on the scene are stored in a separate flight bag. The DRF-Luftrettung operates two different helicopters (see Figure 3) at the HEMS base in Halle (Saale). An Airbus helicopter H 145 (Christoph 84/ Sachsen-Anhalt) with a 24/7 on-call service and an Airbus H 135 (Christoph 85/Halle) operated from 07:00 hours (or sunrise in later) until sunset. Both helicopters are used for primary missions as well as for inter-hospital transfers.

Feasibility Study

The following issues will be evaluated in the feasibility study: technical issues, safety issues, problems regarding CFA access, team problems, time delays and patient outcomes. Currently, all team members are trained and the aircrafts are equipped. REBOA will be used in bleeding patients and in patients with OHCA according to the decision tree in Figure 4 (NCTH) and Figure 5 (OHCA). The feasibility of REBOA within pre-hospital emergency medicine care will be studied in the REIBCAP-HEMS project.

Due to the fact that pre-hospital REBOA is still an item of discussion and is not yet totally accepted, the decision to employ REBOA is made by the physician of the HEMS critical care team. The physician, after taking in all available circumstances on the scene, with a patient orientated perspective, will decide if the REBOA is to be used or not (i.e. decision will be made on a case by case basis considering multiple factors). There is no obligation to employ the REBOA by the physician.

In both situations (trauma and OHCA) time is of the essence and both scenarios can be highly stressful for the pre-hospital critical care teams, which could affect the possible use of REBOA. To avoid unnecessary delay of the pre-hospital time, the time for successful REBOA insertion is limited to 10–12 minutes. This is one of many reasons why it remains unclear if REBOA is feasible in this environment. With the current study we hope to address this critical issue.

Tables 1 to 3 demonstrate the data captured for study purposes. Table 1 captures the general data, whereas Table 2 captures the trauma-specific data and Table 3 the data in OHCA patients. The abbreviations used can be found in the Appendix.

Ethical Approval and Informed Consent

For the feasibility study of the RIBCAP-HEMS project ethical approval was given by the ethics committee of the medical association "Sachsen-Anhalt". Written informed consent was obtained from the enrolled patients.

RESULTS

REBOA Training Course

The training course took place on three different days, with 11 to 12 participants per day. The training was supported by the manufacture of the ER-REBOA-Plus catheter (Prytime Medical, Boerne, TX, USA) with training equipment and an instructor. Overall, 28 HEMS physicians and seven HEMS-TC (critical care paramedic such as helicopter emergency medical service – technical crew member) took part in the course. The results of the pre-course test compared with the post-course test improved from 82% to 96% and all participants felt a relevant improvement of theoretical and practical knowledge, based on the self-assessment questionnaires (see Table 4). All physicians successfully performed REBOA under ongoing CPR, after assuring that advanced cardiovascular life support (ACLS) is performed according to the current ERC guidelines and no ROSC was achieved after at least 10 minutes of high-quality CPR.

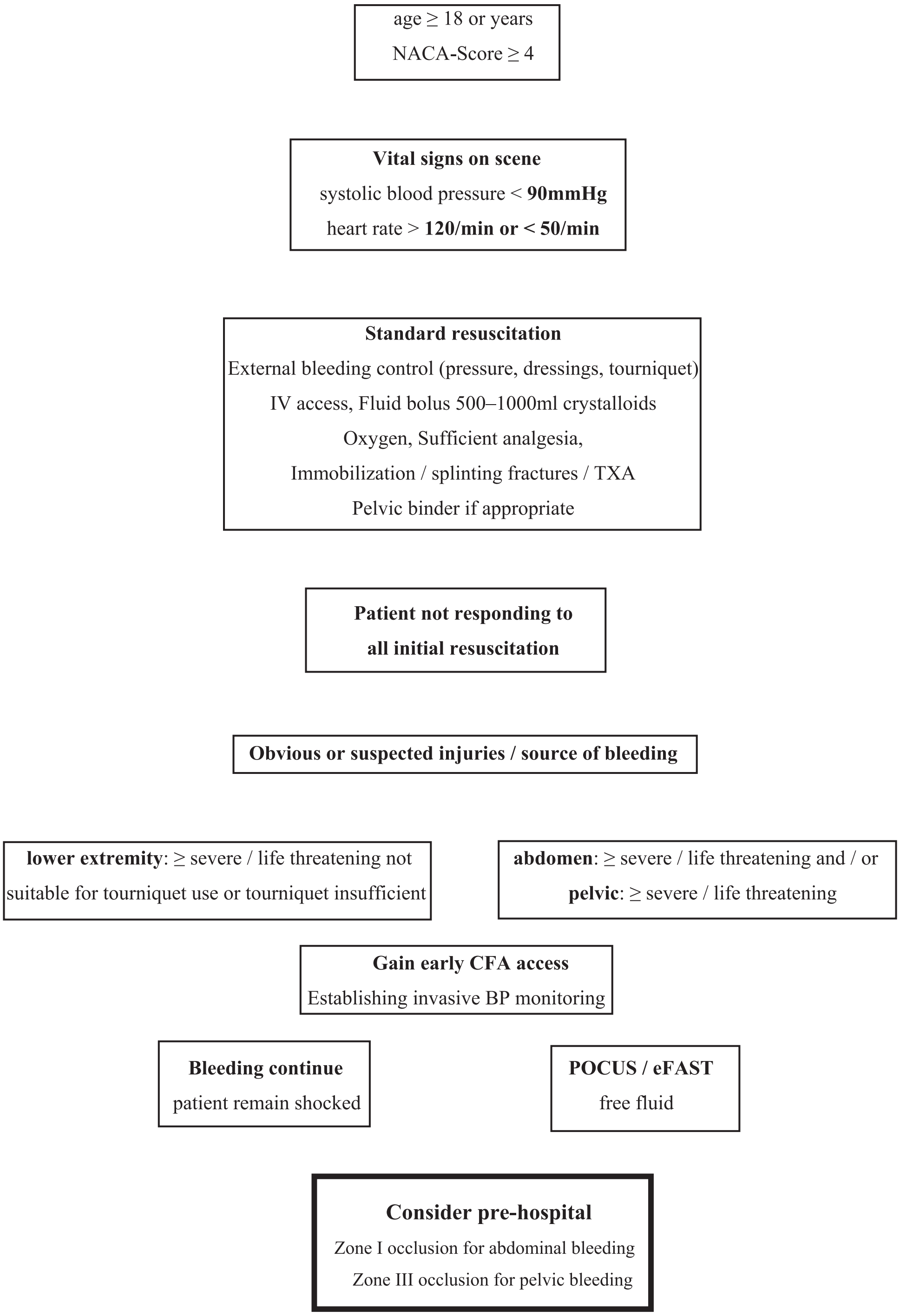

Figure 4 Decision tree to identify potential resuscitative endovascular balloon occlusion of the aorta (REBOA) patients with severe non-compressible torso haemorrhage (NCTH).

The roles of the team members during the pre-hospital REBOA training case scenarios, were as follows:

- HEMS physician: Team leader, obtaining the CFA, advancing the REBOA catheter and observing the patient's response to aortic occlusion and critical decision making.
- HEMS critical care paramedic: Preparing two invasive blood pressure (BP) monitoring systems (one for the sheath and one for the BP monitoring via ER-REBOA-Plus catheter above the balloon), measuring the time to avoid prolongating unsuccessful procedure, after 10 minutes the paramedic has to inform the physician that the time is over and if unsuccessful by now, the procedure has to be stopped and the patient is transferred to the hospital.
- Ambulance paramedics: In the case of CPR they are responsible, that standard ACLS will be carried out

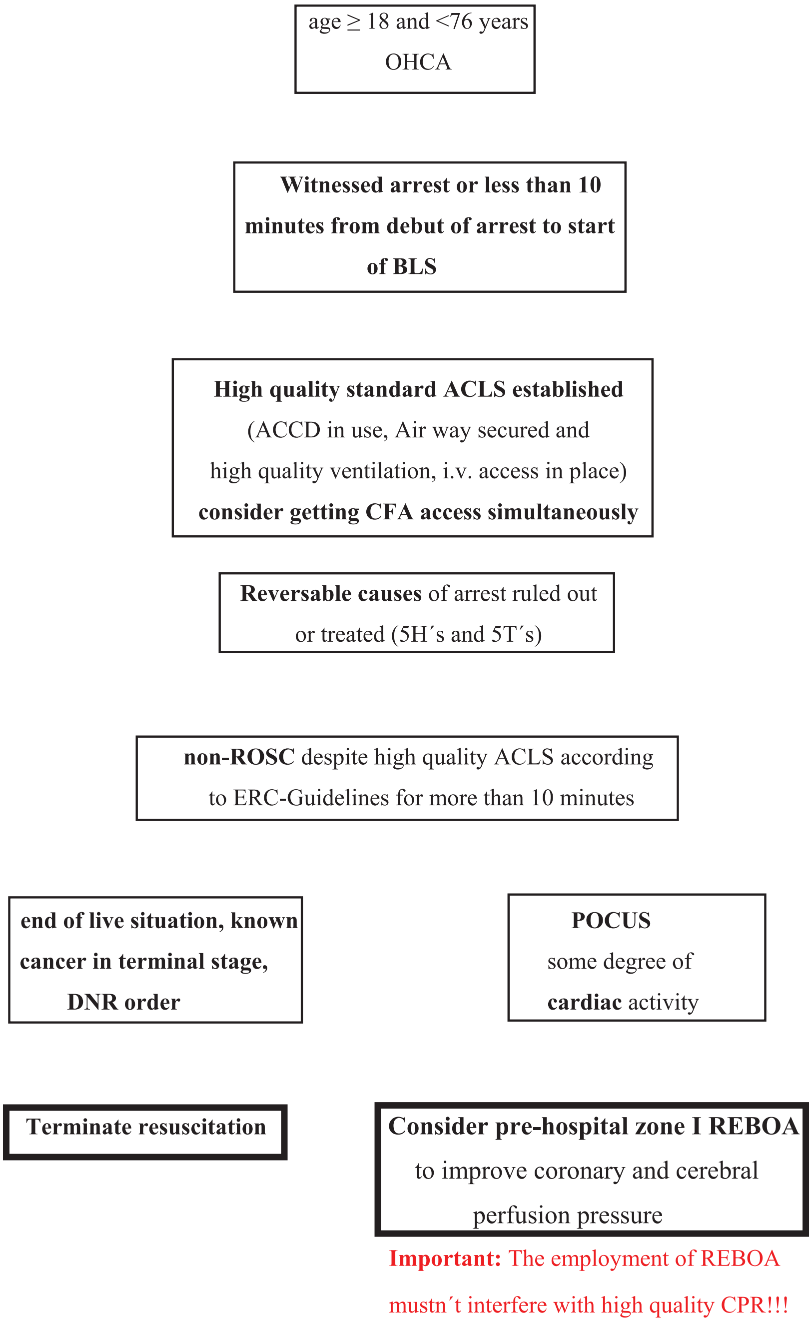

Figure 5 Decision tree to identify potential resuscitative endovascular balloon occlusion of the aorta (REBOA) patients with out-of-hospital cardiac arrest (OHCA).

according to the current European Resuscitation Council (ERC) guidelines, in trauma patients they will ensure that standard care according to Pre-Hospital Trauma Life Support (PHTLS) is appropriate.

Some difficulties occurred when setting up the used defibrillator-monitor unit Corpuls3 (corpuls/GS Elektromedizinische Geräte G; Stemple GmbH, 86916 Kauferingen, Germany) for two different invasive pressure curves, to monitor the BP at the sheath in the CFA and above the balloon in the aorta. Due to the switched on autoscaling of the pressure curves, the curve at the sheath did not disappear as expected, when occluding the aorta. Even the BP reading was correct; for example, 8 mmHg over 5 mmHg, the monitor showed a nice pulsatile curve due to the autoscaling. After switching of the autoscaling the pressure curve at the sheath disappeared to an almost flat line after occluding the aorta. At the end of the training all HEMS physicians felt trained to employ REBOA in NCTH or cardiac arrest in the pre-hospital emergency arena.

Table 1 General part.

Aircraft	☐ CHX 84 ☐ CHX 85
REBOA indication	☐ OHCA
	☐ NCTH
	☐ Pelvic injury
Age ☐ estimated ☐ known	…years
Sex	☐ Male ☐ Female
Estimated height (cm)	☐<160 ☐160–170 ☐170–180 ☐180–190 ☐>190
Estimated weight (kg)	☐<60 ☐60–70 ☐70–80 ☐80–90 ☐90–100 ☐>100
Transport to destination	☐ Air transport
	☐ Ground transport
	☐ Non-transport
REBOA-employed?	☐ Yes
	☐ No
	☐ Tried but failed
Vascular access	☐ Palpatory
	☐ Ultrasound
	☐ Surgical cut down
What problems occur during pre-hospital REBOA use?	
Aim of REBOA use achieved?	
ROSC	☐ Yes ☐ No ☐ Temporary
Bleeding control	☐ Yes ☐ No ☐ Temporary
Haemodynamic stabilisation	☐ Yes ☐ No ☐ Temporary
Do you think REBOA prolonged the pre-hospital time considerably?	☐ Yes ☐ No ☐ Not sure
Would you consider REBOA in a similar situation the next time?	☐ Yes ☐ No ☐ Not sure

Table 2 NCTH-specific data.

Trauma mechanism	☐ MVC ☐ Fall >3 m ☐ Blunt ☐ Penetrating
Non-traumatic bleeding	☐ GIB ☐ PPH ☐ Vascular
Assumed side of bleeding	☐ Abdomen ☐ Pelvic ☐ Multiple
Treatment ahead of REBOA?	☐ Pelvic binder ☐ TXA ☐ Tourniquet ☐ TI
Treatment after REBOA?	☐ Pelvic binder ☐ TXA ☐ Tourniquet ☐ TI
Volume resuscitation (ml)	
Before REBOA	☐<500 ☐500–1000 ☐1000–1500 ☐>1500
After REBOA	☐<500 ☐500–1000 ☐1000–1500 ☐>1500
Haemodynamic effect of REBOA	BP and HR prior to balloon inflation
	…/… mmHg …/min
(BP measurement via ER-REBOA-Plus catheter)	BP and HR after balloon inflation
	…/… mmHg …/min
REBOA-effect on $etCO_2$	$etCO_2$ prior to balloon inflation
	…mmHg or …kPa
	3–5 minutes after balloon inflation
	…mmHg or …kPa
Aortic occlusion zone and insertion depth … cm.	☐ Zone I …cm
	☐ Zone II …cm
	☐ Zone III …cm
Time from balloon occlusion to ER handover	… minutes

Table 3 OHCA-specific data.

CorPuls CPR (ACCD) used?	☐ Yes ☐ No
Heart rhythm	☐ Asystole ☐ PEA ☐ Ventricular fibrillation ☐ Agonal
Prior to REBOA	☐ Asystole ☐ PEA ☐ Ventricular fibrillation ☐ Agonal ☐ SR
After REBOA	☐ Asystole ☐ PEA ☐ Ventricular fibrillation ☐ Agonal ☐ SR
On hospital handover	
ROSC on scene	☐ Yes ☐ No ☐ Temporary
Hospital handover	☐ ROSC ☐ Ongoing CPR
Haemodynamic effect of REBOA	BP and HR prior to balloon inflation
	…/…mmHg …/min
(BP measurement via ER-REBOA-Plus catheter)	BP and HR after balloon inflation
	…/…mmHg …/min
REBOA effect on $etCO_2$	$etCO_2$ prior to balloon inflation
	…mmHg or …kPa
	3–5 minutes after balloon inflation
	…mmHg or …kPa
REBOA balloon deflated after ROSC?	☐ Yes ☐ No
If yes – duration of REBOA?	☐<10 ☐ 10–20 ☐ 20–30 ☐>30 minutes
If yes – patient condition?	☐ Stable ☐ Unstable ☐ New occlusion required
Aortic occlusion zone and insertion depth … cm.	☐ Zone I …cm
	☐ Zone II …cm
	☐ Zone III …cm
Time from balloon occlusion to handover	… minutes
Total REBOA inflation time	

Table 4 Pre and post-course questionnaire.

Question/Statement	*Rating 1 = maximum agreement with the statement 6 = no agreement with the statement*	*Median rating pre and post-course*	
I am familiar with the theory of the REBOA system used	1 – 2 – 3 – 4 – 5 – 6	2	1
I already have used the system myself	yes no	–	–
I know the individual steps involved in the implementation of the used REBOA system	1 – 2 – 3 – 4 – 5 – 6	2	1
I know the indication for pre-hospital use of REBOA	1 – 2 – 3 – 4 – 5 – 6	2	1
The pre-hospital use of REBOA seems to be a big challenge for me	1 – 2 – 3 – 4 – 5 – 6	2	5
The training course prepares me well for the pre-hospital use of REBOA	1 – 2 – 3 – 4 – 5 – 6	2	1

Monitor Settings

As a result of the training course, it was determined that a special set up of the monitoring unit C3 was required. This was developed and named ‘REBOA’ in our units. The used set up on the screen consists of:

- two invasive BP readings and curves (first BP via the sheath in the CFA with switched off autoscaling, second via the ER-REBOA-Plus catheter in the aorta with switched on autoscaling);
- end tidal carbon dioxide ($etCO_2$) curve and reading;
- peripheral oxygen saturation (SpO_2) curve and reading;
- ECG curve;
- stopwatch.

DISCUSSION

REBOA is already performed in highly trained and specialised pre-hospital critical care teams and the procedure has the potential to save lives of patients with massive bleeds, NCTH due to trauma or of non-traumatic causes and in selected patients with OHCA refractory to standard ACLS. Therefore, it seems logical to introduce REBOA in civilian HEMS in order to have further options, for a small percentage of the critically ill patient-cohort, it could make a big difference to normal standard care for these patients. There are already case reports and case studies in the literature describing the pre-hospital use of REBOA, mainly in trauma. Some emergency medical services (EMS) or HEMS providers have already integrated the procedure in their pre-hospital care [10–15]. A recent review has found a total of 44 cases performed for NCTH outside hospitals, both in military and civilian settings, and that the overall survival rate was 88.6%, which was significantly higher than the 50.4% survival of 1807 patients who had REBOA performed in hospitals ($P<0.0001$), indicating the possible benefit of REBOA in the pre-hospital emergency setting [14]. On the other hand, bleeding is not the only indication for pre-hospital REBOA use, some studies take REBOA into consideration as an adjunct in CPR and shows promising effects [16–26]. In human and in animal studies, the data show that REBOA improves coronary and cerebral perfusion pressures and key physiological parameters during cardiac arrest resuscitation and animal data has demonstrated improved rates of ROSC [23].

The results of our REBOA training course demonstrated that the course was able to improve significantly the theoretical and practical knowledge, the REBOA performance under different case scenarios of the involved critical care teams, as well as the self-assessment and self-confidence to perform the procedure in the pre-hospital emergency arena. The course built on the participants' existing knowledge of in-hospital REBOA use. The course demonstrated some unexpected technical issues regarding invasive pressure monitoring. These issues could have had negative influences if they were first discovered in real-life use. But being found during the training, they could be addressed beforehand and therefore will not have any negative influence in pre-hospital emergency settings. This finding highlights the importance of both technical training and simulation to prevent avoidable technical difficulties.

The course itself has some limitations that we would like to mention. Not all possible conceivable problems or technical issues that might occur in the pre-hospital setting can be addressed. Even if we tried to use realistic case scenarios, with integrated pitfalls, under cold environmental conditions, it is impossible to train all possible scenarios and have all possible environmental conditions.

In conclusion, introducing REBOA in the pre-hospital emergency arena needs proper planning, training and has to be accompanied by a feasibility study to ensure that all positive and negative aspects, as well as safety issues, are sufficiently covered. The training course carried out was able to significantly improve theoretical and practical knowledge as well as technical and team performance. Smaller technical issues of the used monitoring unit, revealed during the training, were then addressed and corrected. The future will show if the RIBCAP-HEMS project will be successful.

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Ethics Statement

(1) All the authors mentioned in the manuscript have agreed to authorship, read and approved the manuscript, and given consent for submission and subsequent publication of the manuscript.
(2) The authors declare that they have read and abided by the JEVTM statement of ethical standards including rules of informed consent and ethical committee approval as stated in the article.

Conflicts of Interest

David Baer works for Prytime Medical.

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Author Contributions

PH-C developed the project and wrote the manuscript. JB supported the project, and helped in development and in solving technical issues. JD wrote the manuscript in English. MB helped in writing the manuscript and solving technical issues. JT reviewed the cardiology part and developed the OHCA decision tree. DE helped in writing the manuscript and developed the "fast to ECMOA" concept within the RIBCAP-HEMS project. CG is responsible for the scientific, ethical and legal foundation of the project. FS was involved in developing the project and writing the manuscript. DB helped as an instructor during the REBOA course, improved the manuscript and supported the project with a lot of valuable ideas.

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Appendix: Abbreviations

ACLS	Advanced cardiovascular life support
ACCD	Automated chest compression device
BLS	Basic life support
BP	Blood pressure
CFA	Common Femoral Artery
CHX	Christoph (Callsign for Germane rescue helicopters)
CPR	Cardiopulmonary resuscitation
DNR	Do not resuscitate
eCPR either ECMO	extra-corporal cardiopulmonary resuscitation
EMS	Emergency Medical Service
ER	Emergency room
ERC	European Resuscitation Council
$etCO_2$	End-tidal carbon dioxide
GIB	gastro-intestinal bleeding

HEMS	Helicopter Emergency Medical Service
HR	Heart rate
MTC	major trauma center
MVC	Motor vehicle crash
NCTH	Non-compressible torso hemorrhage
NACA	National Advisory Committee for Aeronautics
OHCA	Out-of-hospital cardiac arrest
PEA	Pulseless electrical activity
PHTLS	Pre-Hospital Trauma Life Support
POCUS	Point of care ultrasound
PPH	post-partum hemorrhage
REBOA	Resuscitative endovascular balloon occlusion of the aorta
ROSC	Return of spontaneous circulation
SR	Sinus rhythm
TI	Tracheal intubation
TXA	Tranexamic acid