



Journal of **ENDOVASCULAR RESUSCITATION** and Trauma Management

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Issue Highlights

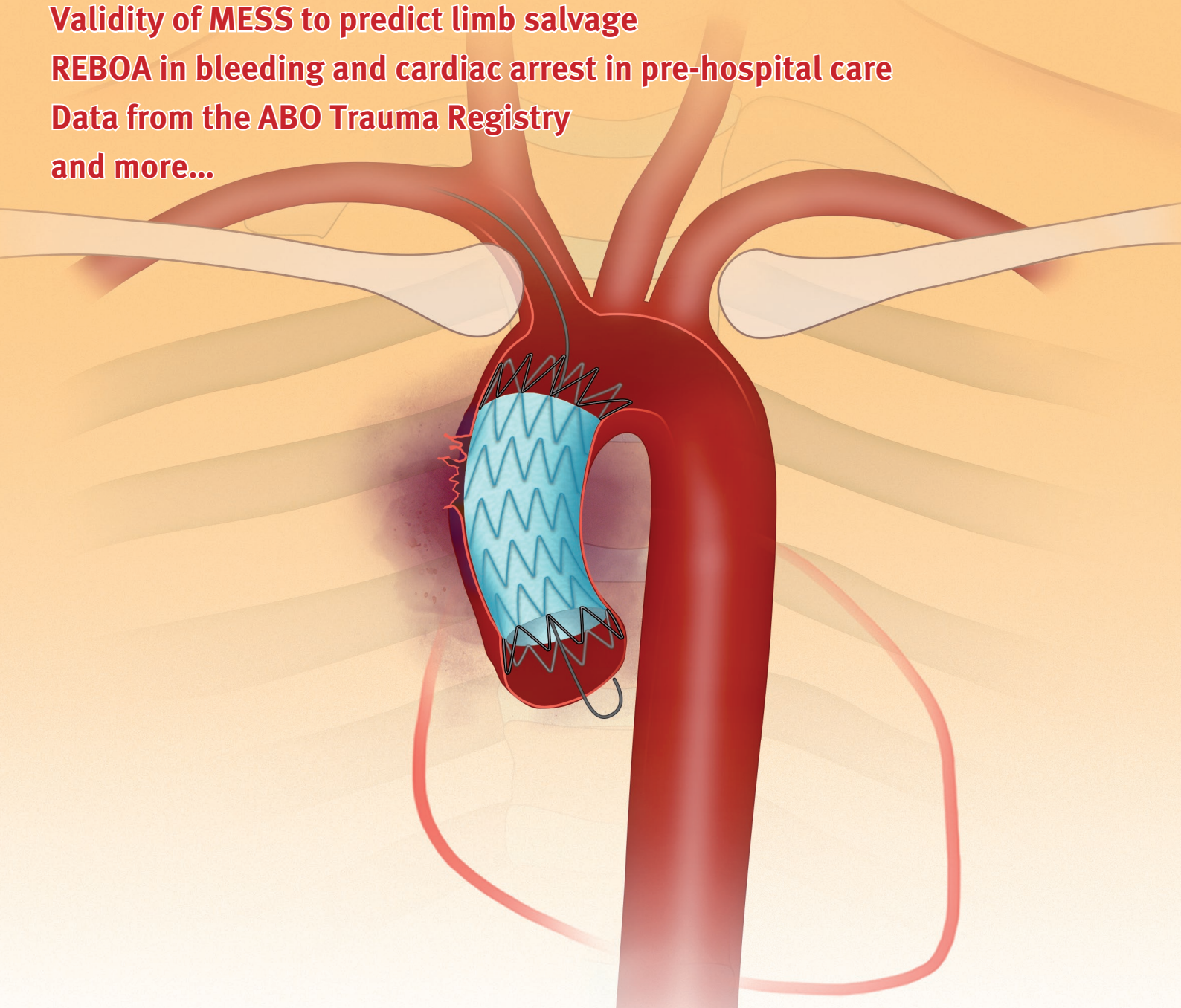
Endovascular repair of aortic pseudoaneurysms

Hybrid management for a traumatic arteriovenous fistula

Validity of MESS to predict limb salvage

REBOA in bleeding and cardiac arrest in pre-hospital care

Data from the ABO Trauma Registry
and more...



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This is the *Journal of Endovascular Resuscitation and Trauma Management*. We want to provide a truly Open Access platform for the dissemination of knowledge and peer-reviewed research in the field of endovascular and hybrid hemorrhage control.

To achieve this, we do not wish to be bound by medical discipline, country, resource or even the conventional rules of medical publishing. To achieve this goal, we have assembled an Editorial Board of clinicians and scientists who are experts within the field. This project is generously supported by a grant from the Department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Sweden.

We are keen to receive manuscript submissions that present new original findings, review important topics or educate our readers on any aspect of hemorrhage control, where an endovascular technique has been employed. This can either be in isolation or in combination with open surgical techniques (hybrid surgery). For further information for authors, please see www.jevtm.com.

As the subject of hemorrhage and resuscitation is a common problem across many medical disciplines, we encourage submissions from all specialties: vascular, trauma, acute care, obstetrics, emergency medicine, to mention a few.

The Journal will publish 3 to 4 times a year and will be truly Open Access. There will be no article processing charges or publishing fees. All articles will be published online and indexed using a digital object identifier. The Archives can be found on www.jevtm.com under journals and are there with no time or access limitations.

JEVTM is indexed in Scopus, Web Of Science, EMBASE and Google Scholar.

Official publication of the Society of Endovascular Resuscitation and Trauma Management (EVTM)

In cooperation with Örebro University Hospital and Örebro University, Sweden.



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Author Guidelines

GUIDELINES FOR SUBMISSION

A manuscript submitted to the Journal must constitute a unique piece of work that is not under consideration for publication, in part or whole, by another journal.

Submissions should preferably be produced using Microsoft Word, although other formats will be considered.

The submission process requires three discreet documents:

1. Cover Letter
2. Title Page
3. Manuscript (including Abstract, Tables and Figures)

Please ensure that names and contact details are included for **all** authors of a manuscript on the online submission system.

Cover Letter

This should be written by the corresponding author and must contain the following:

1. The type of manuscript submission (Original Article, Review Article, etc)
2. A sentence or two on the subject of the study.
3. Confirmation that the study is not under consideration for publication by another journal.
4. Confirmation that all of the authors have made a substantial contribution to the manuscript and that they have seen and approved the submission draft.
5. A conflict-of-interest statement regarding the authors. Where there is none, this should be clearly stated. More information can be found below on the publication ethics of the JEVTM.
6. A clear statement that the authors follow the ethical guidelines as stated in the ethical section of the JEVTM.

Title Page

This should consist of the following:

- Title: This should be concise and reflect the type and purpose of the study.
- Authors: These should be listed in order for publication, with first name, initials and surname.
- Affiliations: The institution(s) that the authors are affiliated with should be listed. A full address is not required, but enough to ensure identification.
- Corresponding Author: This individual should be clearly identified, along with full institutional address and e-mail address.
- Presentation: The meeting where any of the submitted data was presented should be listed.
- Disclosure: To disclose any official information.

- Acknowledgements (Optional): Any acknowledgements that you would like to include.
- Conflicts of Interest (Compulsory): A conflict-of-interest statement regarding the authors. Where there is none, this should be clearly stated.
- Funding Declaration (Compulsory): Any grant funding should be listed or a negative statement should be included.
- Author Contributions (Optional): All authors are expected to have substantially contributed to the study and manuscript writing.

Main Body

This should consist of text in 12 pts, double spaced with a justified margin, written in US English. While each article type has specified headings, the use of sub-headings is encouraged to aid clarity. These should be formatted as follows:

Main Heading **BOLD, FULL CAPITALS**

Sub-Heading ***Bold and Italicized, Title Case***

Sub-sub-heading *Italicized, sentence case*

Abstract

The abstract should be a maximum of 250 words and consist of the following headings (but see specific manuscript types below for exceptions):

Background

Methods

Results

Conclusions

Keywords

Three to six appropriate keywords should be included.

Types of Article

Original Articles

Manuscripts reporting unique scientific studies should be no longer than 3000 words. They should consist of the following sections:

- Introduction: This should concisely present the background to the problem that the study hopes to answer. A hypothesis should be clearly stated.
- Methods: This section should be suitably detailed to permit replication of the study. The regulatory permissions for the study should also be detailed, e.g. Institutional Review Board, ethical committee etc., including a protocol/registration number. Where animal research has been undertaken, the institutional animal care and use guidelines that have been followed should be clearly stated.
- Results: These should involve the reporting of the salient positive and negative findings of the study in

clear language. The use of images, figures and tables are encouraged, of which the data should not be duplicated in the prose. There is no maximum number of figures or tables, but these should be appropriate to the study. Numerical results and *P* values should be reported to three decimal places.

- Discussion: This should place the reported study findings in the context of the literature. Limitations and future direction should also be discussed. Authors must be careful to ensure that conclusions are not overstated and are supported by data.

Editorials

Short, focused Editorials on an important aspect of endovascular hemorrhage control are welcomed. These should endeavor to bring attention to an important topic, or accompany an article published within the Journal. The latter will be invited by the Editor. Submitted manuscripts should be no longer than 1500 words. They will not contain an abstract or keywords.

Narrative Review Articles

This style of article can afford the author considerable latitude in examining a pertinent topic in endovascular hemorrhage control. The literature should be examined objectively and presented to the reader in the context of current understanding. The author should be able to synthesize a narrative, which leaves the reader with a good understanding of an emerging or controversial topic. The author is welcome (and encouraged) to express an opinion, but where this is the case, it should be clearly stated.

Articles should be a maximum of 5000 words. There is no formal structure; however, the use of logical headings/sub-headings is important to enable readers to follow the article easily. The abstract should also be unstructured and be a maximum of 150 words.

Systematic Reviews and Meta-Analyses

Where there is a topic within the subject area of endovascular hemorrhage control that has a substantial evidence base, a Systematic Review with/without a Meta-Analysis is considered more appropriate than a narrative review article. These articles should follow the methodology established by PRISMA.

Submission should be a maximum of 5000 words and authors should include a PRISMA checklist in their submission. The overall aim is to provide a pooled analysis that enables firm conclusions to be drawn on a particular subject.

Tips and Techniques

In the evolving world of endovascular hemorrhage control, the advice and opinion of actively practicing clinicians is of great importance. Both solicited and unsolicited submissions are reviewed, both on major or minor components of endovascular techniques. This can be presented in the context of "evidence" or just as an opinion. The use of quality images and diagrams is encouraged.

The submission should be a maximum of 1500 words. The abstract should be unstructured and be a maximum of 150 words.

Images of Interest

The Journal accepts images of interest, which include a short commentary. The aim of this section is to demonstrate and illustrate an educational message, rather than just to demonstrate dramatic pathology. Images can be submitted as a multi-panel with a series of scans/photographs in order to support the message presented in the narrative. The submission should be a maximum of 250 words. They will not contain an abstract.

Case Reports

These are short case reports including current literature reviews. The submission should be a maximum of 1500 words. An abstract can be included but is not compulsory.

Conference Proceedings

Where a conference is affiliated to the Journal, the proceedings will be published as agreed by the Editorial Board.

Letters to the Editor

Letters for publication can be written to the Editor that comment on anything within the Journal.

EVTM-ST Section

The EVTm-ST Section will be a section of each JEVTM edition geared towards residents/fellows and education. The editors will invite one trainee to submit an interesting case report, and invite a reviewer to review and add a brief editorial. The editors should not be authors nor reviewers.

The components of the section will include a standard case report presentation with figures of CT or angio or anything interesting and pertinent. The discussion should finish with a "what I learned" summary/bullet points for education purposes. The brief editorial by the reviewer is the final paragraph.

The submissions should be a maximum of 1500 words. An abstract can be included but is not compulsory.

References

References should follow the Vancouver Style and should be noted in the text numerically in sequence within the text using square brackets, e.g. [1] or [1,2] or [1–3].

An example article:

Stannard W, Rutman A, Wallis C, O'Callaghan C. Central microtubular agenesis causing primary ciliary dyskinesia. *Am J Respir Crit Care Med*. 2004;169:634–7.

Tang AL, Diven C, Zangbar B, et al. The elimination of anastomosis in open trauma vascular reconstruction. *J Trauma Acute Care Surg*. 2015; In Press. doi: XXXXXXXXXX.

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Rasmussen TE, Tai NRM. Rich's Vascular Trauma. 3rd ed. Philadelphia: Elsevier; 2015.

Thamm DH. Miscellaneous tumors. In: Withrow S, Vail D, editors. Small Animal Clinical Oncology. 5th ed. St. Louis: Elsevier; 2013. pp. 679–88.

Where there are more than six authors, the first three should be included followed by et al.

Figure/Tables

All figures/tables must be cited within the text, presented as Figure 1, Figure 2a,b, Figures 1 and 2, Table 1.

Figure captions should be styled as follows.

Figure 1 Title of figure.

Details of figure described below. **(a)** First sub item.

(b) Second sub-item.

Table captions are styled similarly.

Supplementary Digital Content

Where manuscripts would benefit from additional content (datasets, images, video), which does not necessarily need inclusion in the published article, supplementary digital content (SDC) can be hosted. This includes, but is not limited to, tables, figures or video. Authors should include in their cover letter a description of this content and its purpose.

SUPPORT FOR LANGUAGE AND ARTICLE CONTENT

The aim of the Journal, in addition to the dissemination of peer-reviewed evidence, is to support English-second-language authors and early career scientists. Provided that a submitted manuscript has good scientific merit, the Journal is able to provide a free language editing service. Furthermore, where article content would benefit from high-quality figures, artwork can be commissioned to support the publication.

ETHICAL AND LEGAL CONSIDERATIONS

The Journal is committed to maintaining the highest level of integrity in the content published. This Journal has a Conflict of Interest policy in place and complies with international, national and/or institutional standards on research involving Human Participants and/or Animals and Informed Consent. The Journal follows the Committee on Publication Ethics (COPE) regulations and subscribes to its principles on how to deal with acts of misconduct thereby committing to investigate allegations of misconduct, in order to ensure the integrity of research. The Journal may use plagiarism detection software to screen the submissions. If plagiarism is identified, the COPE guidelines on plagiarism will be followed. Content published in this Journal is peer

reviewed (double blind review process). Detailed information will follow in the text below.

Authors' Responsibilities

A submitted manuscript must be an original contribution not previously published (except as an abstract and should be indicated); cannot be under consideration for publication in other journals; and, if accepted, must not be published or reproduced elsewhere. All authors are obliged to provide retractions or corrections of mistakes after the review process. The final responsibility for the scientific accuracy and validity of published manuscripts rests with the authors, not with the Journal, its editors, or the publisher (Örebro University Hospital).

All published material will include the following Ethics Statement:

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.

Detailed Ethical Guidelines

Maintaining the integrity of the research and its presentation is helped by following the rules of good scientific practice, which are outlined here:

- The manuscript should not be submitted to more than one journal for simultaneous consideration.
- The submitted work should be original and should not have been published elsewhere in any form or language (partially or in full), unless the new work concerns an expansion of previous work. (Please provide transparency on the re-use of material to avoid the concerns about text-recycling ("self-plagiarism").)
- A single study should not be split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (i.e. "salami-slicing/publishing").
- Concurrent or secondary publication is sometimes justifiable, provided certain conditions are met. Examples include: translations or a manuscript that is intended for a different group of readers.
- Results should be presented clearly, honestly, and without fabrication, falsification or inappropriate data manipulation (including image based manipulation). Authors should adhere to discipline-specific rules for acquiring, selecting, and processing data.
- No data, text, or theories by others are presented as if they were the author's own ("plagiarism"). Proper acknowledgements to other works must be given (this includes material that is closely copied

(near verbatim), summarized and/or paraphrased), quotation marks (to indicate words taken from another source) are used for verbatim copying of material, and permissions secured for material that is copyrighted.

- Authors should avoid untrue statements about an entity (who can be an individual person or a company) or descriptions of their behavior or actions that could potentially be seen as personal attacks or allegations about that person.
- Authors are strongly advised to ensure the author group, the Corresponding Author, and the order of authors are all correct at submission. Adding and/or deleting authors during the revision stages is generally not permitted, but in some cases may be warranted. Reasons for changes in authorship should be explained in detail. Please note that changes to authorship cannot be made after acceptance of a manuscript.

In order to maintain the highest scientific standards, the Journal follows strict quality standards:

Upon request authors should be prepared to send relevant documentation or data in order to verify the validity of the results presented. This could be in the form of raw data, samples, records, etc. Sensitive information in the form of confidential or proprietary data is excluded.

If there is suspicion of misbehavior or alleged fraud the Journal and/or Publisher will carry out an investigation following COPE guidelines. If, after investigation, there are valid concerns, the author(s) concerned will be contacted under their given e-mail address and given an opportunity to address the issue. Depending on the situation, this may result in the Journal's and/or Publisher's implementation of the following measures, including, but not limited to:

- If the manuscript is still under consideration, it may be rejected and returned to the author.
- If the article has already been published online, depending on the nature and severity of the infraction:
 - an erratum/correction may be placed with the article
 - an expression of concern may be placed with the article
 - or in severe cases retraction of the article may occur.

The reason will be given in the published erratum/correction, expression of concern, or retraction note. Please note that retraction means that the article is maintained on the platform, watermarked "retracted", and the explanation for the retraction is provided in a note linked to the watermarked article.

Authors have an obligation to correct mistakes once they discover a significant error or inaccuracy in their published article. The author(s) is/are requested to contact the Journal and explain in what sense the error is impacting the article. A decision on how to correct the literature will depend on the nature of the error. This may be a

correction or retraction. The retraction note should provide transparency as to which parts of the article are impacted by the error.

Editors' Responsibilities

The Editors of JEVTM have responsibilities toward the authors who provide the content of the Journal, the peer reviewers who comment on the suitability of manuscripts for publication, the Journal's readers and the scientific community, the owners/publishers of the Journal, and the public as a whole.

Reviewers' Responsibilities

Peer review assists editors in making editorial decisions and, through editorial communications with authors, may assist authors in improving their manuscripts. Peer review is an essential component of formal scholarly communication and lies at the heart of scientific endeavor.

Any invited referee who feels unqualified to review the research reported in a manuscript or knows that its prompt review will be impossible should immediately notify the editors and decline the invitation to review so that alternative reviewers can be contacted.

Any manuscripts received for review are confidential documents and must be treated as such; they must not be shown to or discussed with others except if authorized by the Editor-in-Chief (who would only do so under exceptional and specific circumstances). This applies also to invited reviewers who decline the review invitation.

Reviews should be conducted objectively and observations formulated clearly with supporting arguments so that authors can use them for improving the manuscript. Personal criticism of the authors is inappropriate. Reviewers should identify relevant published work that has not been cited by the authors. Any statement that is an observation, derivation or argument that has been reported in previous publications should be accompanied by the relevant citation. A reviewer should also notify the editors of any substantial similarity or overlap between the manuscript under consideration and any other manuscript (published or unpublished) of which they have personal knowledge.

Any invited referee who has conflicts of interest resulting from competitive, collaborative, or other relationships or connections with any of the authors, companies or institutions connected to the manuscript and the work described therein should immediately notify the editors to declare their conflicts of interest and decline the invitation to review so that alternative reviewers can be contacted.

Unpublished material disclosed in a submitted manuscript must not be used in a reviewer's own research without the express written consent of the authors. Privileged information or ideas obtained through peer review must

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be kept confidential and not used for the reviewer's personal advantage. This applies also to invited reviewers who decline the review invitation.

The scientific editorial technical team has been created in order to support the authors, the editors and the Editorial Board in quality control of all submissions. The team review all submissions and check for scientific problems, errors/bias and quality. Their work is also aimed at checking the ethical issues of all submissions to the JEVTM.

Patient Anonymity and Informed Consent

It is the authors' responsibility to ensure that a patient's anonymity is protected, to verify that any experimental investigation with human subjects reported in the manuscript was performed with informed consent, and follows all the guidelines for experimental investigation with human subjects required by the institution(s) with which all the authors are affiliated and/or ethical committee processing. Authors are asked to comply with the general guidelines for integrity protection, as listed by the health ministries in the EU, the EU commission, and US Department of Health (see, for example, <https://www.hhs.gov/hipaa/forprofessionals/special-topics/research/index.html>). Authors should mask patient's eyes and always remove patient names from figures as well as genital organs as far as possible.

Protection of Human Subjects & Animals in Research

For original articles in the Journal that report research involving animals, the corresponding author must confirm that all experiments were performed in accordance with relevant guidelines and regulations (i.e. IACUC guidelines and federal regulations, or EU guidelines for animal research). One recommended document for animal studies is the ARRIVE reporting guidelines (PLoS Bio. 2010; 8(6), <https://doi.org/10.1371/journal.pbio.1000412>). We encourage authors to follow the RRR principles of animal studies in medicine (https://www.feam.eu/wp-content/uploads/FEAM-Forum_Round-table-animals_Report_Final.pdf).

All studies of human subjects must contain a statement within the Methods section indicating approval of the study by an institutional review body (i.e. Institutional Review Board or ethical committee), and, if appropriate, a statement confirming that informed consent was obtained from all subjects if possible. If no legally informed consent can be obtained, such as in research carried out with human subjects receiving emergency treatment, authors

should indicate when possible if a waiver of regulatory requirements for obtaining and documenting informed consent applies.

Ethical Approval and Informed Consent

Ethical approval to report these cases was given by XXXXX. Written informed consent was obtained from xxxx.

Or in the negative

Ethical Approval and Informed Consent

Ethical approval was not required. Informed consent was not possible because XXXX and the information has been anonymised or Informed consent was not required.

All submissions are screened for inappropriate image manipulation, plagiarism, duplicate publication and other issues that violate research ethics. Depending on the outcome of these investigations, the Journal may decide to publish errata, or, in cases of serious scientific misconduct, ask authors to retract their paper or to impose retraction on them.

General Statement

Patients have a right to privacy that should not be infringed without informed consent. Identifying information, including patients' names, initials, or hospital numbers, should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that a patient who is identifiable be shown the manuscript to be published. Authors should identify Individuals who provide writing assistance and disclose the funding source for this assistance.

Identifying details should be omitted if they are not essential. Complete anonymity is difficult to achieve, however, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.

JEVTM follows guidelines and best practices published by professional organizations, including Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals by ICMJE, and Principles of Transparency and Best Practice in Scholarly Publishing (joint statement by COPE, DOAJ, WAME and OASPA).

Join the Endovascular Resuscitation Platform

The EVTM Society is a non profit organization that aims to share information on advanced methods for bleeding control and endovascular resuscitation, exchange of data, and cooperation and education. It is also designed to serve as a professional platform for the multidisciplinary approach.

By joining the EVTM Society you will be part of this global development.

To join, please visit jevtm.com/evtm-society.

The Membership fee is 50 USD biannually (25 USD per year).

Contact information for payment: lotta@mkon.se

Vision and Mission:

Our mission is to promote optimal treatment and new methods for bleeding control in trauma and non-trauma patients, and state-of-the-art endovascular resuscitation. This will be achieved by a joint international body that will support the following:

- A web-based free platform for EVTM issues (jevtm.com).
- JEVTM – the Journal of Endovascular Resuscitation and Trauma Management, an open access peer-reviewed journal.
- The EVTM round table symposium, a platform for continuous debate and data exchange.
- Educational opportunities in the form of manuals (Top Stent), courses, workshops, and web seminars.
- Promoting open dialogue and cooperation between societies, organizations and the industry.
- Promoting new guidelines and recommendations for EVTM-related issues and protocols.
- Promoting research in EVTM-related areas, both human and animal.
- Promoting PR for EVTM issues, grants, and collaboration with industry.
- Encouraging residents and young colleagues to carry out research on EVTM issues.
- Promoting cooperation and data exchange with other medical instances.

Structure:

The EVTM council, led by the society chair, will change membership periodically (i.e., after two years). The council aims to have one or two representatives from each participating country and discipline.

The EVTM Society is supported at this stage by Örebro University Hospital in all financial respects (as part of EVTM research group support). This support has been granted for the forthcoming five years.

The main task of the council is to pave the way for the EVTM venture, and promote the JEVTM/EVTM symposium, EVTM-related courses, cooperation, and free exchange of information.

Members will obtain free access to all JEVTM information and discussions as well as regular updates on EVTM-related activities, education, and developments. Members will also be offered a reduced fee for the EVTM round table symposium.

The EVTM Society is registered in Sweden, and is managed in collaboration with the EVTM program at Örebro University Hospital, the JEVTM journal and web platform, and other institutes.

Since the society is registered in Sweden, it will follow the rules and guidelines of the Swedish government and the EU. Expansion to other countries is welcome, but should follow our ethical guidelines and the EVTM Society should be named in all documents appropriately.

Call for collaboration: We call out to physicians with an interest in endovascular resuscitation, trauma and bleeding management. We need the contributions of the medical professionals who want to be a part of our venture.

Please consider joining by filling out the form at: <http://www.jevtm.com/evtm-society>

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Would Changing the Term “REBOA” to Intra-luminal Aortic Control Potentially Increase the Adoption of the Procedure?

Kessel–Khan Corner

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Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is a minimally invasive technique that can be used for resuscitative measures and to control arterial bleeding in patients with life-threatening haemorrhage. This can help to buy crucial time to achieve initial haemostasis and allows other interventions or investigations to be performed. REBOA is a relatively new technique and it is not yet widely implemented by surgeons. There are several reasons for this, including concerns about safety and efficacy. In our previous Corner, we have discussed the potential limitations of REBOA use [1]. The world of haemorrhage control surgeons is currently divided into two main groups: those that advocate the use of REBOA and those that are against it. One of the major factors is the apparent industry-led drive to increase the utilization of this device. However, if one were to purely look at the mechanism by which REBOA achieves haemostasis, then it would be appreciable that it achieves the exact same outcome as its open surgical counterpart: intraluminal versus extraluminal occlusion.

One potential way to increase the adoption of REBOA is to change the way that it is described. Clamping of the descending or the supraceliac aorta is a hugely invasive procedure that carries extensive morbidity and mortality, and that can lead to complications such as stroke and kidney failure. REBOA, on the other hand, is a much less invasive procedure. It has its own risks, but benefits from not requiring opening of the thoracic cavity to clamp the aorta, thus decreasing the potential burden of injury by not augmenting it with a thoracotomy.

In our opinion, a more accurate way to describe REBOA is as “intra-luminal control”. Extra-luminal control refers to the placement of a clamp outside of the aorta. Intra-luminal control describes the placement of a balloon inside of the aorta. Both techniques can be used to increase cardiac and cerebral perfusion, as well as arrest subdiaphragmatic haemorrhage. However, the nature of their application does have differing advantages and disadvantages.

Extra luminal control has the potential to be less effective compared with intraluminal occlusion. The effectiveness and proper performing of descending or supraceliac aorta clamping is not well evaluated and is under-reported [2–6]. Intra-luminal control is suggested to be more effective than extra-luminal control and is less invasive, but can carry regional and distal complications, i.e., vessel rupture, distal ischemia, etc. The patient selection for both techniques depends on the specific situation.

REBOA is a minimally invasive technique that can be used in various clinical scenarios of major bleeding. It is not yet widely adopted by surgeons, but it is hypothesized that changing the way it is described may increase its adoption. There is evidence that changing the wording used to describe new processes can change the viewpoint of users and positively effect adoption, in particular, focusing on “attitude” factors [7]. Hence, by undertaking these changes we may possibly increase REBOA adoption by surgeons. We propose that trauma leaders may be more likely to consider using REBOA if it was described as “intra-luminal control” and clamping as “extra-luminal control”.

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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

The authors declare that they have no conflicts of interest.

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Hybrid Management for Traumatic Iliac Arteriovenous Fistula

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Traumatic arteriovenous fistulas are usually the evolution of non-treated contiguous arterial and venous injuries inflicted by firearm projectiles. As time passes, these fistulas can lead to systemic and local repercussions. Endovascular management offers great benefit in reducing the risks of open surgery for correcting these fistulas, but unfortunately some endovascular resources are not always available.

In this situation, a hybrid management offering an endovascular strategy to control bleeding, while allowing an open disconnection of the affected artery and vein, may be useful in dealing with these complex injuries. In this article, the authors report a case of traumatic arteriovenous fistula between the common iliac vessels, managed with a hybrid strategy and make comments about practical issues regarding planning the open part of the procedure and anticipating possible complications when treating such injuries.

Keywords: *Iliac Artery; Iliac Vein; Arteriovenous Fistula; Surgery; Endovascular Procedures*

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INTRODUCTION

Traumatic arteriovenous fistulas (AVFs) are abnormal communications between arterial vessels and adjacent veins secondary to trauma; 90% are due to penetrating injuries, mostly caused by firearm projectile injuries [1–6].

Even though traumatic AVFs can resolve spontaneously, it only happens in 2% of cases [7], making AVFs one of the main chronic complications following vascular trauma [4,5,7,8].

AVFs can lead to local and systemic effects, mostly depending on their size and location, with a tendency towards enlarging the fistula's size and bringing additional complexity to delayed treatments. Traumatic iliac AVFs can be established if injuries to the involved vessels are not detected, for instance when retroperitoneal Zone 3 hematomas are not properly explored after penetrating trauma [7–9].

Systemic repercussions include diminishing vascular peripheral resistance, and increasing venous pressure and heart preload, increasing cardiac output, myocardial hypertrophy and possibly leading to congestive heart failure [4–8,10]; while local consequences can regard lower limb ischemia, varicose veins, edema and even leg ulcers [7–9,11].

The main pillar for traumatic AVF management is ceasing arteriovenous communication, by the open surgical approach or endovascular methods [4–8].

Open surgery may carry some disadvantages, especially when the traumatic AVF has been established for some time; fibrosis, anatomy distortion and venous hypertension can make it difficult to dissect anatomical structures, increasing the possibility of bleeding and adjacent structures' iatrogenic injuries, thus increasing morbidity and mortality [3,7,10,12].

Endovascular techniques include mainly the implantation of endoprotheses/stent grafts in cases in which vascular flow must be preserved or the occlusion of the involved vessels, when flow can be interrupted [4–7,9,13].

In cases of long established iliac vessel AVF open approach and vascular reconstruction can be especially challenging and risky, but sometimes limited endovascular resources can preclude an exclusive endovascular management. Depending on the available tools, a hybrid treatment involving conventional surgery and endovascular techniques may provide lower risks and good results [1,4,6,8,13].

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Figure 1 Physical examination. (a) The arrows point towards dilated veins at the abdominal wall. (b) Lower limb edema.

Ethical Approval and Informed Consent

Ethical approval and informed consent were not required as all data were anonymized. The patient endorsed the description of his clinical course for educational purposes.

CASE REPORT

A 29-year-old male patient was sent to a vascular surgery consult. Two years earlier, the patient was submitted to a median laparotomy at another hospital after sustaining a gunshot wound to the left lower abdominal region; details about this previous procedure were unavailable.

Physical examination revealed left lower limb edema and diminished left femoral pulse; dilated veins were visible at the abdominal wall and thrill and murmur were detected at the left lower abdominal quadrant (Figure 1).

An abdominal computed tomography scan confirmed the presence of a traumatic AVF between the common left iliac vessels and revealed a large saccular dilation of the common left iliac vein and considerable distortion of the regional anatomy (Figure 2).

As endoprosthesis/stent grafts were not available, due to institutional limitations, an elective hybrid management was planned.

An open surgical approach was planned and performed through a transverse laparotomy. A preoperative

bowel preparation was performed and on the surgical table, the patient was positioned with a lumbar cushion and a central line. An 8F sheath was placed at the right jugular vein (Figure 3) and an 8F sheath was also placed on the left common femoral artery.

During laparotomy, visceral adhesions were loosened, when necessary, in order to perform the exposure, through a Mattox maneuver, of the distal aorta and the left common iliac vessels. Before progressing the iliac vessel dissection, a guidewire was advanced to the distal aorta and an angioplasty balloon was placed over the AVF, under angiography guidance.

When the limit of safe dissection was thought to be reached, systemic anticoagulation was performed, followed by the balloon inflation, performing an “endoclamp” of the left common iliac artery (Figure 4).

The iliac vein was dissected as minimally as possible, just enough to place the arterial clamps. When proximal and distal arterial control was achieved, the guidewire and the balloon were removed, and the arterial clamps were applied.

After a longitudinal arteriotomy the communication with the venous system was identified and sutured through the arterial lumen, occluding the fistula.

Proximal and distal arterial stumps were resected, and arterial continuity was restored using a Dacron graft, interposed using end-to-end anastomosis; patency was angiographically documented using right femoral artery access before ending the procedure (Figure 5).

The patient received prophylactic antibiotics and anticoagulation during the hospital stay and was discharged without complications at post-operative day 7.

DISCUSSION

The treatment of complex vascular injuries, especially those difficult to expose surgically, such as iliac AVFs, may benefit from endovascular procedures, mainly because they reduce bleeding and iatrogenic injuries that are risky and avoid large surgical incisions that are often necessary [10,11,14].

Unfortunately, endovascular treatments are not universally available. They require infrastructure, trained personnel and access to a range of endovascular devices.

When planning the endovascular treatment of a high-flow long established traumatic AVF, like the one described in this case, measuring arterial diameters carefully is of paramount importance. As time passes, low resistance flow through the fistula and the distal diminished arterial flow tends to make the proximal arterial diameter much larger than the distal diameter, sometimes making it difficult to find stent grafts/endoprotheses compatible with both proximal and distal arterial diameters [7,13,15,16].

In order to overcome the limitations imposed by these diameters' discrepancy, some endovascular solutions have been developed, such as flared stents, which allow the adaptation to different proximal and distal diameters, by assuming a conical configuration [7,8,13].

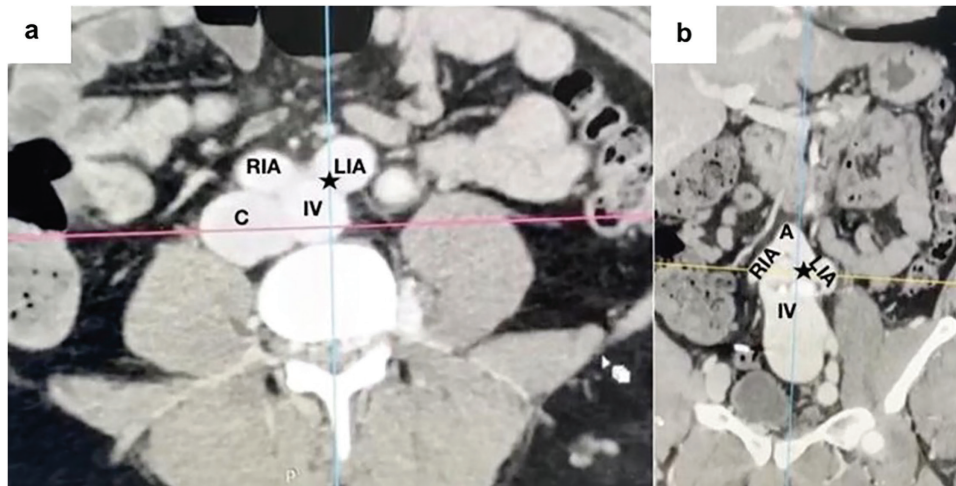


Figure 2 Abdominal computed tomography with intravenous contrast. (a) Axial view; RIA: right iliac artery; LIA: left iliac artery; IV: left iliac vein; ★: arteriovenous fistula (AVF) between the left common iliac vessels; C: inferior vena cava. (b) Coronal view. Note the large saccular dilation of the left common iliac vein.

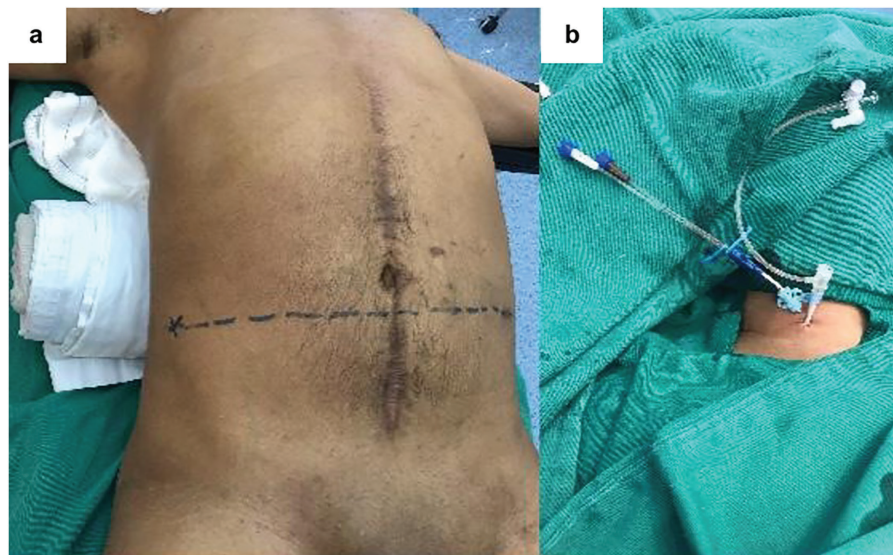


Figure 3 Preoperative preparation. (a) Planning for a transverse laparotomy. Note the presence of the lumbar cushion. (b) A central line and an 8F sheath placed at the right jugular vein.

If no stent grafts are available and vascular flow is required to be maintained, as in the case here described, artery and vein disconnection requires an open approach, in order to avoid further AVF complications [4,6,13].

During preoperative planning, considering complications in advance is important. There are two major risks involved: the first is accidental hollow visceral injury, because of adhesions provoked by previous surgical procedures, contaminating the abdominal cavity; the second is uncontrolled bleeding. Hybrid strategies can help diminish the risks of a purely open treatment.

A transverse laparotomy was chosen in order to avoid most of the adhesions associated with the

previously performed midline incision, and the use of the lumbar cushion favors the exposure of deep pelvic structures. Bowel preparation provides a secondary advantage; by reducing intestinal content, it makes it easier to manipulate the bowel, losing adhesions and visceral rotation during the Mattox maneuver, favoring the exposure of the iliac AVF fistula.

Anticipating a possible hemorrhage, an 8F sheath was placed in the internal right jugular vein, the same access used for the central line. If necessary, the 8F sheath allows rapid blood product infusion, while the conventional central line catheter can be used for drug infusion and hemodynamic monitoring [7,13,16].

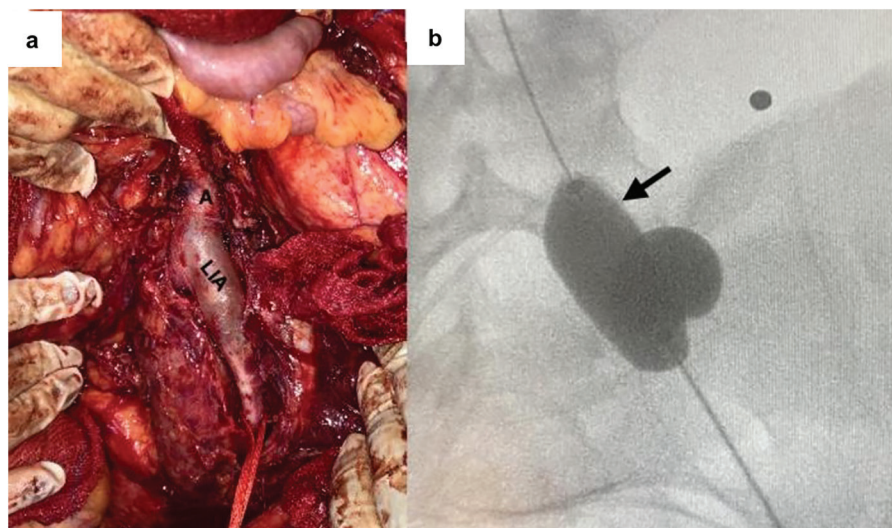


Figure 4 Intraoperative images. (a) A: aorta; LIA: left iliac artery. (b) Balloon inflation at the left common iliac artery performing an “endoclamp”.

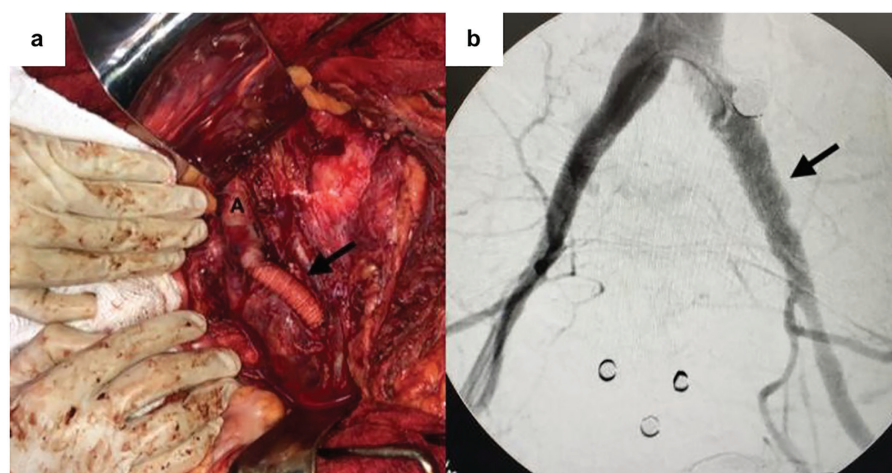


Figure 5 Intraoperative images. (a) A: Aorta. The arrow points towards the Dacron graft used for reconstructing the left common iliac artery. (b) Angiographic control demonstrating the patency of the reconstructed left common iliac artery/Dacron graft (pointed towards by the arrow).

An endoclamp, in this case by inflating the balloon catheter over the fistula, diminishes the AFV pulsation and venous hypertension and, in the case of inadvertent vascular rupture while dissection is being performed, helps obtain hemorrhage control [7,13,15].

Intraoperative communication between surgical and anesthesiology teams is essential; the anesthesiologist team should be prepared to deal with the possibility of bradycardia and hypertension onset, suddenly after AVF occlusion (Nicoladoni–Branham sign), that can be clinically relevant [17,18].

CONCLUSIONS

Endovascular approaches have long been proved to lower complication rates associated with open exposures

of complex traumatic AVFs, especially by reducing bleeding and the duration of the procedure.

When resource limitations preclude complete endovascular management, hybrid treatments may be useful. Preventing massive bleeding, preserving arterial flow and venous drainage and being prepared to deal with possible complications are the key points when performing these hybrid strategies.

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

The authors declare that they have no conflicts of interest.

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All the authors substantially contributed to the study and manuscript writing.

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Use of Intermittent Aortic Balloon Occlusion: Report from the ABO Trauma Registry

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Background: Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is a helpful adjunct in the management of hemorrhagic shock due to bleeding in the abdomen or pelvis. Ischemia distal to the occlusion is a concern; intermittent aortic balloon inflation (i-REBOA) is a novel way to achieve decreased ischemia time.

Methods: This study was conducted using data from the multinational ABO Trauma Registry. All patients entered between January 2016 and December 2019 were included.

Results: The sample consisted of 157 patients. There were 57 patients in the i-REBOA group (36%) and 100 in the REBOA group (64%). The groups were similar in gender ($P = 0.50$), age ($P = 0.17$), mechanism of injury ($P = 0.42$), and injury severity score ($P = 0.13$). The levels of international normalized ratio (INR) ($P < 0.01$), activated partial thromboplastin time (aPTT) ($P < 0.01$) and lactate ($P = 0.02$) were higher in the i-REBOA group. Total balloon inflation times were longer in the i-REBOA group ($P < 0.01$). Major complication rates did not differ between groups. Mortality rates between groups were similar in the Emergency Department (ED) (3.8% for i-REBOA vs 10.1%; $P = 0.17$), within 24 hours (43.4% for i-REBOA vs 38.2%; $P = 0.54$), and at 30 days (63.6% for i-REBOA vs 48.4%; $P = 0.07$).

Conclusions: The data from this registry show that i-REBOA is currently being used and may allow for longer total balloon inflation times without higher morbidity or mortality rates.

Keywords: Intermittent REBOA; ABO Trauma Registry; Trauma Hemorrhage; Trauma

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is an established adjunct to the management of hemorrhagic shock and is part of the endovascular resuscitation and trauma management concept

[1,2]. Balloon placement in the aorta decreases blood loss distally while shunting blood proximally to the more vital neurologic and cardiorespiratory centers [3]. Advantages include minimally invasive access, use without intubation, quick access and hemorrhage control, and use in pre-theatre settings. Comparison of REBOA with resuscitative thoracotomy and aortic cross-clamping noted more rapid aortic occlusion in REBOA patients, with the additional benefits of the possibility of prehospital deployment and independence from sonographic or fluoroscopic techniques, requiring only external anatomic landmarks for prompt insertion [4–6].

Three aortic zones are described, with reference to balloon inflation: Zone 1: between the left subclavian artery and celiac trunk; Zone 2: from the celiac trunk to the lowest renal artery; Zone 3: from beyond the lowest renal

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artery to the aortic bifurcation. Zone 2 is generally avoided while balloon placement in Zone 1 versus Zone 3 is governed by specific indications, with their own impact on overall morbidity and mortality [7]. Due to the complexity of these cases the outcome is not only dependent on the use of REBOA. The level and the duration of balloon inflation both contribute to the increased potential for ischemia–reperfusion syndrome and multi-organ dysfunction [8,9]. This is especially true for Zone 1 occlusion.

Partial balloon inflation (p-REBOA), in which the aortic balloon is partially deflated, allowing a proportion of aortic flow distal to the balloon, and intermittent balloon inflation (i-REBOA) have been proposed as means to mitigate the risk of ischemia–reperfusion syndrome [8–12]. Although the optimal duration of intermittent balloon inflation has not been established, the need for careful, incremental deflation of the aortic balloon as well as expeditious definitive management of the bleeding source has been outlined clearly in recent international literature [13,14]. In this study we aimed to ascertain clinical use and outcomes related to the use of i-REBOA.

METHODS

The study was conducted using the ABO Trauma Registry. This multi-national registry captures patients who underwent REBOA placement secondary to traumatic hemorrhagic shock in selected centers using REBOA. The registry is funded and hosted by the Department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Sweden. Participating centers can register independently or by invitation and can use the data for scientific analysis. There are no center-specific criteria for joining. Centers that participate in data collection arrange ethics approval by their local committees. The data captured is anonymized and receives a generated registry ID.

We performed a retrospective analysis of registry data entered from January 2016 to December 2019. i-REBOA was defined as any patient in whom the aortic balloon was inflated and deflated periodically. Patients in whom it was not specified whether i-REBOA was used/not used were excluded. Entries missing more than 50% of the necessary data were excluded. Those that were included in the study but lacked certain information necessary for any specific analysis were excluded from the relevant analysis.

Ethical Approval and Informed Consent

Ethics approval was obtained from the regional committee (study number 2014/210; Uppsala, Sweden).

Statistical Analysis

Microsoft Excel 365, IBM SPSS Statistics for Windows, version 25.0, and R 4.1.1 were used for data analysis. Standard descriptive and inferential statistics were

analysed and non-parametric tests in the form of Wilcoxon matched-pair tests and Mann–Whitney U tests were performed. Statistics with *P* values of less than 0.05 calculated by Kruskal–Wallis one-way analysis were deemed significant.

RESULTS

Of 253 registry entries, 96 were excluded, leaving a study population of 157 patients. The median age was 38.0 years (standard deviation (SD) 19.9 years; range 10–90 years), and 35 patients (22.3%) were women. Thirty-one patients (20.4%) had comorbidities. Two patient groups were identified: i-REBOA: 57 (36%) versus conventional REBOA with no intermittent inflation: 100 (64%). The groups were similar in gender (*P* = 0.50), age (*P* = 0.17), mechanism of injury, that is, blunt, penetrating or mixed (*P* = 0.42), injury severity score (ISS) (*P* = 0.13), and zone of inflation (*P* = 0.08); however, i-REBOA was used more frequently in patients with comorbidities than in those who were previously healthy (54.8% vs. 32.2%; *P* = 0.02).

There were no differences between groups in median values of systolic blood pressure just before REBOA insertion (*P* = 0.29), hemoglobin level (*P* = 0.27), blood pH (*P* = 0.87), or platelet count (*P* = 0.31); however, the median levels of international normalized ratio (INR) (*P* < 0.01), activated partial thromboplastin time (aPTT) (*P* < 0.01) and lactate (*P* = 0.02) were higher in the i-REBOA group. Total balloon inflation times were longer in the i-REBOA group (*P* < 0.01) (Figure 1).

Fewer patients in whom i-REBOA was used remained hemodynamically unstable (8.9% vs. 17.9%), although more patients in whom i-REBOA was not used (42.1%) gained complete hemodynamic stability (42.1% vs. 30.4%). These distributions differed significantly (*P* = 0.04) (Figure 2).

Balloon migration was more common with i-REBOA (8.8% vs. 2.1%; *P* = 0.05). Balloon rupture was more common with i-REBOA (5.3% vs. 1.0%) but this did not reach statistical significance (*P* = 0.11).

The rate of complications did not differ significantly between groups (Table 1). The mortality rate between groups was similar in the Emergency Department (ED) (3.8% for i-REBOA vs. 10.1%; *P* = 0.17), within 24 hours (43.4% for i-REBOA vs. 38.2%; *P* = 0.54), and at 30 days (63.6% for i-REBOA vs. 48.4%; *P* = 0.07; Table 2). There were no significant associations between the rate of complications and zone of inflation among patients who did and did not undergo i-REBOA (Table 3). While the mortality rate of patients with inflation in Zone 1 who underwent i-REBOA was significantly lower than those who did not in the ED (2.3% for i-REBOA vs. 14.0%; *P* = 0.04), the 30-day mortality rate of patients with inflation in Zone 1 who underwent i-REBOA was significantly higher than those who did not (66.7% for i-REBOA vs. 47.4%; *P* = 0.05; Table 4).

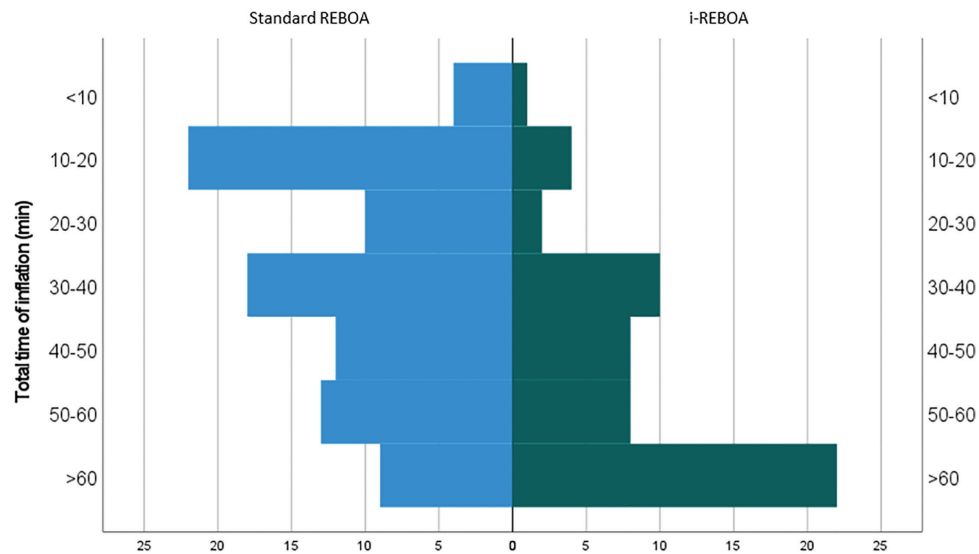


Figure 1 Comparison of total time of balloon inflation between i-REBOA and standard REBOA.

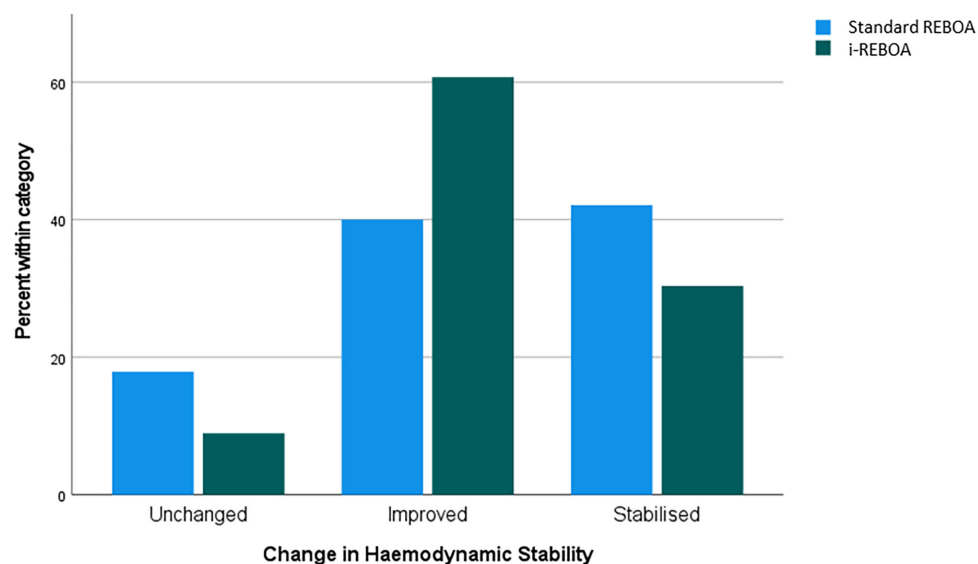


Figure 2 Change in hemodynamic stability with and without i-REBOA.

Table 1 Complication rates.

	<i>i-REBOA</i>	<i>Standard REBOA</i>	<i>P Value</i>
Pulmonary failure	7 (18.4%)	24 (30.8%)	0.16
New onset renal failure	10 (22.7%)	12 (14.0%)	0.21
Sepsis/SIRS	5 (12.8%)	15 (19.0%)	0.40
Extremity ischemia	5 (10.6%)	8 (10.1%)	0.93
Embolization/thrombus formation	3 (5.9%)	9 (10.2%)	0.38
Aorta/iliac perforation	1 (2.0%)	2 (2.2%)	0.91
Hematoma over access site	1 (2.2%)	1 (1.2%)	0.67
Major bleeding from access site	1 (2.0%)	1 (1.1%)	0.67
Intimal injury	0 (0.0%)	1 (1.1%)	0.45

Table 2 Mortality rates in ED, within 24 hours and after 30 days.

	<i>i</i> -REBOA	Standard REBOA	<i>P</i> Value
Death in ED	2 (3.8%)	9 (10.1%)	0.17
Death within 24 hours	23 (43.4%)	34 (38.2%)	0.54
Death within 30 days	35 (63.6%)	44 (48.4%)	0.07

Table 3 Complication rates in patients with Zone 1 inflation.

	<i>i</i> -REBOA	Standard REBOA	<i>P</i> Value
Pulmonary failure	6 (19.4%)	16 (32.7%)	0.19
Acute kidney injury	6 (17.6%)	9 (17.0%)	0.94
Sepsis/SIRS	3 (9.7%)	8 (16.3%)	0.40
Extremity ischemia	2 (5.1%)	4 (8.3%)	0.56
Embolization/thrombus formation	2 (4.9%)	3 (5.5%)	0.90
Aorta/iliac perforation	0 (0.0%)	0 (0.0%)	—
Hematoma over access site	1 (2.6%)	0 (0.0%)	0.25
Major bleeding from access site	1 (2.5%)	1 (1.8%)	0.82
Intimal injury	0 (0.0%)	1 (1.8%)	0.39

Table 4 Mortality rates in ED, within 24 hours and after 30 days in patients with Zone 1 inflation.

	<i>i</i> -REBOA	Standard REBOA	<i>P</i> Value
Death in ED	1 (2.3%)	8 (14.0%)	0.04
Death within 24 hours	22 (50.0%)	22 (38.6%)	0.25
Death within 30 days	30 (66.7%)	27 (47.4%)	0.05

DISCUSSION

It has been reported that prolonged ischemia after REBOA followed by reperfusion results in multiple organ failure and is more prominent with continuous balloon inflation [15–17]. Kuckelman et al. [18] reported that *i*-REBOA enabled extension of the occlusion time for Zone 1 without an overt increase in complications in an animal study.

When using *i*-REBOA, two options have been described, namely time-based and pressure-based techniques. The pressure-based technique employs mean arterial pressure (MAP) < 40 during deflation with 10-minute inflation increments, while the time-based technique employs 3-minute deflation periods, irrespective of MAP, with 10-minute inflation periods. In their swine model, Kuckelman and co-workers reported that the time-based technique had a superior survival benefit [18]. In the present study the emphasis was not on choice of technique and therefore this comparison was not made.

Intermittent inflation may prompt concerns as to the effectiveness of REBOA to bring about hemodynamic stability. The use of *i*-REBOA in this study resulted in a more pronounced initial improvement of hemodynamic status, but it was less likely to result in ultimate stabilization. This can be explained by the greater degree of

coagulopathy and shock in the *i*-REBOA group, as reflected by higher levels of INR, aPTT, and lactate.

In this study, although the *i*-REBOA group had worse shock parameters and the duration of balloon inflation was on average three times longer, there were no differences in morbidity and mortality rates between groups. This implies that *i*-REBOA may be instrumental in allowing an extended overall duration of balloon inflation to facilitate referral and transport of a patient to appropriate facilities for definitive care, without additional morbidity or mortality.

Repetitive manipulation of the balloon during the use of *i*-REBOA carries inherent technical concerns. Balloon migration in this study was significantly more common with *i*-REBOA than without. Repeated re-inflation and manipulation of the catheter with longer inflation times could be responsible for this finding. The risk of balloon migration can be minimized by securing the catheter once proper positioning is achieved. With *i*-REBOA the catheter position is of utmost importance, as the lack of apposition to the aortic wall can cause downstream migration [19–21]. Inflation of the balloon during REBOA is usually performed blindly and is ceased when distal pulses disappear or when there is resistance during inflation [22,23]. Experience with the procedure can help with procurement of the necessary

tactile feedback of adequate inflation. Johnson and coworkers [21] reported that the distal arterial waveform may be measured and is a useful adjunct to determine complete aortic occlusion during balloon inflation. Over-inflation could lead to balloon or arterial rupture, arterial dissection and intimal injuries [22–24]. Balloon rupture in this study was more frequently encountered with i-REBOA than with standard REBOA, although this did not reach statistical significance. There were also no significant differences between groups in terms of intimal injuries or arterial ruptures, and the same held for distal ischemia, embolization, and renal failure.

This study has several limitations. The ABO Trauma Registry is an international registry and the indications, technical application, and efficacy of REBOA differ across the various contributing facilities. Furthermore, this database does not take into account the failed attempts at REBOA deployment, while non-reporting also needs to be considered. Finally, a major limitation is the absence of a control group.

CONCLUSIONS

It appears that i-REBOA can be employed with longer total balloon inflation times without higher morbidity or mortality rates, thereby alleviating some of the time-associated concerns related to aortic occlusion. The technique may be of value in severely shocked patients in whom resuscitation is ongoing and transport is required. Attention to balloon position, monitoring and security are of utmost importance and can prevent adverse events related to repetitive manipulation.

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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

The authors declare that Tal Hörer has a conflict of interest due to his affiliation as editor in chief of the *Journal of Endovascular Resuscitation and Trauma Management*. The remaining authors declare that they have no conflicts of interest.

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Author Contributions

J Buitendag: Principal investigator; S Variawa S: Data preparation, data analysis, manuscript preparation; A Diayar: Data preparation, data analysis, manuscript preparation; P Snyders: Data preparation, data analysis, manuscript preparation; P Rademan P: Data preparation, data analysis, manuscript preparation; N Allopi: Data preparation, writing, data analysis, manuscript preparation; B Kessel B: Data collection, data preparation, manuscript revision; D McGreevy D: Data collection, data preparation, manuscript revision; T Hörer: Data Collection, data preparation, manuscript revision; G Oosthuizen: Critical revision and overall supervision.

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Comparison of Outcomes Relating to REBOA Inflation Zones: Report from the ABO Trauma Registry

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Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a temporary management modality for non-compressible torso haemorrhage that can be deployed in the pre- and intrahospital setting. This study aimed to compare outcomes following balloon placement in the three aortic zones.

Methods: This is a retrospective study using data from the ABO Trauma Registry. Relevant entries from January 2014 to December 2019 were used and stratified into three groups: those who received Zone 1, 2, or 3 balloon placements.

Results: The study sample consisted of 237 patients: 63 (27%) women and 174 (73%) men, median age 35 years. The primary location of the REBOA balloon was in Zone 1 for 180 patients, while it was nine in Zone 2 and 48 in Zone 3. Complication rates and total durations did not differ significantly between inflation zones. Emergency department mortality rates for Zones 1 and 2 patients were significantly higher than for Zone 3 ($P = 0.04$), but there was no difference between groups in 24-hour and 30-day mortality rates.

Conclusions: REBOA is currently used in the emergency setting for temporary stabilisation of the bleeding patient. In this cohort, balloon placement occurred in all zones of the aorta for similar durations, with no difference in complication rates between zones. Inadvertent Zone 2 placement was not found to be associated with increased complication rates.

Keywords: REBOA; Trauma; Inflation Zone; Acute Haemorrhage; Endovascular Intervention

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INTRODUCTION

Resuscitative endovascular occlusion of the aorta (REBOA) is a temporary management modality of non-compressible haemorrhage. It can be deployed at

both pre and intrahospital settings, to temporarily stabilise a patient's haemodynamic status for the purpose of achieving imaging and definitive interventions, and it forms part of the endovascular resuscitation and trauma management concept [1,2].

REBOA is mostly used in the adult trauma setting to decrease bleeding and to maximise cerebral and

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cardiopulmonary circulation [3,4], but is also described in post-cardiopulmonary resuscitation (CPR), obstetrics, and even in the paediatric population for instances of traumatic and non-traumatic haemorrhage [5,6].

Although the insertion of the REBOA catheter has been simplified, enabling pre-hospital or limited setting insertion via the use of anatomical landmarks alone without ultrasonographic or fluoroscopic assistance, standardised training is needed prior to adequate utilisation of this device. A discrepancy in usage is noted between high and low-to-middle income countries [7–9].

Aortic zones have been described for REBOA balloon deployment; Zone 1 being between the left subclavian artery and celiac trunk, Zone 2 between the celiac trunk and inferior-most renal artery, and Zone 3 between said renal vessel and aortic bifurcation. Varying morbidity and mortality rates have been reported for corresponding zones [10]. Examples of local complications include haemorrhage at insertion site, failed cannulation of artery, haematoma, and pseudo-aneurysm formation, while systemic complications are related to ischaemia–reperfusion concerns including acute kidney injury [11].

Zone 1 balloon placement can be expected to be associated with more pronounced ischaemia–reperfusion-related complications compared with Zone 3. Zone 2 placement is generally avoided for fear of acute ischaemia to the solid and hollow viscera supplied by the celiac trunk and superior mesenteric artery. Nonetheless, inadvertent Zone 2 placement does occur.

This study aimed to compare outcomes relating to balloon placement in the three zones.

METHODS

This is a retrospective study using data from the multi-national ABO Trauma Registry which captures the use of REBOA in selected centres. The ABO trauma registry was created to capture REBOA-specific data, prospectively and retrospectively, in patients in whom REBOA was used specifically in traumatic haemorrhagic shock. Data entered into the registry include: country of data collection, demographics (gender and age), anthropometric measurements (weight, height and body mass index (BMI)), pre-existing cardiovascular disease, mechanism of injury, type of injury sustained, presence of concomitant head injury, body temperature at injury site, lowest blood pressure on injury site, lowest blood pressure during transport, Glasgow coma scale on site, CPR on site, presence of pneumothorax or haemothorax, injury severity score (ISS), lowest blood pressure on arrival to trauma centre, temperature on arrival, heart rate, occurrence of arrhythmia or asystole, electrocardiographic changes on monitor, lowest saturation in the emergency room (ER), administration of supplemental oxygen, pupillary response, presence of dilated pupils, ongoing CPR

on arrival, intubation in the ER, patient arrived intubated, problems with intubation, and performance of cricothyroidotomy. All entries from January 2014 to December 2019 were considered. Entries with insufficient data for analysis were excluded. Ethics approval was obtained from the regional committee (study number 2014/210, Uppsala, Sweden). Centres that participate in data collection obtained ethics approval via local committees. The data captured are anonymised and receive a generated registry ID. All data are held on a secure electronic database and are password protected.

Ethical Approval and Informed Consent

Ethics approval was obtained from the regional committee (study number 2014/210; Uppsala, Sweden).

Statistical analysis

Microsoft Excel 365, IBM SPSS Statistics for Windows, versions 25.0 and R 4.1.1, were used for data analysis. Standard descriptive and inferential statistics were analysed and non-parametric tests in the form of Wilcoxon matched-pair tests and Mann–Whitney U tests were performed. Statistics with *P* values of less than 0.05 calculated by Kruskal–Wallis one-way analysis were deemed significant.

RESULTS

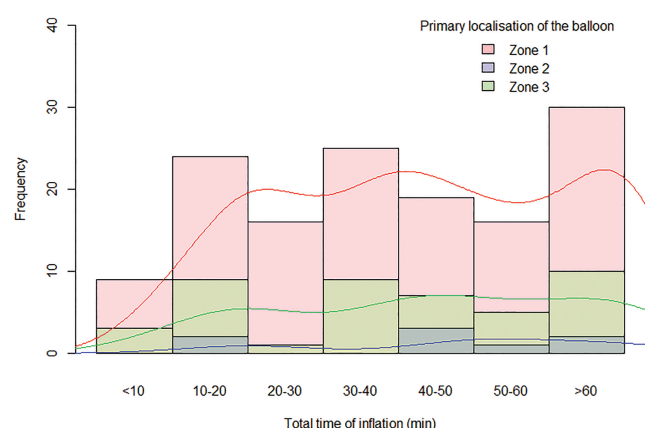
From a total of 253 patients, 16 were excluded (insufficient data regarding inflation zone), resulting in a study population of 237 patients. The median age was 35 years (standard deviation (SD) 20.3 years; range 4–96 years), with 63 (27%) women and 174 (73%) men. Comorbidities were identified in 64 (31%) patients. The primary location of the balloon was in Zone 1 of the aorta in the majority of patients 180 (76%), with nine (4%) in Zone 2 and 48 (20%) in Zone 3. The groups of patients in whom the balloon was inflated in Zones 1, 2, and 3 of the aorta were similar in genders (*P* = 0.70), age (*P* = 0.96), BMI (*P* = 0.11), and injury severity score (*P* = 0.90). Patients in whom the balloon was inflated in Zone 3 (16%) were significantly less likely to have comorbidities (*P* = 0.04) than those in whom the balloon was inflated in Zones 1 (35%) or 2 (38%). The mechanism of injury – that is, blunt, penetrating or mixed – varied significantly (*P* = 0.03) among locations of the balloon, see Table 1.

There were no significant differences between the haemoglobin, platelet levels, blood pH, international normalised ratio, activated partial thromboplastin time or lactate levels of patients in whom the balloon was inflated in Zones 1, 2, or 3. The total duration of balloon inflation did not differ significantly between locations of the balloon (*P* = 0.33), see Figure 1.

Table 1 Mechanism of injury and zone of REBOA placement.

	Zone 1	Zone 2	Zone 3	Total
Blunt	126 (72%)	5 (3%)	44 (25%)	175 (74%)
Penetrating	49 (89%)	3 (5%)	3 (5%)	55 (23%)
Combined	4 (80%)	0 (0%)	1 (20%)	5 (2%)
Unspecified	1 (50%)	1 (50%)	0 (0%)	2 (1%)

REBOA: Resuscitative endovascular occlusion of the aorta.

**Figure 1** Total time of inflation in each zone.

The mean \pm SD systolic blood pressure (SBP) recorded just prior to REBOA insertion was significantly lower in patients with Zone 1 balloon placement compared with those with Zones 2 and 3 placement ($P = 0.05$), whereas just after REBOA insertion this was significantly higher in Zones 1 and 2 patients compared with Zone 3 ($P < 0.01$), see Figure 2.

While few patients remained haemodynamically unchanged post-REBOA insertion, more patients in the Zones 2 and 3 groups gained complete haemodynamic stability than those in the Zone 1 group ($P < 0.01$), see Figure 3.

Aside from aorta/iliac artery perforation and haematoma over the access site, complications were not found to be different between the three groups (Table 2).

Death in the emergency department (ED) was significantly higher for Zones 1 and 2 patients, with post-hoc power analysis ($\alpha = 0.05$) showing adequate power (>0.8) for detecting significant differences between mortality rates in Zones 1 and 3 in the ED. The difference in mortality rates at 24 hours and at 30 days did not reach statistical significance between groups, see Tables 3 and 4.

DISCUSSION

The mechanism of injury is one of the main determinants with regard to the zonal approach. In our study, the locations of REBOA balloon placement varied significantly, with Zone 1 most used for penetrating trauma and Zone 3 most used for blunt trauma; this observation

is in keeping with other literature. Thrailkill and coworkers made a similar observation in their study, in which penetrating trauma favoured Zone 1 placement [12]. The authors also reported that Zone 1 placement with penetrating trauma is well justified as it efficiently and rapidly increases central and carotid flow.

In keeping with findings from the present study, a report by Beyer et al. [13] using data from the AORTA Registry demonstrated that Zone 1 REBOA balloon placement achieved significantly higher SBP as compared with Zone 3 (58 ± 4 mmHg vs. 41 ± 4 mmHg, $P = 0.008$).

Although some patients in this study remained haemodynamically unchanged post-REBOA insertion, a majority of Zone 2 patients (88%) and almost half of Zone 3 patients (47%) gained complete haemodynamic stability, in comparison to 27% for Zone 1 patients. One may postulate that the degree of shock was more severe in patients with penetrating injury and Zone 1 REBOA, with low SBP prior to insertion and thus a more profound response post-inflation. Indeed, although the ISS did not differ significantly between groups, Zone 3 patients (84%) were significantly more stable from a haemodynamic perspective than patients from Zone 1 (65%) or Zone 2 (63%).

In this patient population, the rates of complications in the form of vessel perforation and haematoma formation over the access site differed significantly among the three groups. Due to the fact that very few patients developed these complications, it is difficult to assess the accuracy of these associations. According to our research, the rates of all other complications did not differ significantly between patients independent of the zone of occlusion, further supported by Matsumoto et al., who noted that survival and complications were not related to a non-target Zone 2 placement [14]. It was conceded however, that Zone 2 placements must have negative effects on outcomes on the basis of predisposing Zone 2 placements to gastrointestinal ischaemia. An animal study performed by Tibbitts et al. showed that the placement zones differed in terms of fluid requirements and metabolic complications [15]. Despite this, additional research is still needed to analyse the negative effects of Zone 2 REBOA placement.

Qasim and colleagues reported that Zone 3 is arguably the least complicated of the three zones, and that consensus opinions indicate that Zone 3 generally allows for longer inflation times [16,17]. In the current

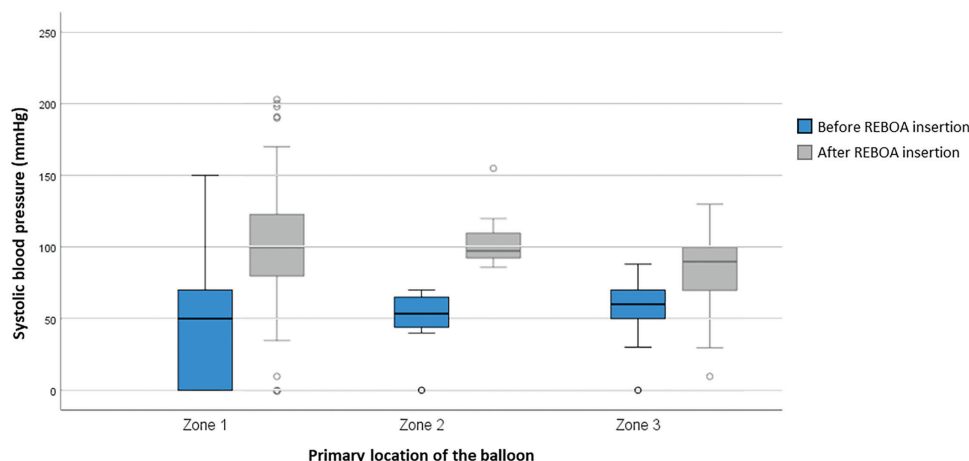


Figure 2 Systolic blood pressure before and after resuscitative endovascular occlusion of the aorta (REBOA) insertion.

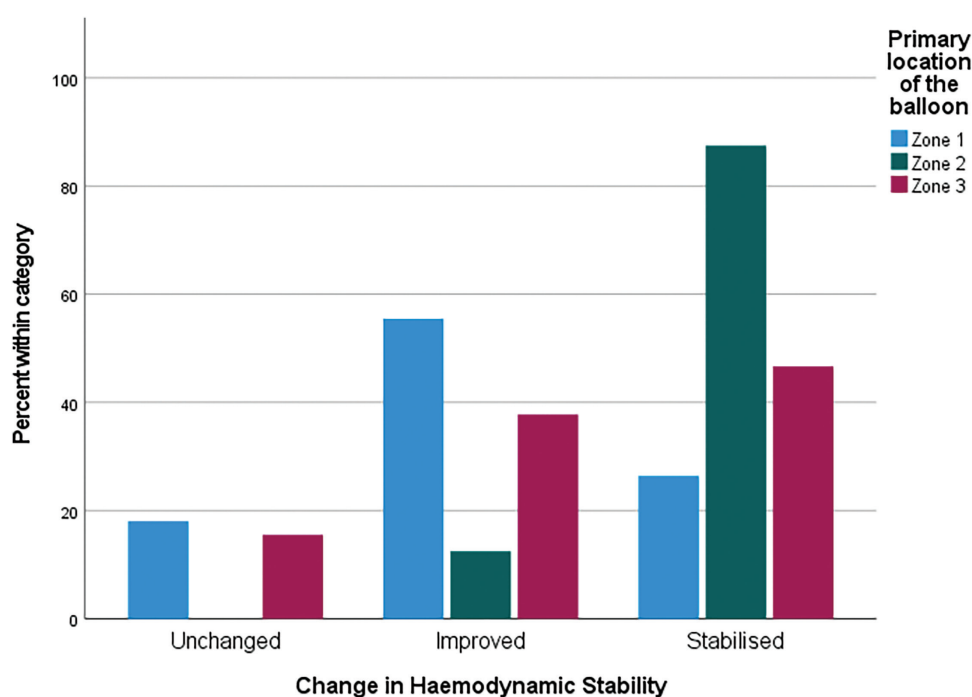


Figure 3 Primary location of balloon inflation and change in haemodynamics.

study, the complication rate did not differ significantly between inflation zones while the total duration of balloon inflation did not differ significantly between balloon locations, with the median duration of inflation being 30–40 minutes, and the modal duration of inflation being greater than 60 minutes in both Zone 1 and Zone 3 locations.

The mortality rates in the ED of patients in which the balloon was inflated in Zones 1 and 2 of the aorta were significantly higher than that of patients in whom the balloon was inflated in Zone 3. This observation correlates with our previous postulation that a greater degree of shock was present during insertion; however,

the 24-hour and 30-day mortality rates did not differ significantly. Perkins and colleagues reported a similar survival rate to our patient population with the Zone 1 survival rate at 39.4% and the Zone 3 survival rate at 54% [12,18].

In Japan, guidelines published by Sato et al. depicted that Zone 1 REBOA should be employed irrespective of injury location. In a case series conducted on 24 patients in which REBOA was placed in four Japanese emergency departments that did not have immediate access to a trauma surgeon, the median balloon inflation time was 65 minutes in Zone 1, with a 50% mortality rate at 24 hours [19,20]. The median time of inflation is higher than with

Table 2 Complication rates according to inflation zones.

	Zone 1	Zone 2	Zone 3	P value
Pulmonary failure	28 (16%)	2 (22%)	10 (21%)	0.85
Sepsis/SIRS	15 (8%)	3 (33%)	9 (19%)	0.08
Acute kidney injury	16 (9%)	1 (11%)	7 (15%)	0.99
Extremity ischaemia	9 (5%)	1 (11%)	6 (13%)	0.11
Embolisation/thrombus formation	7 (4%)	1 (11%)	6 (13%)	0.12
Compartment syndrome	6 (3%)	0 (0%)	5 (10%)	0.28
Balloon migration	6 (3%)	0 (0%)	1 (2%)	0.78
Balloon rupture	4 (2%)	0 (0%)	1 (2%)	0.93
Aorta/iliac perforation	1 (1%)	1 (11%)	2 (4%)	0.03
Haematoma over access site	1 (1%)	1 (11%)	0 (0%)	<0.01
Intima injury	2 (1%)	0 (0%)	0 (0%)	0.68
Major bleeding from access site	2 (1%)	0 (0%)	0 (0%)	0.68

SIRS: Systemic inflammatory response syndrome.

Table 3 Mortality rates by zone of inflation and time of death.

	Zone 1	Zone 2	Zone 3	P value
Death in ED	31 (18%)	1 (14%)	1 (2%)	0.04
Death within 24 hours	74/172 (43%)	1/6 (17%)	11/43 (26%)	0.06
Death within 30 days	103/174 (59%)	2/7 (29%)	19/44 (43%)	0.06

ED: Emergency department.

Table 4 Post-hoc power for detecting significant differences in mortality rates.

	Zone 1 vs. Zone 2	Zone 1 vs. Zone 3	Zone 2 vs. Zone 3
Death in ED	0.03	0.83	0.38
Death within 24 hours	0.19	0.56	0.05
Death within 30 days	0.35	0.48	0.09

ED: Emergency department.

the present study but the mortality rate within the first 24 hours in this study is very similar at 43%. In comparison, the 24-hour mortality rate in the present patient population was 17% for Zone 2 and 26% for Zone 3.

Several limitations exist for this study. The ABO Trauma Registry is an international registry and the indications, use of and efficacy of REBOA are diverse and differ from facility to facility. This database also does not take into account the failed attempts at REBOA deployment. Due to the limited control of data entries and participation criteria there might be selection bias. Finally, there were missing data variables in the registry that caused the exclusion of 16 patients to this study.

CONCLUSIONS

REBOA is currently being used in the emergency setting for temporary stabilisation of the haemorrhagic patient. In the studied cohort REBOA was used in all zones of the aorta with no significant difference in total duration and complication rates between the three zones.

Non-targeted Zone 2 placement did not increase complication rates, with ischaemic time kept to a median of 30–40 minutes in this cohort. It should, however, be emphasised that 76% (180 patients) of the sample was represented by those undergoing REBOA with Zone 1 inflation, 20% (48 patients) Zone 3 and only 4% (nine patients) in Zone 2. In light of the small number of patients in the Zone 2 group, the results may not be an accurate reflection of the true incidence of Zone 2 inflation time and complication rates and should therefore be interpreted with reserve.

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

The authors declare a conflict of interest as Tal Martin Hörer, the editor in chief of the *Journal of Endovascular Resuscitation and Trauma Management*, is one of the researchers. The remaining authors declare that they have no conflicts of interest.

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Author Contributions

JB was the principal investigator. SV, AD, PS, PR, and NA were responsible for data preparation, data analysis, and manuscript preparation. BK and DTM were responsible for data collection, data preparation, and manuscript revision. TMH was responsible for data collection and manuscript revision. GO was responsible for critical revision and overall supervision.

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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

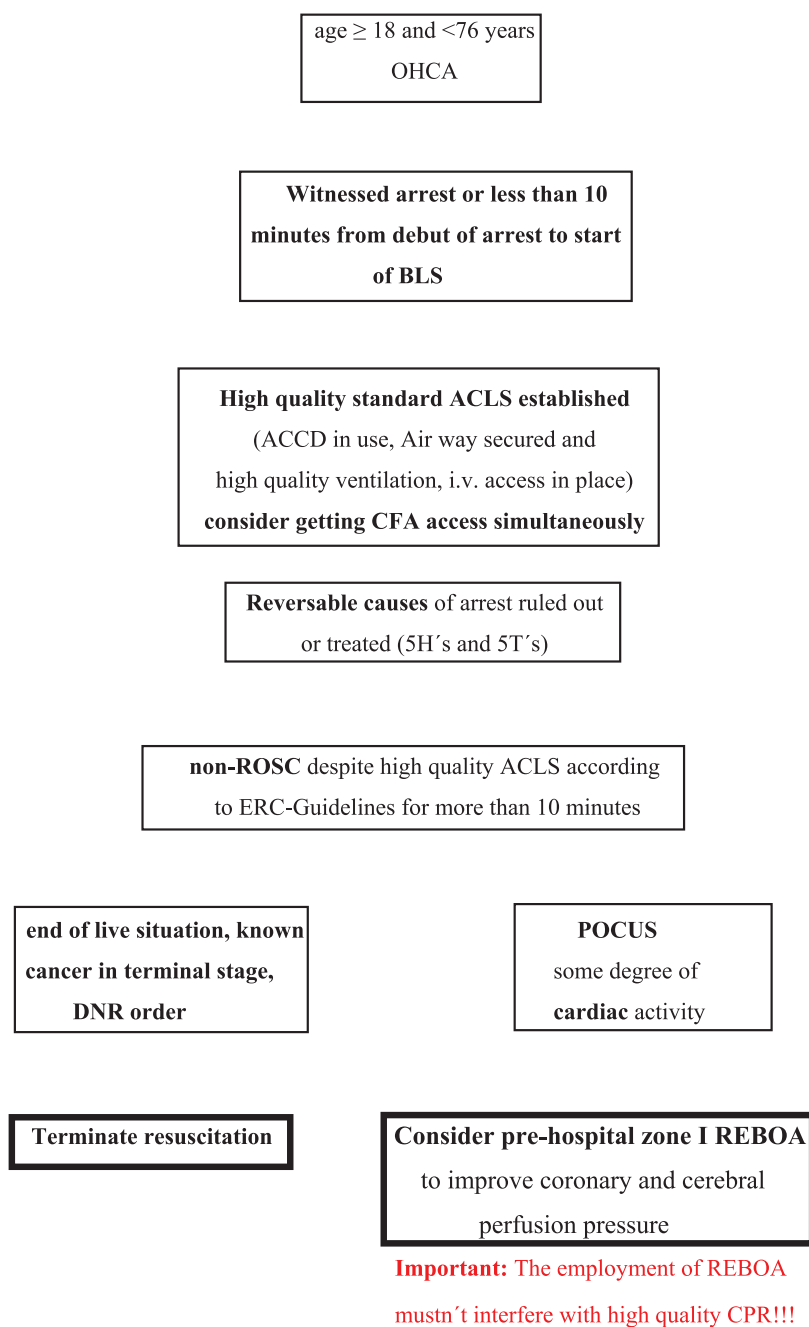


Figure 5 Decision tree to identify potential resuscitative endovascular balloon occlusion of the aorta (REBOA) patients with out-of-hospital cardiac arrest (OHCA).

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

Table 2 NCTH-specific data.

Trauma mechanism	<input type="checkbox"/> MVC <input type="checkbox"/> Fall >3 m <input type="checkbox"/> Blunt <input type="checkbox"/> Penetrating
Non-traumatic bleeding	<input type="checkbox"/> GIB <input type="checkbox"/> PPH <input type="checkbox"/> Vascular
Assumed side of bleeding	<input type="checkbox"/> Abdomen <input type="checkbox"/> Pelvic <input type="checkbox"/> Multiple
Treatment ahead of REBOA?	<input type="checkbox"/> Pelvic binder <input type="checkbox"/> TXA <input type="checkbox"/> Tourniquet <input type="checkbox"/> TI
Treatment after REBOA?	<input type="checkbox"/> Pelvic binder <input type="checkbox"/> TXA <input type="checkbox"/> Tourniquet <input type="checkbox"/> TI
Volume resuscitation (ml)	
Before REBOA	<input type="checkbox"/> <500 <input type="checkbox"/> 500–1000 <input type="checkbox"/> 1000–1500 <input type="checkbox"/> >1500
After REBOA	<input type="checkbox"/> <500 <input type="checkbox"/> 500–1000 <input type="checkbox"/> 1000–1500 <input type="checkbox"/> >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.	<input type="checkbox"/> Zone I ...cm
	<input type="checkbox"/> Zone II ...cm
	<input type="checkbox"/> Zone III ...cm
Time from balloon occlusion to ER handover	... minutes

Table 3 OHCA-specific data.

CorPuls CPR (ACCD) used?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Heart rhythm	<input type="checkbox"/> Asystole <input type="checkbox"/> PEA <input type="checkbox"/> Ventricular fibrillation <input type="checkbox"/> Agonal
Prior to REBOA	<input type="checkbox"/> Asystole <input type="checkbox"/> PEA <input type="checkbox"/> Ventricular fibrillation <input type="checkbox"/> Agonal <input type="checkbox"/> SR
After REBOA	<input type="checkbox"/> Asystole <input type="checkbox"/> PEA <input type="checkbox"/> Ventricular fibrillation <input type="checkbox"/> Agonal <input type="checkbox"/> SR
On hospital handover	
ROSC on scene	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Temporary
Hospital handover	<input type="checkbox"/> ROSC <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes – duration of REBOA?	<input type="checkbox"/> <10 <input type="checkbox"/> 10–20 <input type="checkbox"/> 20–30 <input type="checkbox"/> >30 minutes
If yes – patient condition?	<input type="checkbox"/> Stable <input type="checkbox"/> Unstable <input type="checkbox"/> New occlusion required
Aortic occlusion zone and insertion depth ... cm.	<input type="checkbox"/> Zone I ...cm <input type="checkbox"/> Zone II ...cm <input type="checkbox"/> Zone III ...cm
Time from balloon occlusion to handover	... minutes
Total REBOA inflation time	

Table 4 Pre and post-course questionnaire.

Question/Statement	Rating		Median rating pre and post-course	
	1 = maximum agreement with the statement	6 = no agreement with the statement		
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 (etCO₂) curve and reading;

- peripheral oxygen saturation (SpO₂) 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 German 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	PEA	Pulseless electrical activity
HR	Heart rate	PHTLS	Pre-Hospital Trauma Life Support
MTC	major trauma center	POCUS	Point of care ultrasound
MVC	Motor vehicle crash	PPH	post-partum hemorrhage
NCTH	Non-compressible torso hemorrhage	REBOA	Resuscitative endovascular balloon occlusion of the aorta
NACA	National Advisory Committee for Aeronautics	ROSC	Return of spontaneous circulation
OHCA	Out-of-hospital cardiac arrest	SR	Sinus rhythm
		TI	Tracheal intubation
		TXA	Tranexamic acid

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) After Traumatic Brain Injury

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Background: The effects of resuscitative endovascular balloon occlusion of the aorta (REBOA) on progression of traumatic brain injury (TBI) are unclear. Two hypotheses prevail: increased mean arterial pressure may improve cerebral perfusion, or cause cerebral edema due to elevated intracranial pressure. This study compares outcomes in hypotensive, blunt trauma patients with TBI treated with and without REBOA.

Methods: A retrospective analysis compared hypotensive (systolic blood pressure [SBP] <90) blunt trauma patients with TBI treated with REBOA to those treated without. Patients with spontaneous circulation at admission and at initiation of aortic occlusion were included. Patients requiring cardiopulmonary resuscitation in the emergency department (ED) were excluded. Radius matching used age, injury severity score (ISS), abbreviated injury score (AIS)-head, and Glasgow coma score (GCS) and SBP at ED arrival.

Results: Of 232 patients, 135 were treated with REBOA and 97 without. REBOA patients were older and had higher ISS, AIS-head, AIS-chest and AIS-extremity. There was no difference in TBI severity, and mortality. In the matched analysis ($n = 76$ REBOA, $n = 54$ non-REBOA), there was no difference in ISS, AIS-head, pre-hospital, ED, or discharge GCS, ED SBP, or mortality. Despite longer hospital stays for REBOA patients, there was no difference in intensive care unit length of stay, rate of discharge home, or discharge GCS.

Conclusions: REBOA was used in more severely injured patients, but was not associated with higher mortality rate. REBOA should be considered for use in patients with non-compressible torso hemorrhage and concomitant TBI, as it did not increase mortality, and outcomes were similar to non-REBOA patients.

Keywords: Traumatic Brain Injury; REBOA; Non-Compressible Torso Hemorrhage, Trauma Surgery

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) can be a valuable tool to minimize blood loss in the acute setting of non-compressible torso hemorrhage (NCTH) before definitive control can be achieved. The effect of REBOA on the progression of traumatic brain injury (TBI) in the setting of NCTH is still unclear. Animal models have shown conflicting

results; with one showing REBOA use leading to exacerbation of shock and TBI [1], another found REBOA increased carotid flow with no detrimental impact on the injured brain [2], and another reported mixed results for short and long-term outcomes [3]. Human data on the subject are lacking. In one study using human data, Elkbuli et al. compared outcomes of REBOA-treated patients who had concurrent TBI to those without TBI and found no difference in mortality rate between groups [4]. Norii et al. found that in Japan (which notably differs from the United States in terms of trauma volume and type, pre-hospital care, and wide acceptance

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of REBOA use in Japan), blunt trauma patients with TBI treated with REBOA had a higher mortality rate compared to those treated without it [5].

Two hypotheses largely prevail regarding the impact of REBOA in the setting of TBI: the increased mean arterial pressure caused by REBOA improves cerebral perfusion, crucial for the injured brain, or conversely, causes cerebral edema due to elevated blood pressure and intracranial pressure (ICP). Increased ICP has been associated with detrimental outcomes, including increased mortality rate [6]. In a swine model of TBI and hemorrhagic shock, rapid blood resuscitation, not REBOA, resulted in large ICP increases [2]. While hypertension has detrimental effects on TBI, hypotension is also associated with poor outcomes, including increased mortality [7].

Maintaining normotension in TBI patients is critical. Animal models of TBI with hemorrhagic hypotension have demonstrated neuronal death [8] and enlarged contusion area due to hypotension [9]. Analysis of human data from the Traumatic Coma Databank found hypotension and hypoxemia in the setting of TBI to be associated with increased morbidity and mortality [10, 11]. Even single episodes of hypotension early in TBI management have been associated with increased mortality. In the pre-hospital setting, the Excellence in Pre-hospital Injury Care (EPIC) study increased survival to hospital discharge in TBI patients after implementing guidelines for TBI management focusing on prevention and treatment of hypotension and hypoxia before arrival at a hospital [12].

Here, we focused on REBOA, an in-hospital method to address hypotension (defined as systolic blood pressure (SBP) < 90 mmHg) in the acute setting until definitive control can be obtained. The current study investigated outcomes of hypotensive patients who suffered both blunt trauma and a TBI and were treated with REBOA to those treated without, using data from multiple trauma centers in the United States. The primary outcome of interest was survival to hospital discharge, and secondary outcomes included non-mortality, functional outcomes: hospital and intensive care unit (ICU) length of stay (LOS), ventilator days, discharge Glasgow coma score (GCS), and discharge location. Based on prior studies which reported association between hypotension and poor outcomes in TBI patients, we hypothesized that REBOA use would be associated with improved outcomes for hypotensive blunt trauma and TBI patients compared to patients treated without REBOA.

METHODS

Study Design and Subjects

Patients included were hypotensive (SBP <90 mmHg) adults (≥ 18 years old) with spontaneous circulation

who suffered blunt trauma and a computed tomography-verified TBI with an abbreviated injury score (AIS)-head of 2 or greater between 1 January 2016 and 31 December 2021. Patients treated with REBOA were selected from the Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry [13]. Non-REBOA patients were selected from the institutional trauma registry of University Medical Center New Orleans, a large, urban level I trauma center. REBOA patients all had SBP of less than 90 mmHg and greater than 0 mmHg at the initiation of aortic occlusion. Patients who were pregnant, minors, prisoners, and/or required cardiopulmonary resuscitation (CPR) in the emergency department (ED) were excluded. A population-based registry study by Fröhlich et al. found the mortality rate for patients with TBI and shock index (SI) of 1–1.4 (average prehospital SI = 0.1 in non-REBOA patients in this study) to be 36.6% [14], and Elbuki et al. found a mortality rate of 62.4% for hypotensive trauma patients with TBI treated with REBOA [4]. Using these mortality rates, power analysis found that for a power of 0.8 and an alpha of 0.05, the sample size required in each group would be 58 for a total population of 116.

Study Variables

Data collected included patient demographics, mechanism of injury, pre-hospital vital signs and interventions, transfer from an outside hospital, ED vital signs and injury severity measured by the GCS, injury severity score (ISS), and AIS. Data points used to analyze outcomes included mortality, mortality day and location, hospital and ICU LOS, ventilator (vent) days, discharge location, and discharge GCS. Information on transfusion requirements including blood products and crystalloids for the entire hospital stay was collected.

Statistical Analysis and Methods

Univariate analysis was performed using either chi-squared and Mann–Whitney U tests for categorical or continuous variables, respectively. A subset analysis of matched REBOA versus non-REBOA groups was performed. To account for differences in injury severity between groups, propensity score matching with common support and radius matching with a caliper of 0.1 was used to match groups based on clinical factors that may be considered when deciding to place a REBOA in the acute setting: age, injury severity measured here by IS and AIS-head, ED GCS, and ED SBP. In the propensity score-matched cohorts, McNemar's test was utilized to assess categorical variables, while paired Wilcoxon signed-rank tests were used for continuous variables. A *P* value less than 0.05 was considered statistically significant. Matching and statistical analysis was performed using Stata version 14.

Ethical Approval and Informed Consent

Ethical approval to report these cases was given by our institutional review board and hospital research review committee. Written informed consent was not required as a waiver of consent was obtained for this study.

RESULTS

Analysis included 232 hypotensive, blunt trauma patients with TBI, 135 treated with REBOA and 97 treated without. Demographics, injury, pre-hospital and ED characteristics are found in Table 1. The REBOA group was significantly older compared to the non-REBOA group ($P = 0.02$). There was no difference in sex between groups with the majority of patients being male in both groups. Mechanism of injury (motor vehicle crash (MVC), motorcycle crash (MCC), auto vs. pedestrian, and fall) differed significantly between groups. Despite REBOA patients being more severely injured with higher ISS, AIS-head, AIS-chest, and AIS-

extremity, there was no difference in TBI severity between groups.

Mortality did not differ between groups in the unmatched analysis (Table 2). There was also no significant difference in mortality day between groups, although location of death (ED, operating room (OR), interventional radiology (IR), ICU, or ward) was significantly different. The rate of craniectomy/craniotomy did not differ between groups. While REBOA patients had longer hospital LOS ($P = 0.05$), there was no difference in ICU LOS or vent days. The rates of discharge to home, to a rehab/nursing facility or other location (e.g. law enforcement or transfer) were significantly different between groups. The majority of both REBOA (87.0%) and non-REBOA (63.0%) patients were discharged to a rehab/nursing facility; however, a higher percentage of REBOA patients were discharged to these facilities. While discharge GCS differed significantly between groups (15 (15–15) for non-REBOA and 15 (11–15) for REBOA, $P = 0.04$), the median was 15 for both groups, and there was no difference in the proportions of patients with mild, moderate, and severe TBI noted by GCS at discharge.

Table 1 Cohort demographic, injury, pre-hospital and emergency department characteristics.

	Non-REBOA (n = 97)	REBOA (n = 135)	P Value
Age, years (median (IQR))	43 (24–58)	48 (31–61)	0.02
Male	73 (69.1%)	79 (74.5%)	0.34
Mechanism of injury			
MVC	26 (26.8%)	47 (34.8%)	<0.001
MCC	34 (35.1%)	54 (40.0%)	
Auto vs. pedestrian	12 (12.4%)	25 (18.5%)	
Fall	25 (25.8%)	9 (6.7%)	
Transfer from outside hospital	21 (21.6%)	19 (14.1%)	<0.001
Pre-hospital CPR	14 (14.4%)	6 (4.4%)	0.01
Pre-hospital intubation	33 (34.0%)	37 (27.0%)	0.48
Pre-hospital SBP	98 (78–118)	96 (79–121)	0.42
Pre-hospital HR	90 (79–117)	110 (88–130)	0.002
Pre-hospital GCS	3 (3–10)	3 (3–11)	0.54
ED SBP	75 (52–81)	80 (65–90)	<0.001
ED HR	96 (66–122)	115 (89–131)	<0.001
ED GCS	3 (3–15)	3 (3–9)	0.56
ED TBI severity			
Severe (GCS 3–8)	66 (70.1%)	98 (72.6%)	0.195
Moderate (GCS 9–12)	3 (3.2%)	11 (8.1%)	
Mild (GCS 13–15)	24 (25.8%)	26 (19.3%)	
ISS	27 (19–34)	43 (34–50)	<0.001
AIS-head	3 (2–3)	4 (3–5)	<0.001
AIS-chest	3 (2–3)	3 (3–4)	<0.001
AIS-abdomen	3 (2–4)	3 (2–4)	0.18
AIS-extremity	2 (2–3)	3 (2–4)	0.02

Values are reported as n (%) unless otherwise stated. Continuous variables are presented as median (interquartile range; IQR).

REBOA: resuscitative endovascular balloon occlusion of the aorta; MVC: motor vehicle crash; MCC: motorcycle crash; CPR: cardiopulmonary resuscitation; SBP: systolic blood pressure; HR: heart rate; GCS: Glasgow coma score; ED: emergency department; TBI: traumatic brain injury; OR: operating room; IR: interventional radiology; LOS: length of stay; ISS: injury severity score; AIS: abbreviated injury score.

Table 2 Cohort outcomes.

	Non-REBOA (n = 97)	REBOA (n = 135)	P Value
Mortality	51 (52.6%)	81 (60.0%)	0.26
Mortality day (median (IQR))	1 (1–3)	1 (1–4)	0.43
Mortality location			
ED	17 (33.3%)	8 (9.9%)	0.002
OR	1 (2.0%)	15 (18.5%)	
IR	0 (0%)	1 (1.2%)	
ICU	33 (64.7%)	56 (69.1%)	
Ward	0 (0%)	1 (1.2%)	
Craniectomy/ craniotomy	0 (0%)	2 (1.5%)	0.09
Hospital LOS (median (IQR))	3 (1–19)	6 (1–31)	0.05
ICU LOS (median (IQR))	4 (2–11)	5 (1–16)	0.80
Vent days (median (IQR))	4 (2–10)	4 (1–14)	0.40
Discharge location			
Home	13 (28.3%)	7 (13.0%)	<0.01
Rehab/nursing facility	29 (63.0%)	47 (87.0%)	
Other (law enforce- ment, transfer)	4 (8.7%)	0 (0%)	
Discharge GCS	15 (15–15)	15 (11–15)	0.04
Discharge TBI severity			
Severe (GCS 3–8)	0	0	0.38
Moderate (GCS 9–12)	6 (17.8%)	9 (23.7%)	
Mild (GCS 13–15)	32 (84.2%)	29 (76.3%)	

Values are reported as n (%) unless otherwise stated. Continuous variables are presented as median (interquartile range; IQR).

ED: emergency department; OR: operating room; IR: interventional radiology; ICU: intensive care unit; LOS: length of stay; GCS: Glasgow coma score; TBI: traumatic brain injury; CPR: cardiopulmonary resuscitation; HR: heart rate.

Pre-hospital

The rate of transfer from outside hospital was significantly higher in non-REBOA patients ($P < 0.001$) and non-REBOA patients received pre-hospital CPR at a significantly higher rate than REBOA patients ($P = 0.01$) (Table 1). However, there was no difference in the rate of pre-hospital intubation between groups. Pre-hospital heart rate (HR) was significantly higher in REBOA patients ($P = 0.002$), but there were no differences in pre-hospital SBP or GCS between groups.

Emergency Department

Examination of initial vital signs on ED arrival showed SBP and HR to be significantly higher in REBOA patients ($P < 0.001$ for both) compared to non-REBOA patients (Table 1). There was no significant difference in average GCS or in rate of severe, moderate, or mild TBI between groups in the ED.

Transfusion

During the entire hospital course, REBOA patients received significantly more units of packed red blood cells ($P < 0.001$), fresh frozen plasma ($P < 0.001$) and platelets ($P < 0.01$) compared to non-REBOA patients (Table 3). There was no significant difference between groups in the volume of cryoprecipitate or crystalloids transfused during resuscitation.

REBOA Group

Of the 135 patients treated with REBOA, the majority (77.8%) had REBOA placed in the ED, with fewer (17.0%) in the OR. Ultrasound guidance was used in approximately half (54.1%) of the cases, with percutaneous landmarks used in the rest. Most REBOAs were placed in Zone I between the left subclavian artery and celiac trunk, or the infrarenal Zone III. The vast majority of REBOAs (96.3%) achieved successful aortic occlusion, with improved hemodynamics in 86.7% of patients, and hemodynamic stability in 73.3% of the group. Nine (6.7%) cases were converted to open aortic occlusion. The average SBP was not hypotensive immediately after REBOA placement (median interquartile range (IQR) 108 (95–120) mmHg). On average, when REBOA was used, hemodynamic stability was achieved in 69 minutes from arrival at the ED. Definitive hemorrhage control was achieved, on average, within two hours of arrival, and an average time between successful aortic occlusion and definitive hemorrhage control was 74 minutes. Overall, duration of initial aortic occlusion was 50 minutes on average, with REBOAs in Zone I up for an average of 50 minutes, and those in Zone III up for 48 minutes. Twelve patients required a second aortic occlusion after the initial REBOA placement.

Radius Matching Analysis

As REBOA and non-REBOA patients differed in injury severity and blood pressure in the ED, the groups were

Table 3 Transfusion information (entire hospital course).

	Non-REBOA (n = 97)	REBOA (n = 135)	P Value
PRBCs (units)	3 (2–7)	14 (7–29)	<0.001
FFP (units)	2 (2–6)	10 (4–24)	<0.001
Platelets (packs)	1 (1–2)	3 (1–11)	<0.01
Cryoprecipitate (packs)	2 (0–3)	0 (0–1)	0.09
Crystalloids (1000 cc units)	5 (3–8)	4 (2–8)	0.09

Values are reported as median (interquartile range; IQR).

PRBCs: packed red blood cells; FFP: fresh frozen plasma.

Table 4 Radius matched analysis results.

	Non-REBOA (n = 76)	REBOA (n = 54)	% Bias	P Value
Age, years	45.3	44.4	−4.1%	0.83
ED SBP	72.7	74	10.6%	0.57
ED GCS	6.5	6.5	1.6%	0.93
ISS	32.8	34.1	10.7%	0.48
AIS-head	3.1	3.1	−2.2%	0.9
Pre-hospital GCS	6.5	6.8	6.2%	0.76
Discharge GCS	13.7	13.4	−10.70%	0.72
ICU LOS	10.3	11.3	8.2%	0.69
Hospital LOS (days)	13.6	20.1	34.4%	0.08

Values are reported as mean.

ISS: injury severity score; AIS: abbreviated injury score; GCS: Glasgow coma score; ED: emergency department; SBP: systolic blood pressure; ICU: intensive care unit; LOS: length of stay.

matched by age, ED SBP, ED CGS, ISS, and AIS-head. After radius matching, 54 REBOA patients and 76 non-REBOA patients remained for analysis. In comparing these groups, there was no significant difference in mortality (average treatment effect of the treated (ATT) = −0.028, standard error = 0.102). After matching, there was no significant difference in pre-hospital, ED, ED SBP, ICU LOS, hospital LOS, or in-hospital mortality rate between REBOA and non-REBOA groups (Table 4).

CONCLUSIONS

For patients who suffer non-compressible torso hemorrhage, occlusion of the aorta with REBOA can be a valuable tool to minimize blood loss in the acute setting before definitive hemorrhage control can be obtained. Investigation is ongoing to identify the optimal patient selection criteria for REBOA, as no universal guidelines exist. In a comparison of REBOA and resuscitative thoracotomy for NCTH patients with TBI, REBOA-treated patients were found to have improved survival and no difference in complications [15]. This supports the idea that REBOA should be considered for use in this patient population. Here, we investigated the effects of REBOA in hypotensive blunt trauma patients with concurrent TBI to compare mortality and functional outcomes in these patients treated with REBOA to those treated without.

In the unmatched groups, REBOA patients were more severely injured compared to non-REBOA patients, as noted by higher ISS, AIS-head and AIS-chest. Despite being more severely injured, there was no difference in mortality, ICU LOS, or vent days between groups. REBOA patients did have longer hospital LOS compared to non-REBOA patients, but the similar length of ICU stay indicates that REBOA patients were

stable to step down to the floor and did not require longer-term high acuity care compared to non-REBOA patients.

In the matched analysis results, there was no difference between REBOA and non-REBOA groups in terms of mortality, prehospital or discharge GCS, ICU LOS, or total hospital LOS.

Mortality was the primary outcome of interest for this study. When comparing patients treated with REBOA and without in both the unmatched and matched analysis, there was no significant difference in mortality, which suggests that the use of REBOA does not increase mortality of blunt trauma patients with concurrent TBI. Therefore, concurrent head trauma should not delay the deployment of REBOA in a hypotensive blunt trauma patient.

REBOA patients required significantly higher volumes of blood products transfused compared to non-REBOA patients. Interestingly, REBOA patients had both a higher ED HR, and a higher average ED SBP when compared to non-REBOA patients. The higher transfusion requirements in the REBOA group may reflect the procedure allowing time for additional stabilization or interventional radiology procedures before definitive control. Time to hemorrhage control was not available for analysis in the non-REBOA group. Notably, prior research has shown blood resuscitation, and not REBOA, to exacerbate TBI progression, with rapid blood transfusion increasing ICP more than REBOA [2].

As REBOA patients were more severely injured than non-REBOA patients, the radius matching analysis allows for a better understanding of the effect of REBOA in TBI patients, having accounted for other relevant clinical factors. While REBOA patients had longer hospital LOS compared to non-REBOA patients, discharge GCS, and discharge destination were not significantly different between the groups. These results suggest that REBOA use does not have a negative impact on functional outcomes in patients with head trauma.

Blunt trauma NCTH patients are often hypotensive by the time they arrive at the hospital and are in acute need of hemorrhage control. Pre-hospital TBI management protocols aimed at prevention and treatment of hypotension, hypoxia, and hyperventilation before arrival at definitive care have improved patient outcomes. The EPIC study showed increased survival to hospital discharge after implementing this protocol specific for TBIs [12]. Increased blood pressure up to 125 mmHg was associated with improved outcomes, including increased survival in TBI patients [16]. Notably, this threshold is higher than the commonly used 90 mmHg definition for hypotension. This emphasizes the importance of maintaining blood pressure and cerebral perfusion in TBI patients. Like these pre-hospital efforts to maintain blood pressure, REBOA is a tool to increase early cerebral perfusion until definitive control is achieved.

The size of the study population was a limitation of the study, and further subgroup statistical analysis based on AIS-head scores was prohibited by the number of patients. To identify any nuances in REBOA use in patients with mild, moderate, and severe TBI, future investigation with a larger patient population is needed. Detailed analysis of functional outcomes was limited by the data points collected in the AORTA registry and our institutional trauma registry. Glasgow outcome score (GOS) was not available. GOS would be an indicator of functional status after TBI, which was measured in this study by using discharge GCS and discharge location as proxies. ICP would have been valuable to this study to understand the effects of REBOA on ICP in the patient group, but was also not available. Not every subject included in this study had every data point present, and while we used all data points available to us, missing data present a limitation. Additionally, as we compared data from two separate databases, there is the chance for differences in the methods of data collection and recording between a multi-center database and a single institution trauma registry.

In conclusion, our findings show that functional outcomes are not detrimentally impacted by the use of REBOA to treat hypotensive blunt trauma in patients with concurrent TBI. Despite REBOA patients being more severely injured, this study found no difference in mortality rate between REBOA and non-REBOA patients. In the radius matched group analysis, the similar rates at which patients were discharged to home indicate that patients have a comparable functional status at the time of discharge, regardless of REBOA use. REBOA therefore should be considered for use in hypotensive NCTH patients with TBI.

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Reduction of Distal Ischemia with pREBOA-PRO in a Trauma Laparotomy Requiring Extended Occlusion Time

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Keywords: *pREBOA; Blunt Trauma; Hemorrhagic Shock; Endovascular Balloon Occlusion of Aorta; Ischemia-Reperfusion Injury*

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INTRODUCTION

The partial Resuscitative Endovascular Balloon Occlusion of Aorta (pREBOA)-PRO system is utilized to temporize non-compressible truncal hemorrhage in the setting of trauma. Since the first reported instance of the use of aortic balloon occlusion in the 1950s in a battlefield setting, much progress has been made in development of this minimally invasive portable technology with the goal of reducing loss of life due to hemorrhage [1]. In practice, immense variation exists in the range of specific locations and occlusion times of the pREBOA-PRO system. Current guidelines suggest that a Zone 1 occlusion time greater than 30 minutes is considered extended and carries a higher risk of both distal ischemia and catastrophic reperfusion injury. This particular limitation of the REBOA has been the subject of discussion in the field of endovascular trauma, with the aim of ultimately broadening the utilization of pREBOA [2]. Studies have looked at associations between occlusion time and increased lactate as well as the sequelae of occlusions at Zones 1–3 [3].

The objective of this case report is to present a clinic scenario in which extended Zone 1 occlusion time allowed for successful operative intervention and did not result in clinically significant distal ischemia.

Ethical Approval and Informed Consent

Ethical approval was not required. Informed consent was not possible and the information has been anonymized.

CASE REPORT

A 23-year-old male patient status post unrestrained motor vehicle collision with ejection was brought to a Level 1 trauma center. Upon arrival, the patient was hypotensive. An arterial line was placed. The patient initially responded to blood transfusion and he was taken to the computerized tomography (CT) scanner, which revealed grade V kidney laceration as well as grade III splenic laceration. He remained hemodynamically stable and was then admitted to the trauma Intensive Care Unit (ICU). He began to decompensate in the ICU and bilateral tube thoracostomies were performed as well as placement of pREBOA-PRO, which was slowly inflated until the patient's blood pressure stabilized. He was transferred to the OR for nephrectomy. Sixty minutes of partial occlusion of Zone 1 was required and the balloon was deflated and removed in the operating room following successful nephrectomy. No intraoperative signs of ischemia were noted. The patient suffered no immediate complications and no other intra-abdominal injuries were noted. Postoperatively the patient returned to the ICU in a stable condition with peak creatinine of 1.6 mg/dL.

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DISCUSSION

In this patient who was acutely decompensating in the ICU, pREBOA-PRO was effective in temporizing blood pressure for transfer to the operating room for definitive treatment of life-threatening injuries. Although this particular case required an extended Zone 1 partial occlusion time of 60 minutes, there was no subsequent evidence of end organ damage. This is particularly notable in the setting of nephrectomy.

CONCLUSION

Future directions in animal models and clinical research involving the pREBOA-PRO system are focused on allowing for both pre-hospital placement as well as in-hospital modifications in order to temporize non-truncal hemorrhage in the trauma setting and ultimately decrease morbidity from this cause. Circumstances such as the one discussed in this case report in which extended Zone 1 partial occlusion time does not result in distal ischemia or reperfusion injury are important in the ongoing discussions of research goals and in the development of guidelines and clinical practice for the pREBOA-PRO system.

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

Alison A. Smith is a paid consultant for Prytime Medical. The remaining authors have no conflicts of interest to disclose.

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Endovascular Repair of Ascending Aortic Pseudoaneurysm After Open Aortic Replacement Through Percutaneous Right Axillary Artery Access

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Keywords: Endovascular; Thoracic Aorta; Pseudoaneurysm

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We present a case of a 71-year-old patient admitted to our department with a suspected pseudoaneurysm in a follow-up echocardiogram study after ascending aortic aneurysm repair. The pseudoaneurysm was confirmed by a computed tomography angiography (CTA) exam. Although the patient was asymptomatic the finding

required an urgent repair. We opted an endovascular repair over open surgical repair in order to avoid redo thoracotomy, decompression of the pseudoaneurysm with the need for full cardiopulmonary arrest.

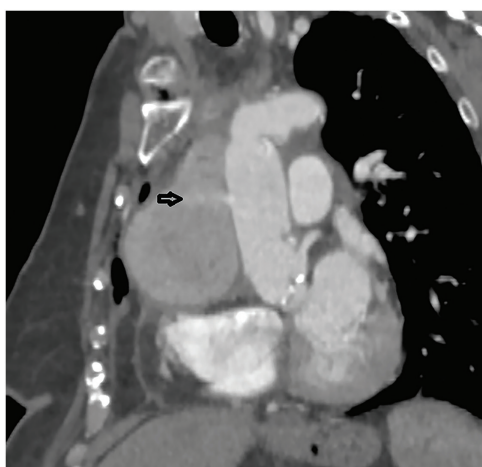


Figure 1 A CTA revealed a large pseudoaneurysm with a clear jet of contrast – marked with arrow.

Ethics Statement

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- (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.

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Figure 2 The defect in the ascending aortic graft and the jet leak seen on angiography in the lateral oblique view (a). An aortic extender endoprosthesis (GORE 36–36–45 mm) was introduced through the right axillary artery in an 18 Fr sheath and the graft was positioned (b) and then deployed under rapid pacing. Angiography showing good results (c).



Figure 3 Completion angiography of the axillary access after closure with Proglide (Abbott) showed critical stenosis (marked with arrow, most probably due to a faulty puncture). The stenosis was crossed through the femoral access and treated with a Viabahn 10 mm/5 cm endoprosthesis (GORE) with good results.

Alternative Methods for Endovascular and Hybrid Bleeding Control

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Puncture site or vascular access bleeding may be managed with open or endovascular methods. In this paper, we shortly describe alternative methods for endovascular and hybrid bleeding control.

Keywords: *Endovascular; Vascular Access; Bleeding*

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Iatrogenic access bleeding in the common femoral artery (CFA) can be managed by open surgery, endografts or hybrid (endo and open) solutions, as part of the EndoVascular resuscitation and Trauma Management (EVTM) concept. The most common method has historically been open surgical repair, but as techniques and products are developing, more solutions are becoming available. At times, the placement of an endograft in the CFA or a balloon in the external iliac using a cross over technique from the contralateral side is possible and may save both you and the patient a complicated and

lengthy procedure. Some images of interest displaying these procedures follow below in Figures 1–3.

Ethics Statement

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- (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.
- (3) Clinical photos used with permission.

Conflicts of Interest

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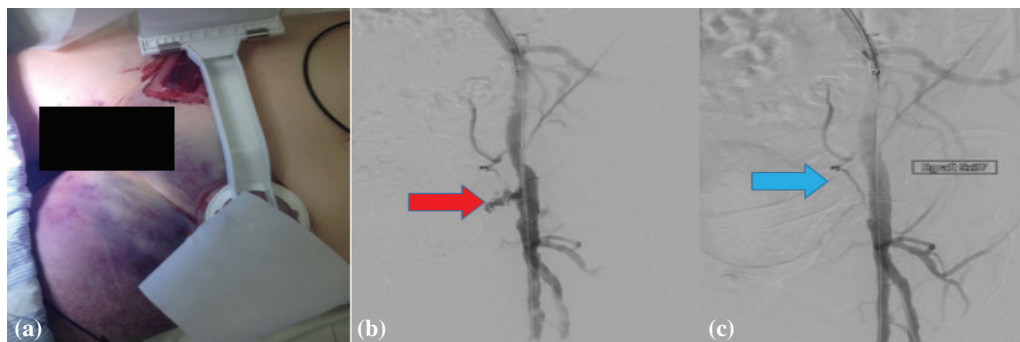


Figure 1 From left to right. The development of a large hematoma (a) following an endovascular procedure despite the FemoStop being placed (illustration only, not same patient). Angiography can be performed from the contralateral side displaying ongoing extravasation (b, red arrow). To avoid the risks of complicated surgery due to the large hematoma and postoperative infection, an endograft can be placed in the CFA (c, blue arrow), avoiding covering the deep femoral artery and arresting the extravasation.

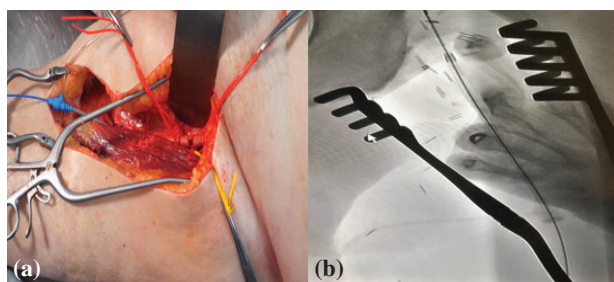


Figure 2 Another option for hemorrhage control from the CFA is by access through retrograde puncture of the superficial femoral artery (SFA) with balloon or endograft placement, displayed in a tissue model (a). It is important to not cover the deep femoral artery. Closure of the puncture site can be done by open repair or closure device (we prefer Proglide closure device). Note the manual compression on the angiography image while the sheath (b) is being placed with the balloon later being inflated for bleeding control in a clinical case.



Figure 3 Another example for bleeding control in the CFA is by using a hybrid approach (a) with balloon inflation in the CFA, seen here in the angiography image (b), controlling the bleeding while open surgical exposure and repair can be performed in a traditional manner.

Using Double Wires as a Stability Solution

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At times, when the endovascular delivery or catheter system is unstable, two wires can be used, forming a double wire system.

Keywords: *Endovascular; Vascular Access; Catheter*

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Placing a second 0.018 Fr wire, instead of changing to a single 0.035 Fr wire for stability, can help when faced with extreme angulations. This technique is displayed below (Figure 1) where stent graft alignment was needed

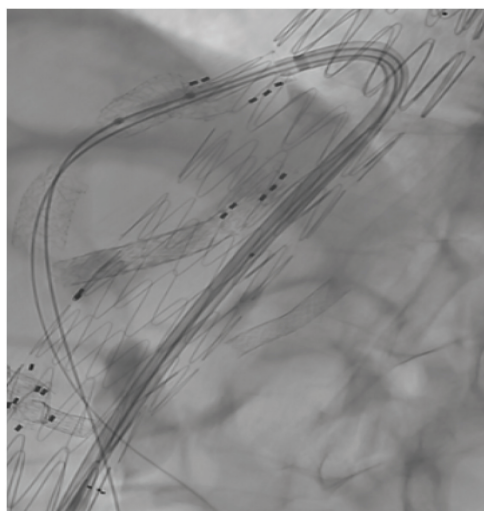


Figure 1 Introducing a sheath with two 0.018 Fr wires.

after graft separation in a complex aortic case. This is a simple method, and the limitation is usually the catheter size and the types of wires and catheters that are available. Double wires can be used in both acute and elective cases, and the use of steerable sheaths is very helpful in these situations.

Ethics Statement

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- (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

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EVTM Landmark Articles



ENDOVASCULAR RESUSCITATION AND TRAUMA MANAGEMENT
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ENDOVASCULAR RESUSCITATION AND TRAUMA MANAGEMENT

LANDMARK ARTICLES

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Editors:

Tal M. Hörer
Boris Kessel
Anna Maria Ierardi
David T. McGreevy

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Education



EndoVascular resuscitation and Trauma Management – Specialists in Training (EVTM-ST) is a newly formed group within the EVTMM Society and EVTMM Council who represent the interests of trainees, especially with regards to training, education, research and exchange programmes.

One of the main EVTMM-ST events is the monthly multidisciplinary international case discussions on Zoom. An appreciated concept with focus on allowing the participating trainees to discuss a presented EVTMM case, with only one consultant present for guidance. Participants are from all around the world, from various disciplines and with different levels of experience. We have great discussions, exchange of knowledge and hear about different local experiences that everyone can learn from.

If you are interested in joining the EVTMM-ST case discussions,
please email: david.mcgreevy@regionorebrolan.se

Coming Meetings

International Conference on Complications in Interventional Radiology (ICCIR), 1–3 June 2023, Poertschach, Austria
<https://www.cirse.org/events/iccir/>

LINC, 6–9 June 2023, Leipzig, Germany
www.leipzig-interventional-course.com

CIRSE, 9–13 September 2023, Copenhagen, Denmark
www.cirse.org

American Association for the Surgery of Trauma for the 82nd Annual Meeting of AAST, 20–23 September 2023, Anaheim, CA, USA
<https://www.aast.org/annual-meeting/2023-annual-meeting>

EVTM Workshop, 21–22 September 2023, Örebro University Hospital, Sweden
<https://jevtm.com/workshop/>

ESVS Annual Meeting 2023, 26–29 September 2023, Belfast, Northern Ireland
<https://esvs.org/events/annual-meeting/annual-meeting-2023/>

Paris Vascular Insights (PVI), 8–10 November 2023, Carrousel du Louvre, Paris
https://www.paris-vascular-insights.com/?gclid=Cj0KCQiA-oqdBhDfARIsAO0TrGFoe51P3UW8bzwWUkw68fh_HshDIR-wN6n2O8FTri5ZYf9nTc4ws-egaAIOYEALw_wcB

VEITH Symposium, 14–18 November 2023, New York
<https://www.veithsymposium.org/index.php>

23rd European Congress of Trauma and Emergency Surgery (ECTES), 28–30 April 2024, Lisbon, Portugal
<https://estes-congress.org/>

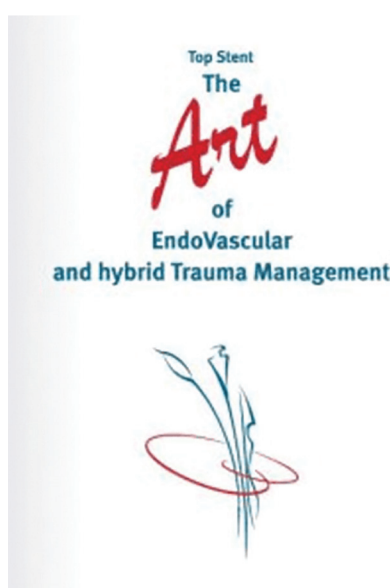
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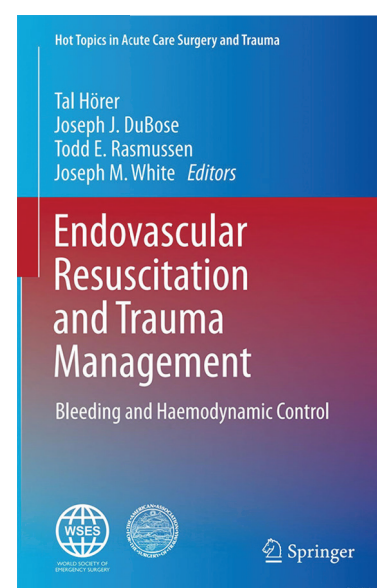
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EndoVascular resuscitation *and* Trauma Management (EVTM)

Hands-on Workshop 21-22 September 2023

Örebro University Hospital, Sweden



**EndoVascular Resuscitation
and Trauma Management**

EVTM instructors

Paul Rees (ED, UK), Jon Barratt (ED, UK), Anna Maria Ierardi (IR, IT), Frank Planz (Trauma, ZA),
Kevin Mani (Vascular, SE), Zoran Rancic (Vascular, CH), Artai Pirouzram (Vascular, SE), Mansoor Khan
(Trauma, UK), Martin Malina (Vascular, UK/SE), Mario D'Oria (Vascular, IT), Hayato Kurihara (Trauma, IT)

TBA (not final)

Local team: TBA

Target: Surgeons, Vascular, IR, ED, Intensivists, Trauma, civilians and Military with interest in trauma/bleeding/resuscitation, emergency & pre-hospital teams

Date: 21-22 September 2023 in Örebro, Sweden

Workshop Directors: Tal Hörer and David McGreevy

Workshop Registration: tal.horer@regionorebrolan.se; david.mcgreevy@regionorebrolan.se

Cost (cover expenses only): 500Eu. 400Eu for EVTMM Society members

Place: Facility for experimental studies and surgical training, Örebro University Hospital.

Partners: Örebro University Hospital, Limedic, Penumbra, Baxter, Mediel- Ziehm **TBA**

The aim of this two day workshop is to train, stimulate discussion, **mutual learning and sharing** of experiences while practicing EndoVascular resuscitation *and* Trauma Management (EVTM) using a multidisciplinary team approach with emphasis on local resources. “No ego, just good science, care and collaboration” is the main motion of the event.

The workshop is built on an individual, professional level and we will together explore different methods for resuscitation, bleeding control, hemostasis, trauma management and bail-outs. Some methods are used clinically world-wide, while some are under development and have been used on selected patients. This workshop concentrates on basic and advanced aspects

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More info at www.jevtm.com/workshop and social media #EVTMM

of *open and endovascular* bleeding control techniques. We will combine open hemostasis and endo aspects with vascular access, angiography, embolization, endografts, shunts and other endo/hybrid solutions for the unstable patient. Hemodynamic instability in focus with trauma, non-trauma, bleeders and non-bleeders. From ruptures, to trauma with a wide range of hemodynamic instabilities in focus.

We will focus on clinical data and lessons learned from 20 years use of these methods in clinical practice.

- Vascular access:
 - Different methods (blind, doppler, ultrasound, fluoroscopy and cut down)
 - Its use in hemodynamic unstable patients
- Aortic Balloon Occlusion (REBOA) basic and advanced methods and SAAP
- Basic/advanced angiography principles and practical tips
- Damage Control EVTM and Bailout methods - Open, endo and hybrid
- Maintaining and closing a vascular access
- Basic and advanced postoperative considerations
- Up-to-date research and clinical experience
- ABO Trauma Registry cases; Trauma and non-trauma
- Knowledge of basic/advanced material and new technologies on the market
- Endografts, embolization material on the market and what to use, and when
- Intensive training on live tissue
- ICU and post-operative aspects
- Basics for building an “EVTM service”; Tools needed
- Advanced experimental methods in resuscitation using REBOA and ECMO with CPR on live tissue models.
- When to choose open surgery and stop playing with endo?

The workshop is individually tailored during the practical parts (advanced and basic as needed). Participants will get basic training and knowledge of vascular access, angiography, endografts, embolization and REBOA placement and other basic catheters and hybrid tools as part of the EVTM concept. This will be combined with open techniques and bleeding control maneuvers. The workshop has been certificated by the EACCME and acknowledged by collaboration with societies like the European Society for Trauma and Acute Care Surgery, the European vascular society and others.

Program at the live tissue lab training and dry lab/cadaver lab.

Day 1:

The day starts around 12 o'clock with Lunch at the training facilities at Örebro University Hospital, Sweden. Talks and discussions:

Bleeding control issues; Hemostasis; The hemodynamic unstable patients. Short presentations on vascular access, how to, complications, indications for REBOA (pREBOA, iREBOA), Abdominal compartment and complications. Endografts, embolization, choosing correct products etc. Data regarding EVTm will be presented. Different hemodynamic instabilities will be discussed as GI bleeding, trauma, Gyn, rAAA and others. Basic and advanced techniques for diagnostic and treatment of hemodynamic instability. Methods to use endografts, embolization agents, balloons and other tools will be presented and discussed. When open surgery is the best option and when not to play endo.

Detailed schedule TBA

Day 2:

07:00 Gathering/changing at the Training Center

07:15-08:40 "EVTm hands-on review - what can we do?" (Cadaver)
(Preliminary - if available, to be announced the day before)

08:40-09:30 Breakfast with the industry. Short presentations on EVTm and up to date data.

Hands-on animal lab including:

Every station is led by a highly experienced instructor with one-to-one training on live tissue as well as group scenario discussions (Lunch and coffee will be served in the lab). Changing stations according to interest is encouraged. Dedicated stations per discipline/area according to the groups.

Practical training points in the animal lab:

1. Material usage in bleeding patients, general considerations and management scenarios
2. Open techniques for bleeding control/Hemostasis and combinations with endo/hybrid.
3. Vascular Access
 - Basic principles/advanced methods
 - Cut-down techniques
 - Endoshunts and shunts
 - Hybrid procedures
 - Puncture methods
 - Seldinger technique
 - The failing access - alternatives
 - Venous access and Ultrasound
 - Basic and advanced methods

4. Upgrading/introducers/guide wires
5. REBOA
 - Material and REBOA kit
 - Deflation and re-positioning
 - Intermittent/Partial inflation (MAP as target - iREBOA/pREBOA)
 - Ongoing bleeding practice
 - CPR procedures and pending arrest
6. Balloon in alternate locations (Iliac, Subclavian, Brachiocephalic trunk/Zone 1 neck)
7. Hybrid procedures for hemostasis
8. Aortography and Angiography considerations (type, volume etc.)
9. Endografts/embolization advanced as needed - what, when, how
10. Bailouts in endovascular and hybrid surgery

All training aspects will be modified to the participants' level and interest.

15:00 End of workshop and evaluation; Diploma

“No ego, just good science, clinical care and cooperation”



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