



Journal of Endovascular Resuscitation and Trauma Management

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Issue Highlights

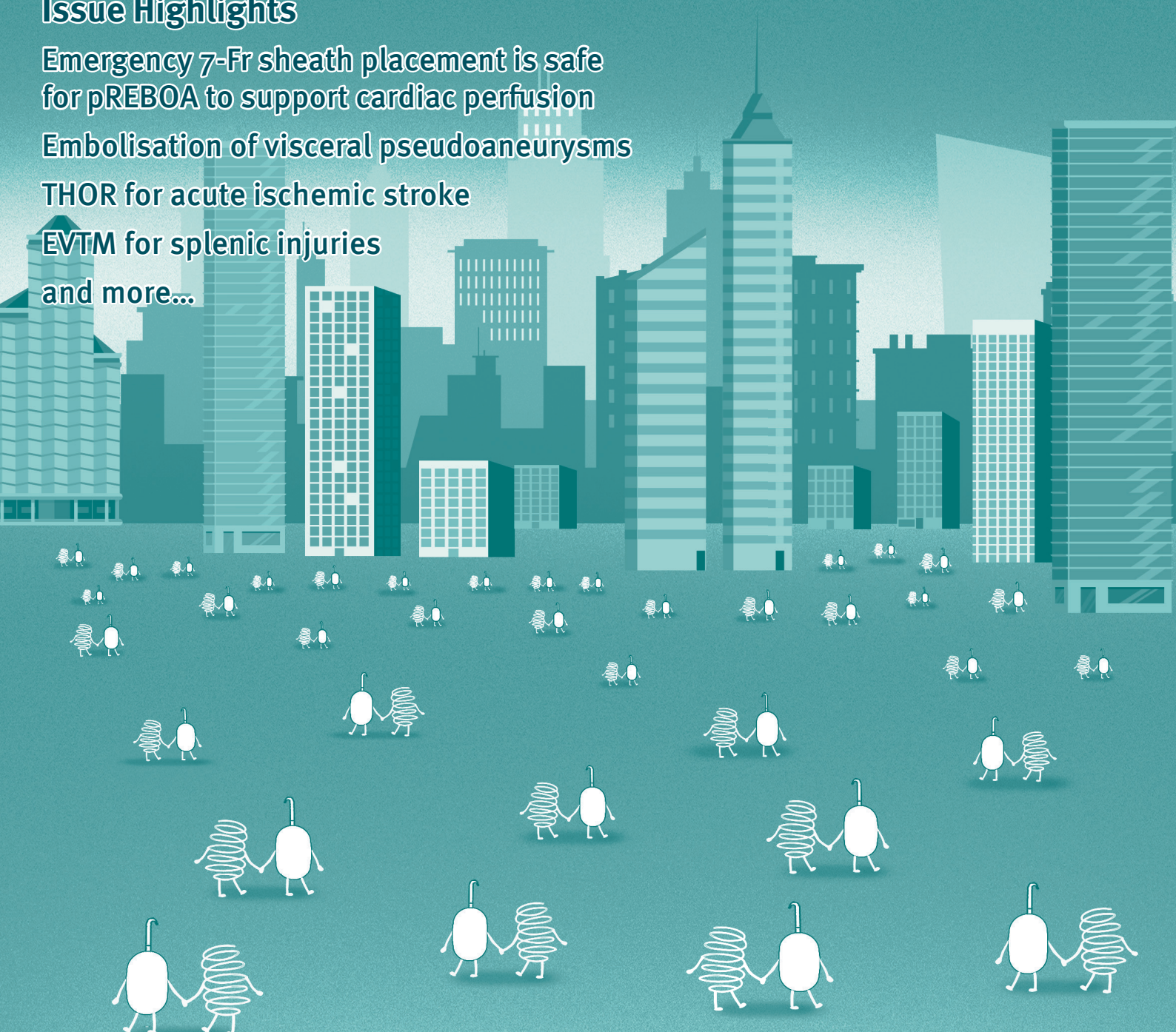
Emergency 7-Fr sheath placement is safe for pREBOA to support cardiac perfusion

Embolisation of visceral pseudoaneurysms

THOR for acute ischemic stroke

EVTM for splenic injuries

and more...



NO EGO, JUST GOOD SCIENCE, CARE AND COLLABORATION

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JEVTM

Journal of Endovascular Resuscitation and Trauma Management

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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 animals 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 XXXX. 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).

EVTM Society

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.

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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Why Don't Trauma Surgeons use Resuscitative Endovascular Balloon Occlusion of the Aorta: Evidence, Holy Grail or Fear?

Kessel–Khan Corner

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Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is an additional tool for the management of non-compressible torso hemorrhage in certain selected patients. Over the last decade, REBOA has gained widespread utilization in several trauma centers worldwide, and some promising publications have supported its effectiveness in various clinical scenarios [1,2]. Moreover, the American College of Surgeons Committee on Trauma (ACSCoT) clearly states that REBOA is currently standard practice for a select patient group at a small number of trauma centers, where surgeons are immediately available for the management of REBOA [3].

However, the review of the current literature has shown that most trauma surgeons who work in hospitals with the necessary facilities for the utilization of REBOA do not use it. We agree that currently there is no high-level evidence that clearly demonstrates REBOA improves outcomes or survival compared to standard treatment of severe hemorrhage. Even in the management of severe pelvic fractures, recommendations regarding REBOA use for pelvic fracture management vary across published guidelines. For example, the last Eastern Association for the Surgeon of Trauma (EAST) recommendations do not include the utilization of REBOA [4]. The Trauma Quality Improvement Project endorses REBOA as a potential alternative initial intervention, or in addition to preperitoneal pelvic packing in

patients in extremis solely from pelvic bleeding [5]. Contemporarily, the World Society of Emergency Surgery (WSES) guidelines list REBOA as one of the first lines of treatment for severe hemodynamically unstable pelvic fractures [6].

Despite this current academic and institutional support, a prospective cross-sectional survey, including all 158 trauma medical directors at ACSCoT-verified Level I Trauma Centers, showed that a small number of trauma directors authorize the usage of REBOA [7]. In injuries other than isolated pelvic fractures, the rate of REBOA utilization is even less.

In this inaugural Kessel–Khan Corner, we try to analyze why trauma surgeons are still apprehensive of using REBOA. As with all explanations in modern medicine, the reasons are invariably multifactorial. There is a lack of sufficient high-quality prospective studies and potential perceived bias due to industry promotion. Significant numbers of our academic and clinical colleagues prefer to practice solely supported by evidence-based medicine (EBM). However, it should be emphasized that this is the nirvana that one should aspire to and certainly is the right direction to go. However, in our Corner we wish to raise again the endless discussion regarding the true value of EBM in our practice. One can argue that an appropriate balance between strict guidance to aid in the decision-making process and deciding what is best for our patients must be reached based on rational thinking and personal experience – thus making medicine more of an art. The hemorrhaging patient does not read medical articles and has no idea about score matching analysis. If REBOA is a potential way to save their life, we need to do this.

We believe that an additional reason for limited REBOA use is a misunderstanding of the concept. Many trauma surgeons still believe that REBOA was implemented to replace resuscitate thoracotomy and open

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aortic clamping. There are several publications demonstrating that patients who underwent REBOA had no improved mortality compared with Resuscitative Thoracotomy (RT) [8,9]. The experience in performing RT is much more extensive than REBOA utilization as RT has been practiced for decades. However, we believe that a major impact of REBOA use is not in patients who need RT, but when properly timed balloon inflation prevents rapid deterioration, which requires RT. The study by Brenner and her colleagues on nearly 300 trauma patients clearly demonstrated the survival benefit of REBOA over RT, particularly in patients not requiring CPR [10].

In only a minority of trauma centers are trauma surgeons sufficiently trained enough to perform REBOA. To the best of our knowledge, in a significant proportion of the hospitals, vascular surgeons or interventional radiologists perform REBOA. We may only assume that such a dependence on these specialties, a lack of their immediate availability, insufficient REBOA use by trauma surgeons, and a lack of systemic thinking and implementation of REBOA may add to the apprehension of its usage and affect outcomes. It is a well-known phenomenon in the Western world that the fear to cope with risk management results in apprehension of utilization, enforced by trials that report higher risks of mortality in REBOA patients and devastating, life-threatening complications such as leg amputations [11].

However, it is imperative to enforce that REBOA is a system technique and not reliant on the individual. It is a bridge to definitive control or intervention. This is best undertaken in trauma centers where a system is in place that has around-the-clock availability of necessary personnel for the right indication. The right indications are still up for debate, but one can say that surgery is an art as well as a science, with no patients being the same. Therefore, the indications can be patient-specific, based on the judgement of a highly trained team managing the patient to the best of their ability, ensuring that they uphold the medical value of doing no harm – “primum non nocere”.

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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Acute Ischemic Stroke Therapy in a Hybrid Emergency Room: An Institutional Observational Cohort Study

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Background: Endovascular therapy within an appropriate time has been shown to improve neurological outcomes in patients with ischemic stroke. A hybrid emergency room is an emergency unit that can be used for resuscitation, computed tomography (CT), surgery, and angiography. Therefore, immediate CT and endovascular therapy can be performed without transfer to other rooms. We aimed to evaluate the possibility of using a hybrid emergency room to shorten the time to endovascular therapy in patients with ischemic stroke.

Methods: This was a single-institutional, retrospective, and observational study. Patients with acute ischemic stroke who underwent endovascular therapy in the hybrid emergency room between May 2018 and May 2020 were included in the study. The main outcome was door-to-puncture time. The secondary outcomes were door-to-reperfusion and onset-to-puncture time. Descriptive statistics were also calculated. Outcome times were compared with those recommended by recent guidelines.

Results: Twenty-seven patients were included in this analysis. The median age was 77 (69–83) years. The median National Institutes of Health Stroke Scale score on admission was 15 (10–21.25), while the median door-to-puncture, door-to-reperfusion, and onset-to-puncture times were 45 (29–63), 140 (100–170), and 120 (71–224) minutes, respectively. The door-to-puncture time was within the recommended time of 60 minutes for approximately 75% of the patients.

Conclusions: The door-to-puncture time in our study was shorter than that recommended by the guidelines. Acute ischemic stroke management in a hybrid emergency room could shorten door-to-puncture time, which may contribute to improving patients' neurological outcomes.

Keywords: Acute Ischemic Stroke; Endovascular Therapy; Hybrid Emergency Room System

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INTRODUCTION

Reperfusion therapy for acute ischemic stroke is evolving remarkably. Recently, the effectiveness of endovascular therapy has been proven in patients with large vascular occlusions in both the anterior and posterior circulation [1–7]. Although the eligible time window for

endovascular therapy can be up to 24 h from the time last known to be well [8], a large observational study that enrolled 6,756 patients with anterior circulation large vessel occlusion acute ischemic stroke treated with endovascular therapy showed that a shorter time to reperfusion was significantly associated with better neurological and survival outcomes [9].

A hybrid emergency room is an emergency unit that can be used to perform resuscitation, computed tomography (CT), surgery, and angiography, and is designed for treating patients with severe trauma. Using this has been suggested to improve clinical outcomes in patients with trauma [10,11], however, only one report has suggested its efficacy in treating patients with acute ischemic

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stroke [12]. Immediate endovascular therapy following CT evaluation can be performed without transfer to other rooms, which may contribute to improving the outcome in patients with ischemic stroke.

In this study, we aimed to evaluate the possibility of using a hybrid emergency room to shorten the time to endovascular therapy in patients with ischemic stroke.

METHODS

Study Design, Setting, and Participants

This observational cohort study retrospectively collected the data of all patients admitted to the hybrid emergency room system at Tohoku University Hospital between May 2018 and May 2020. Patients were eligible if they were ≥ 18 years of age and suspected to have had a stroke. Patients were excluded if they were: (a) not diagnosed with ischemic stroke; (b) diagnosed with intracranial hemorrhage, subarachnoid hemorrhage, or transient ischemic attack; (c) diagnosed with ischemic stroke but were not candidates for revascularization; or (d) if data were not available. We analyzed patients who received reperfusion therapy in the hybrid emergency room, after excluding patients who had undergone magnetic resonance imaging (MRI) before endovascular therapy, were transferred to other hospitals after administration of recombinant tissue-type plasminogen activator (rt-PA), received endovascular therapy not at the hybrid emergency room, or were treated with rt-PA but without endovascular therapy.

The study protocol was reviewed and approved by the institutional review board of Tohoku University (2020-1-805). The requirement for informed consent was waived because of the retrospective nature of the study, and the analysis used anonymous clinical data.

Data Collection and Measurements

We collected the following data: age, sex, Glasgow Coma Scale (GCS) score on admission, National Institutes of Health Stroke Scale (NIHSS) score [13], Alberta Stroke Program Early CT Score (ASPECTS) [14], past medical history, and medications before admission. We also collected data on the time course of door-to-image, puncture, needle, revascularization, last-known well to arrival, culprit vessel, thrombolysis in cerebral infarction (TICI) grade [15], Modified Rankin Scale (mRS) at discharge [16], time spent in the ICU, and the hospital discharge date. All information was collected from the medical records.

Outcomes

The main outcome measure was door-to-puncture time. The secondary outcome measures were door-to-reperfusion and onset-to-puncture times.

Comparison with Recommendations and Evidence

We compared door-to-puncture and door-to-reperfusion times demonstrated or recommended to be appropriate in large studies or guidelines. We performed a literature review to identify the recommended door-to-puncture, door-to-reperfusion, and onset-to-puncture times associated with better neurological outcomes. First, we performed a PubMed database search using the keywords (stroke AND endovascular AND [reperfusion OR “endovascular therapy” OR “mechanical thrombectomy”] AND guideline) for guidelines and ([door-to-puncture OR door-to-reperfusion OR onset-to-puncture] AND stroke) for clinical studies. Subsequently, eligible articles were reviewed. We selected guidelines regarding recommended or better neurological outcomes-associated door-to-puncture, door-to-reperfusion, or onset-to-puncture times. For clinical studies, we selected articles that evaluated the association between door-to-puncture, door-to-reperfusion, or onset-to-puncture time and neurological outcomes as primary or secondary outcomes.

Definitions

We defined the time from the event to the procedure as follows: door-to-image time was the time from the arrival of patients at the hospital to the start of head CT; door-to-puncture time was the time from arrival of patients at the hospital to groin puncture; door-to-reperfusion time was the time from arrival of patients at the hospital to reperfusion of the culprit vessel proven by angiography; and onset-to-puncture time was the time from presentation of patients with stroke symptoms to puncture.

Statistical Analyses

This study used descriptive statistics. The median and interquartile range (IQR) were used for all continuous variables. Categorical variables are presented as numbers and proportions. All statistical analyses were performed using the JMP Pro Version 15 software (SAS Institute Japan Ltd., Tokyo, Japan).

Ethical Approval and Informed Consent

Ethical approval was not required. Informed consent was not required.

RESULTS

During the study period, 270 patients with suspected stroke were eligible. Of these, 58 patients with stroke mimics, 70 patients with intracranial hemorrhage, 65 patients with transient ischemic attack or ischemic stroke but not applicable for revascularization, and one patient whose data were unavailable, were excluded. Of the remaining 41 patients who received reperfusion

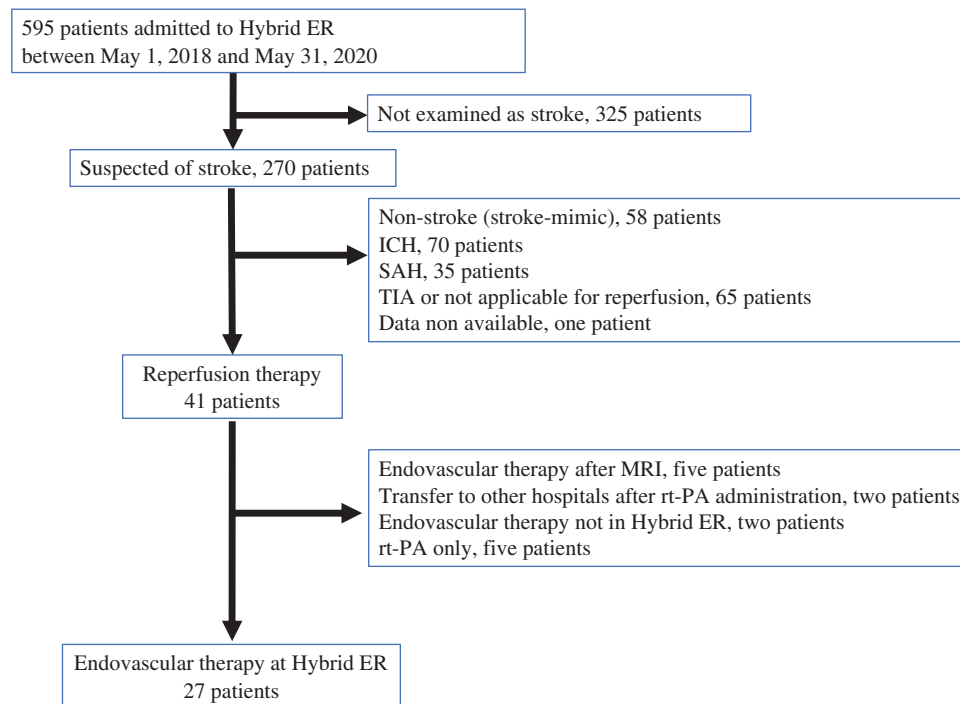


Figure 1 Flow chart of patient selection and exclusion details. ER, emergency room; ICH, intracranial hemorrhage; MRI, magnetic resonance imaging; rt-PA, recombinant tissue-type plasminogen activator; SAH, subarachnoid hemorrhage; TIA, transient ischemic attack.

therapy, five patients who received endovascular therapy after MRI, five patients who were treated with rt-PA only, two patients who were treated with rt-PA and then transferred to other hospitals, and two patients who received endovascular therapy not in a hybrid emergency room were excluded. Finally, 27 patients were included in the final analysis (Figure 1).

Patient Characteristics

Patient characteristics are shown in Table 1. The median patient age was 75 (69–83) years. The median GCS score on admission was 13 (10–14), the median NIHSS score was 15 (10–21), and the median ASPECTS score was 9 (6–10). In most patients, the culprit vessel was the middle cerebral artery (18/27).

Primary and Secondary Outcomes

The median time for door-to-puncture was 45 (29–63) min (Table 2). The median door-to-reperfusion and onset-to-puncture times were 140 (100–170) min and 120 (71–224) min, respectively (Table 2).

Comparison with Recommendations and Evidence

A literature search yielded 241 guidelines. After a full review, only one guideline provided recommendations for door-to-puncture and door-to-reperfusion times in

endovascular reperfusion for patients with acute ischemic stroke. No guidelines have provided recommendations for the onset-to-reperfusion time. The guidelines from the Society of Neurointerventional Surgery state that door-to-puncture and door-to-reperfusion should be performed within 60 min and 90 min, respectively [17]. A literature search for clinical studies on door-to-puncture, door-to-reperfusion, and onset-to-puncture yielded 56, 27, and 61 articles, respectively. After a full review, no studies have evaluated the association between door-to-reperfusion, or onset-to-puncture, and neurological outcome as the primary outcome. In our study, door-to-puncture time was within 60 min for 20 of the 27 patients, and door-to-reperfusion time was within 90 min for three of the 27 patients (Figure 2).

DISCUSSION

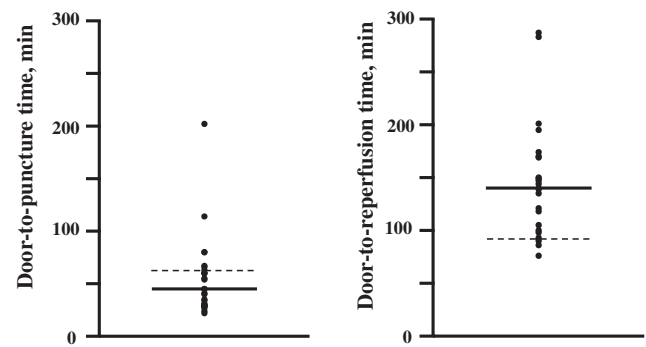
We found that the median door-to-puncture, door-to-reperfusion, and onset-to-puncture times were 45, 140, and 120 min, respectively, in patients with ischemic stroke treated in a hybrid emergency room. In 20 of the 27 patients treated with endovascular therapy without preceding MRI, the door-to-puncture time was within the recommended time frame.

According to our systematic review, only one guideline indicated the time goals of door-to-puncture and door-to-reperfusion for endovascular therapy. The guidelines from the Society of Neurointerventional

Table 1 Characteristics of patients with ischemic stroke treated with endovascular therapy in a hybrid emergency room system.

Characteristics	Total n = 27
Age, median (IQR)	75 (69–83)
Men (%)	12 (44.4)
GCS on admission, median (IQR)	13 (10–14)
NIHSS, median (IQR)	15 (10–21)
ASPECTS, median (IQR)	9 (6–10)
Culprit vessels	
IC	7
ACA	1
MCA	18
Basilar artery	1
Medical history, n (%)	
Hypertension	16 (59)
Dyslipidemia	9 (33)
Atrial fibrillation/flutter	9 (33)
Diabetes mellitus	5 (19)
Previous stroke/TIA	5 (19)
Heart failure	3 (11)
Smoker	5 (19)
Renal insufficiency	2 (7)
Vascular disease	3 (11)
Respiratory disease	1 (4)
Malignancy	7 (26)
Medication before admission, n (%)	
Antiplatelets	6 (22)
Anticoagulants	3 (11)
Antihypertensives	13 (48)
Cholesterol reducers	3 (11)
Antidiabetics	2 (7)

ACA, anterior cerebral artery; ASPECTS, Alberta Stroke Program Early CT Score; GCS, Glasgow Coma Scale; IC, internal carotid artery; IQR, interquartile range; MCA, middle cerebral artery; NIHSS, National Institutes of Health Stroke Scale; TIA, transient ischemic attack.

**Figure 2** Time distribution of door-to-puncture and door-to-reperfusion times. Each dot indicates the time required by each patient. The horizontal line indicates the median time. A dotted line indicates the time recommended in the NeuroInterventional Surgery guidelines.

Surgery recommend that door-to-puncture time should be <60 min and door-to-reperfusion time should be <90 min, although there is no clear description of the evidence [17]. The door-to-puncture time in our study was much shorter than that recommended by the guidelines, whereas the door-to-reperfusion time was much longer. It is assumed that since the hybrid emergency room, equipped with CT and angiography, can be used to perform immediate endovascular therapy following a CT scan without patient transfer, we could achieve a shorter door-to-puncture time [10,11].

Recent studies have shown that a reduction in the time to reperfusion leads to favorable neurological outcomes. A recent observational study showed that the probability of a good clinical outcome decreased as the time to angiographic reperfusion increased in patients

Table 2 Clinical course, outcomes, and culprit vessels.

Times to diagnosis and treatment	Total n = 27
Last known well to arrival, min, median (IQR)	56 (33–162)
Door-to-image, min, median (IQR)	7 (4–11)
Door-to-puncture, min, median (IQR)	45 (29–63)
Door-to-needle, min, median (IQR)	49 (38–57)
Door-to-reperfusion, min, median (IQR)	140 (100–170)
Onset-to-puncture, min, median (IQR)	120 (71–224)
Clinical outcomes	
TICI grade $\geq 2a$, n (%)	23 (85)
mRS at discharge, median (IQR)	4 (1–5)
Length of ICU stay, days, median (IQR)	5 (4–9)
Length of hospital stay, days, median (IQR)	19 (13–35)

Door-to-image is the time from arrival of patients at the hospital to the start of head computed tomography. Door-to-needle is the time from the arrival of patients at the hospital to the administration of rt-PA. Door-to-puncture is the time from the arrival of patients at the hospital to the groin puncture. Door-to-reperfusion is the time from the arrival of patients at the hospital to large vessel reperfusion proven by angiography. Onset-to-puncture is the time from the presentation of stroke symptoms to groin puncture. ICU, intensive care unit; IQR, interquartile range; mRS, modified Rankin Scale; rt-PA, recombinant tissue-type plasminogen activator; TICI, thrombolysis in cerebral infarction.

with middle cerebral artery and distal internal carotid occlusions with successful reperfusion [18]. Retrospective analysis of the combined database showed that shorter onset-to-reperfusion time was associated with improved 90-day Modified Rankin Scale (mRS) score in patients with acute ischemic stroke treated with a stent retriever [19]. A meta-analysis of five randomized control trials for patients with acute ischemic stroke due to large-vessel occlusions also showed that a shorter time from onset to reperfusion was associated with an improved 90-day mRS score [6].

The varied door-to-puncture times might have been caused by the situation in our hospital, such as the availability of neurologists or neurosurgeons. The hybrid emergency room may be a novel and favorable space for shortening door-to-puncture time. In-hospital systems are also essential; they are another requirement for the software. Improvements in the in-hospital systems are also required. The door-to-reperfusion times in our cases were longer than those recommended by the guideline [17]. The hybrid ER system is equipped with a single-plane angiography system, whereas the majority of neurosurgeons mostly use a bi-plane system. Inexperience with the single-plane system causes longer door-to-reperfusion times at the early stage of installing the hybrid ER system. This could lead to unfavorable outcomes in patients [6]. However, treating more patients with single-plane system may improve the door-to-reperfusion time. Development of a novel operator-supporting system, such as navigation, is also required.

Acute ischemic stroke management in a hybrid emergency room could shorten door-to-puncture time, which may lead to improved neurological outcomes. The hybrid emergency room has the potential to be an innovative system for acute ischemic stroke management. Further investigation is required to elucidate whether a hybrid emergency room can improve a patient's neurological outcomes.

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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Author Contributions

YI was responsible for the conception, methodology, formal analysis, investigation and drafting the manuscript. DK was responsible for the methodology, formal analysis, investigation, reviewing and editing the manuscript, and funding acquisition. MF was responsible for the methodology and investigation. SO and AN were responsible for the investigation and review of the manuscript. SK was responsible for the conception, reviewing and editing the manuscript, and supervision. All authors commented on the previous versions of the manuscript. All authors read and approved the final manuscript.

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Place the Sheath: Emergent 7 French Femoral Sheath Placement is Low Risk During Initial Trauma Resuscitation

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Background: We hypothesized that emergent placement of 7 French (Fr) common femoral artery (CFA) sheaths during trauma resuscitation for potential resuscitative endovascular balloon occlusion of the aorta (REBOA) carries a low complication rate.

Methods: Trauma patients at a Level I trauma center with emergent CFA access from January 2016 through to December 2020 were reviewed. CFA access was categorized as (1) 7 Fr sheath plus REBOA (REBOA) and (2) 7 Fr sheath without REBOA (Sheath). Outcomes included mortality and vascular complications.

Results: 157 patients underwent emergent CFA access. Sixty-nine (43.9%) patients had a 7 Fr CFA sheath, and 88 (56.1%) progressed to REBOA. The mortality rate was similar (Sheath 30.4% vs. REBOA 34.1%, $p = 0.63$). The REBOA cohort had a significantly higher complication rate (22.7%) compared to the Sheath cohort (4.3%, $p = 0.001$).

Conclusions: Emergent 7 Fr CFA sheath placement during trauma resuscitation is low risk, suggesting empiric sheath placement is warranted in potential REBOA candidates.

Keywords: Trauma Resuscitation; Emergent Common Femoral Artery Access; Resuscitative Endovascular Balloon Occlusion of the Aorta; Endovascular Resuscitation Complications

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INTRODUCTION

There have been substantial advancements in trauma resuscitation through newly developed devices and re-emphasized techniques. The resuscitative endovascular balloon occlusion of the aorta (REBOA) is a popular yet controversial modality in managing trauma. REBOA is a valuable adjunct during the resuscitation of advanced hemorrhagic shock [1–3]. Multiple institutions and several multicenter studies have evaluated REBOA indications, outcomes, and complication rates. Current literature establishes the efficacy of this procedure for

use by skilled trauma surgeons within the hospital setting [2–5], and multiple studies report that the critical, time-consuming step to ensure REBOA success is obtaining rapid and safe femoral artery access [6,7].

Early common femoral artery (CFA) access for REBOA is associated with improved time to definitive hemorrhage control with improved survival [7,8]. This suggests that CFA access should be initiated early in the clinical course [8]. However, little research has focused on potential complications associated with emergent CFA access. Complications during CFA access in non-emergent procedures, such as percutaneous coronary and endovascular interventions for peripheral and central vascular disease, vary based on definitions but range from 1.2 to 2.8% for access site hematomas [9,10], and are as high as 5.7% for any access-related complication [11].

Current Advanced Trauma Life Support guidelines do not recommend emergent CFA access during trauma resuscitation [12]. Reticence regarding access complications delays this procedure until the patient meets REBOA indications. However, several theoretical advantages are

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associated with the empiric sheath placement in unstable trauma patients, including monitoring of continuous central aortic blood pressure and rapidity of REBOA deployment should the patient decompensate further. If the patient progresses to this point before obtaining access, placement of the CFA sheath becomes more difficult.

Early REBOA cases were performed through CFA cutdown and had multiple access-related complications [13]. Technological evolution led to ultrasound (US) guided CFA access with smaller, 7 French (Fr) sheaths [14]. In 2020, our level 1 trauma center initiated a specific protocol emphasizing early US-guided 7 Fr CFA access for potential ER-REBOA (Prytime Medical Devices, Inc., Boerne, TX) use. We hypothesized that placement of a 7 Fr CFA sheath under emergent trauma resuscitation conditions is a low-risk procedure. We compared the complication rates following 7 Fr CFA sheath placement with the complications rates of CFA sheath plus REBOA catheter placement.

METHODS

This is a retrospective and prospective cohort study of 7 Fr CFA sheath placement during initial trauma resuscitation at a single, urban level 1 trauma center. The Institutional Review Board approved the study under protocol #18-1953. Subjects were identified using registry data from January 2016 to December 2020. Inclusion criteria included all admitted patients aged 15 years and older following the highest level of trauma team activation who underwent 7 Fr CFA placement for potential ER-REBOA. Over the study period, the decision to place a sheath was at the discretion of the trauma attending but generally included a presenting systolic blood pressure <90 mmHg. Furthermore, general indications for REBOA deployment included transient or non-response to blood products in the setting of blunt and penetrating trauma. CFA access for an interventional radiology procedure or hemodynamic monitoring was excluded. Subjects admitted from a custody facility were also excluded.

Identified patients underwent chart review by two separate individual reviewers. De-identified data were collected and managed using Research Electronic Data Capture (REDCap) tools [15,16]. Data collected included: demographics; mechanism of injury; injury severity score; procedural information, including the time and location of CFA sheath and REBOA placement; mortality, and arterial and procedural complications; and treatment of complications. The principal investigator further evaluated all complications and respective treatment plans. Complications were considered related to CFA access or REBOA procedure if they met three requirements: (1) arterial abnormality or organ dysfunction diagnosed by clinical exam (hematomas only), labs, or imaging; (2) temporal and spatial relationship to the CFA access or REBOA procedure; and (3) determined to be unrelated to the initial trauma.

A practice change was initiated in 2020 in which all patients who underwent emergent CFA access had a duplex US evaluation within 48 hours of sheath removal.

Patients were stratified for analysis into a 7 Fr sheath only group (Sheath) and a 7 Fr sheath plus REBOA group (REBOA). Data analysis occurred in SAS® Software Version 9.4 (SAS Institute, Cary NC). The primary outcome was the complication rate for each procedure. Secondary outcomes included mortality rate, number of complications requiring interventions, and yearly trends in Sheath and REBOA procedures and complication rates. Univariate analysis was performed to compare baseline characteristics between groups. Where appropriate, categorical variables were compared using the Chi-square test or Fisher's test. Continuous variables (Abbreviated Injury Scale (AIS), Injury Severity Score (ISS)) underwent distribution analysis with the Kolmogorov-Smirnov test and were analyzed using the Wilcoxon rank sum test (non-parametric). A *p*-value of <0.05 was considered significant.

Ethical Approval and Informed Consent

Ethical approval to report these cases was given by the Colorado Multiple Institutional Review Board, under protocol #18-1953. A waiver of informed consent was approved by the Institutional Review Board.

RESULTS

A total of 14,480 patients were admitted to the trauma registry during the study period. Two hundred thirty-four (1.6%) underwent CFA access, of which 157 (67.1%) were performed under emergent conditions and included in the analysis. The majority of patients were middle age (median: 43; IQR: 30–54), White (67.1%), and male (73.2%). Sixty-nine (43.9%) patients underwent a 7 Fr CFA sheath only, and 88 (56.1%) progressed to REBOA. A single patient in the REBOA cohort required surgical cutdown while all others underwent percutaneous CFA access. There were no significant demographic characteristic differences between the cohorts (Table 1).

Most injuries were due to blunt mechanisms (76.4%), with motor vehicle crashes being the most common (35.0%). The REBOA cohort had a higher percentage of injuries due to motorcycle crashes and pedestrians struck (*p* = 0.01). The REBOA cohort had more severely injured patients (*p* = 0.01), specifically with higher abdomen/pelvis (*p* = 0.003) and extremity AIS scores (*p* = 0.001). Injury characteristics are reported in Table 2.

Procedural information is reported in Table 3. The Sheath cohort comprises patients admitted in 2020, while the REBOA cohort is more evenly spread across all five study years (*p* = 0.001). The REBOA cohort had all CFA access procedures in either the emergency department (ED) or operating room (OR). The Sheath cohort had access most commonly in the ED, with the

Table 1 Demographic breakdown of patients who received a CFA Sheath only and those who progressed to REBOA placement.

Variables	Total N = 157	Sheath N = 69	REBOA N = 88	P Value
Age, years	43 [30–54]	46 [35–54]	40 [26–54]	0.10
Gender:				0.87
Female	42 (26.8%)	18 (26.1%)	24 (27.3%)	
Male	115 (73.2%)	51 (73.9%)	64 (72.7%)	
Ethnicity:				0.43
Missing	5 (3.18%)	4 (5.80%)	1 (1.14%)	
Hispanic	40 (25.48%)	15 (21.74%)	25 (28.41%)	
Not Hispanic	112 (71.34%)	50 (72.46%)	62 (70.45%)	
Race:				0.05
Missing	2 (1.27%)	1 (1.45%)	1 (1.14%)	
African American	18 (11.46%)	9 (13.04%)	9 (10.23%)	
Asian	2 (1.27%)	2 (2.90%)	0	
Native American	1 (0.64%)	1 (1.45%)	0	
Other/unknown	30 (19.11%)	7 (10.14%)	23 (26.14%)	
White	104 (66.24%)	49 (71.01%)	55 (62.50%)	

For categorical groups, total N and (%) are reported. For numerical variables, median and interquartile range are reported.

Table 2 Injury characteristics of the Sheath cohort compared to the REBOA cohort.

Variables	Total (N = 157)	Sheath (N = 69)	REBOA (N = 88)	P Value
Mechanism of injury				0.38
Missing	1 (0.64%)	1 (1.45%)		
Blunt	120 (76.43%)	50 (72.46%)	70 (79.55)	
Penetrating	36 (22.93%)	18 (26.09%)	18 (20.45)	
Cause of injury				0.01
Missing	1 (0.64%)	1 (1.45%)		
Assault	3 (1.91%)	2 (2.90%)	1 (1.14%)	
Bike crash	3 (1.91%)	2 (2.90%)	1 (1.14%)	
Fall	11 (7.01%)	9 (13.04%)	2 (2.27%)	
Gunshot wound	24 (15.29%)	9 (13.04%)	15 (17.05%)	
Motor vehicle crash	55 (35.03%)	23 (33.44%)	32 (36.36%)	
Motorcycle crash	19 (12.10%)	4 (5.80%)	15 (17.05%)	
Other	6 (3.82%)	4 (5.80%)	2 (2.27%)	
Pedestrian vs. auto	25 (15.92%)	7 (10.14%)	18 (20.45%)	
Sport injury	1 (0.64%)	1 (1.45%)		
Stab wound	9 (5.73%)	7 (10.14%)	2 (2.27%)	
ISS	29 [20–41]	26 [17–35]	34 [25–41]	0.01
AIS head and neck	0 [0–3]	0 [0–4]	1 [0–3]	0.85
AIS face	0 [0–1]	0 [0–1]	0 [0–1]	0.91
AIS chest	3 [0–3]	3 [0–3.5]	3 [0–3]	0.76
AIS abdomen and pelvis	2 [0–3]	0 [0–3]	2 [0–4]	0.003
AIS extremities	3 [0–4]	2 [0–3]	3 [2–4]	0.001
AIS external	1 [1–1]	1 [1–1]	1 [1–1]	1.0

For categorical groups, total N and (%) are reported. For numerical variables, median and interquartile range are reported. ISS, Injury Severity Score; AIS, Abbreviated Injury Scale.

second most common location being the surgical intensive care unit (ICU). The mortality rate was the same for both cohorts (Sheath mortality rate, 30.4% vs. REBOA

Table 3 Procedural characteristics of the Sheath cohort and the REBOA cohort, and complication and mortality rates.

Variables	Total N = 157	Sheath N = 69	REBOA N = 88	P Value
Year of admission				0.001
2016	10 (6.4%)	2 (2.9%)	8 (9.1%)	
2017	40 (25.5%)	14 (20.3%)	26 (29.5%)	
2018	24 (15.3%)	7 (10.1%)	17 (19.3%)	
2019	21 (13.4%)	6 (8.7%)	15 (17.0%)	
2020	62 (39.5%)	40 (58.0%)	22 (25.0%)	
Location where access first obtained				0.0005
Missing	4 (2.55%)	4 (5.80%)	0	
ED	123 (78.34%)	51 (73.91%)	72 (81.82%)	
ICU	9 (5.73%)	9 (13.04%)	0	
OR	21 (13.38%)	5 (7.25%)	16 (18.18%)	
Complication rate secondary to femoral arterial access				0.001
No	134 (85.3%)	66 (95.6%)	68 (77.2%)	
Yes	23 (14.7%)	3 (4.3%)	20 (22.7%)	
Final outcome				0.63
Deceased	51 (32.5%)	21 (30.4%)	30 (34.1%)	
Alive	106 (67.5%)	48 (69.6%)	58 (65.9%)	

Data are reported as total N and (%).

mortality rate, 34.1%, $p = 0.63$). The REBOA cohort had a significantly higher complication rate of 22.7% (20 out of 88 patients) compared to 4.3% (three out of 69 subjects) in the Sheath cohort ($p = 0.001$).

All three complications identified in the Sheath group were access site hematomas without further surgical intervention. The REBOA cohort had a total of 23 complications: two instances of acute renal infarction or acute kidney injury (AKI); two incidents of lower extremity ischemia resulting in one amputation and one four-compartment fasciotomy; six arterial occlusions; four vasospasms; two dissections; two incidents of non-vasospasm related arterial stenosis; one access site hematoma; and one contrast extravasation of undetermined significance. Five of these complications required non-surgical intervention. The dissections and stenoses were treated with anticoagulation. One patient with an AKI was treated with continuous venovenous hemofiltration. Five complications required surgical intervention, of which two were immediately treated following REBOA removal in the OR, and three required a separate operative procedure. Of the 2020 cohort who underwent routine CFA duplex US sheath or REBOA placement, two complications were identified in the REBOA cohort: one dissection and one stenosis.

Temporal trends showing REBOA volume and associated complications are shown in Figure 1. There was a significant difference in the number of REBOAs placed over time ($p = 0.03$). The REBOA complication rate decreased over the first three years and trended up from 2019 to 2020. These differences were not significant ($p = 0.46$) and likely reflect the practice change of

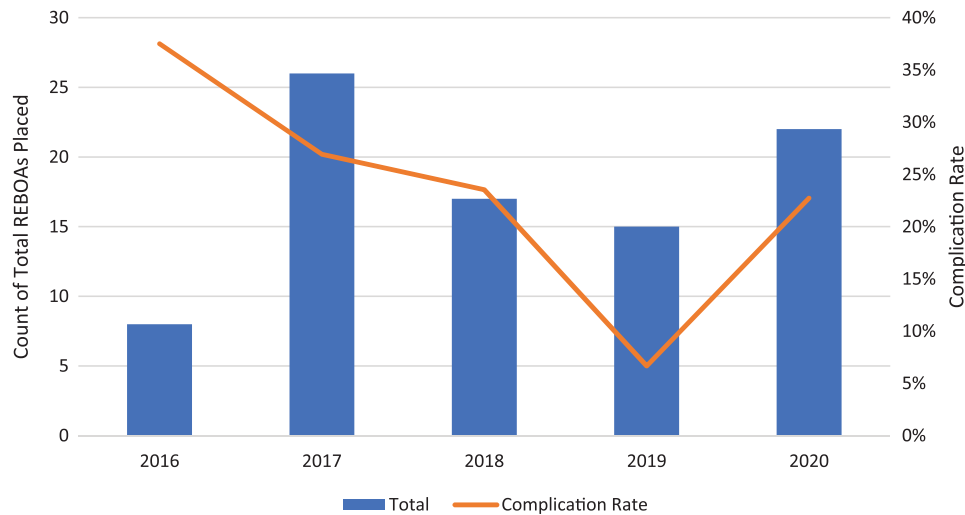


Figure 1 Yearly counts of REBOA catheters placed and corresponding complication rate per year. Yearly complication rate is as follows: 2016, 38%; 2017, 27%; 2018, 24%; 2019, 7%; in 2020, 23%.

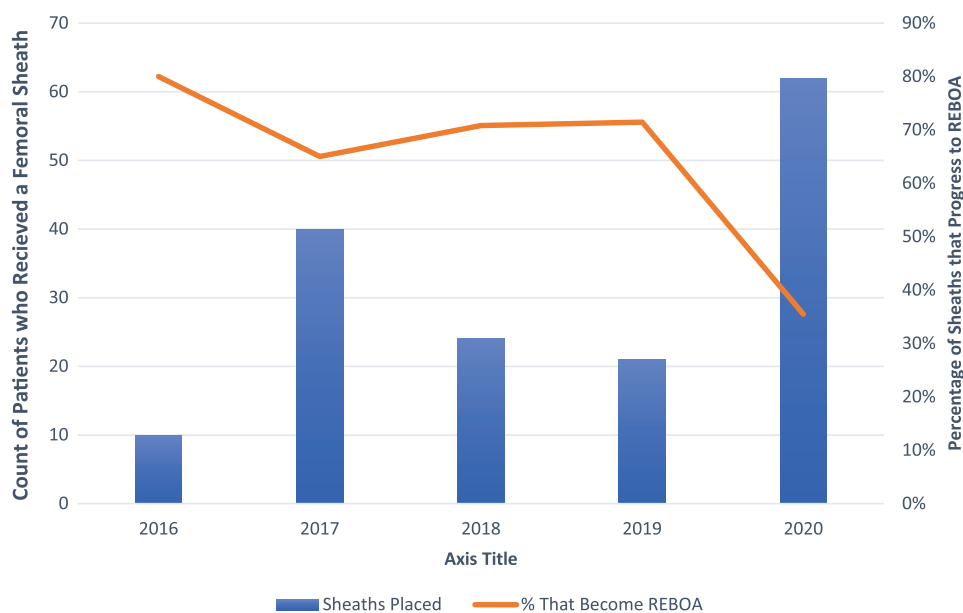


Figure 2 Total count of CFA sheaths placed during emergent resuscitation per year and corresponding conversion to REBOA with aortic occlusion. Yearly rate in sheath to REBOA progression is as follow: 2016, 80%; 2017, 65%; 2018, 71%; 2019, 71%; in 2020, 35%. CFA: common femoral artery access. REBOA: resuscitative endovascular balloon occlusion of the aorta.

routine arterial duplex following sheath removal. Figure 2 shows the number of CFA sheaths per year with the subsequent sheath conversion rate for that year. There was a significant change in sheath conversion rate over time ($p = 0.001$). In 2016, 80% of femoral sheaths progressed to REBOA compared to 35% in 2020.

DISCUSSION

The objective of this retrospective single-center cohort study was to compare the complication rates following emergent 7 Fr CFA sheath placement with those that progressed to REBOA. In patients who underwent a

CFA sheath only, the complication rate was below 5%, while the complication rate in the patients who progressed to REBOA was 23%. After femoral sheath placement alone, the only complication that developed were access site hematomas that did not require any interventions. This suggests that early placement of femoral arterial sheaths is a safe practice that could benefit trauma resuscitation protocols by allowing for rapid endovascular interventions, such as REBOA deployment, in the event of hemodynamic decompensation.

The rate-limiting step of REBOA deployment is obtaining CFA access [6, 17–21]. This finding has been supported by several studies and acknowledged by the joint statement from the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP) [22]. One multicenter study evaluating the feasibility of REBOA in patients with critically low systolic blood pressures found that only 58.5% of patients had successful arterial access completed on the first attempt [19]. Another single-center review found that more than 50% of the time spent initiating REBOA was dedicated to obtaining CFA access [6]. When the authors compared the time it took to perform a resuscitative thoracotomy (RT) with aortic occlusion, they found that successful aortic occlusion during RT was more than 2 minutes faster than REBOA. However, if REBOA was deployed with CFA access already established, the time to aortic occlusion was significantly shorter for REBOA. Successful CFA access was achieved in 86% of patients in hemorrhagic shock, but only 14% of patients in cardiac arrest [6]. Obtaining early CFA access when a patient is hypotensive but not in extremis should improve the time to aortic occlusion with REBOA.

Here, we provide evidence that emergent 7 Fr CFA sheath placement is a low-risk procedure that can be safely incorporated into trauma resuscitation protocols. Barriers to obtaining successful vascular access in emergency scenarios range from low vascular volume, active CPR, unfamiliarity with endovascular access procedures, the chaotic environment of the trauma bay, and the stress added by the emergent nature of the procedure. Early and standardized preemptive CFA cannulation may mitigate many of these barriers. Additionally, lower thresholds for cannulation can lead to improved training opportunities and experience for both resident and attending physicians. Routine preemptive 7 Fr catheter placement for the mildly hypotensive patient during trauma resuscitation may decrease access complications associated with REBOA by increasing experience with its rate-limiting step. Several studies have shown that experience is related to improved outcomes following REBOA [23,24]. Our institution began using aortic balloon occlusion techniques in 2015. We transitioned to the ER-REBOA catheter in 2016. This analysis confirms improved complication rates following increased ER-REBOA catheter experience in a single institution over five years

(Figure 2). Our rise in complication rates for REBOA patients in 2020 is likely due to additional routine arterial duplex US screening after catheter removal.

The time-consuming and challenging process of obtaining access to the CFA has likely contributed to the slow pace of adaptation of REBOA into trauma resuscitation protocols. Initially, REBOA usage was commonly described as an alternative to RT [13,25,26], but more contemporary databases show that using REBOA as a last attempt to prevent circulatory collapse is associated with worse outcomes [14,27]. This supports the use of REBOA as an early adjunct to provide circulatory support instead of a procedure to reverse circulatory collapse [28,29]. More recent studies demonstrate that early CFA access in REBOA patients is associated with improved time to definitive hemorrhage control and increased survival [7,8] providing evidence that early 7 Fr CFA access should be incorporated into standardized trauma resuscitations protocols. At Maine Medical Center, emphasis is placed on early CFA access for invasive monitoring with a “Step Up” approach to REBOA [29]. This is a very limited experience without evaluation of complications that could have been associated with emergency CFA cannulation. Our study builds upon this experience.

Limitations of this study include its retrospective nature for most patients. Firstly, REBOA details regarding procedural success and times are often missing from clinical charts, limiting REBOA success or failure evaluation. Secondly, we cannot determine the cause of REBOA complications as we could not definitively determine the etiology of access site hematomas in the REBOA cohort. Additionally, in severely injured patients who require REBOA, ischemic and vascular anomalies identified as complications are often multifactorial. They could be caused by the combination of preexisting hemorrhagic shock and ischemia, which may be exacerbated by catheter insertion and aortic occlusion. We could not reliably obtain systolic blood pressures at the precise time of cannulation, as retrospective chart review showed this vital sign was not commonly reported with accuracy at the time of cannulation, but instead was reported with the time of aortic occlusion for the REBOA cohort. Lastly, this study does not consider the number of attempts to obtain femoral access or how many were successfully placed by US-guided access versus the landmark technique. We were also unable to identify any failed attempts at REBOA catheter placement.

CONCLUSION

Routine placement of 7 Fr CFA sheaths during emergent trauma resuscitation resulted in a low rate of complications and was limited to local hematomas not requiring intervention. This patient population represents an excellent opportunity for trauma surgeons and emergency

physicians to gain experience in endovascular techniques while expediting REBOA catheter placement in cases of hemodynamic compromise by providing reliable hemodynamic monitoring and access for endovascular interventions.

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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Author Contributions

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

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Percutaneous Imaging Guided Puncture and Embolization of Visceral Pseudoaneurysms

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Background: Visceral pseudoaneurysms (PSAs) are usually treated endovascularly. No official guidelines exist regarding the correct management when this management option fails. The aim of this study is to assess the efficacy and safety of percutaneous imaging guided puncture of visceral PSAs in patients where intra-arterial embolization was unsuccessful or unfeasible.

Methods: Five patients with visceral artery pseudoaneurysms (VAPAs) were enrolled in the study. The diagnosis was made using a 64-slice multi-detector computed tomography (MDCT) scanner and all patients were previously considered unsuitable for the procedure or underwent the procedure unsuccessfully; all patients had anemia with hemoglobin loss greater than 2 g/dL in the last 24 hours. A 22-gauge Chiba needle was used to get percutaneous access to the lesion, where N-butyl cyanoacrylate (NBCA) and lipiodol or coils and onyx were subsequently injected.

Results: Four patients received a mixture of NBCA and lipiodol in a 1:2 ratio (80%, $n = 4$), and only one participant received coils and onyx. Primary clinical success was 100% and embolization was not repeated in any cases. No life-threatening secondary conditions or major complications were observed throughout the follow-up period; in one patient an asymptomatic embolic agent migration was reported. Secondary clinical success was also obtained in the current study. None of the remaining four participants experienced re-bleeding episodes or any procedure-related problems.

Conclusions: Percutaneous embolization of visceral PSAs is a safe and effective treatment alternative that should be considered when the trans-arterial method cannot be used.

Keywords: *Visceral; Pseudoaneurysm; Percutaneous; Trans-arterial; Embolization*

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INTRODUCTION

Pseudoaneurysms (PSAs) are vascular conditions characterized by a severe disruption in the continuity of the arterial walls. The debilitating damage to the arterial lining results in the formation of an adventitia-lined sac [1]. According to the literature, the debilitating nature of this abnormality is evidenced by literature findings that show that the secondary conditions that developed

due to PSAs are related to both high mortality and morbidity rates [2]. Patients diagnosed with PSAs might experience deteriorating health linked to the development of a wide spectrum of chronic conditions that can result from the compression of neurovascular structures, infections, or deep vein thrombosis [1]. Ultimately, the efficacy of the medical treatments used to manage PSAs are primarily based on the early diagnosis of the condition before it progresses into debilitating stages.

The leading causes of the formation of PSAs are events that cause disruption in the continuity of the arterial wall, such as trauma, anastomotic disruptions, accidental intra-arterial delivery of controlled substances, localized inflammatory reactions, and invasive procedures [1]. Around 75% of all accidental intra-arterial drug injections occur at the lower limb; the latter has been found to be the most frequent site of PSA formation [3].

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Imaging can clarify the condition's progression by displaying the blood's speed and movement pattern inside the artery, measuring the PSA diameters and showing the sac's communication with the artery, and the presence of contrast. The detectable symptoms considered in diagnosing PSAs are caused directly by the presence of the PSA itself, its rupture, or the secondary effects of the mass on adjacent neuro-vascular structures.

The main diagnostic tool used in emergency settings is contrast-enhanced computed tomography (CE-CT) [4].

Although surgery has been the first line of treatment in PSA management for years, interventional radiology procedures have proven to be a safe and effective alternative. One primary interventional treatment approach is the endovascular exclusion of the PSA, achieved through different tools such as stents, coils, and injectable liquids, each one with their use case depending on the nature, size, and location of the PSA, but also on the team's experience and preference. Radiological methods possess some clear advantages over traditional open surgery, with lower invasiveness and less post-procedural complications as the main ones, avoiding some of the risks associated with open surgery and allowing patients unfit for such procedures to be treated. One of the most widely adopted radiological treatments is trans-arterial embolization [5].

This study's aim is to report the outcome of percutaneous PSA embolization in patients for whom a trans-arterial approach was attempted but was unsuccessful. The study also attempts to propose another option in treating visceral arterial pseudoaneurysms (VAPAs).

MATERIALS AND METHODS

Patients

The patient group analyzed in this study consisted of patients for whom the trans-arterial embolization approach was unsuccessful. All of the diagnoses were made using multidetector CT employing a 64-slice CT scanner. Trans-arterial embolization was attempted in all cases but was deemed ineffective due to the impossibility to catheterize the feeding PSA artery, inadequate catheterization of the feeding artery and/or an inability to catheterize the "exit" artery beyond the PSA.

The sample consisted of five patients, of whom three were males and two were females. Patient selection was based on the need to have a representative population so that the results of the current research could be extrapolated and generalized.

Inclusion and Exclusion Criteria

The subjects included in the trial had severe anemia, characterized by a hemoglobin level loss greater than 2 g/dL within 24 hours that could be attributed to

recent bleeding. All of the patients included were hemodynamically stable or achieved stability through resuscitation techniques.

Outcomes

Technical success: Total embolization of the PSA at the end of the procedure.

Primary Clinical success: Stabilization of the patient's vitals and hemoglobin level recovery within 5 to 6 days after the procedure.

Secondary Clinical success: Absence of bleeding recurrence over the 12-month follow-up period, demonstrated at CE-CT follow-up performed before discharge, at 6 months and at 12 months after the procedure.

Safety: Major and minor complications were classified and recorded in accordance with the standard operating procedure stipulated by the Cardiovascular and Interventional Radiology Society of Europe [6].

The Intervention and its Follow-Up

The intervention deployed in the current study was the percutaneous procedure. Three interventional radiologists with more than 15 years of experience in endovascular and percutaneous techniques were tasked to perform the procedures on an angiographic table. Arterial access via the femoral artery was obtained using a 5 Fr vascular access sheath in all of the patients. Cobra C1 or Simons 1 catheters were used to catheterize the celiac trunk or, in some patients, the mesenteric arteries. The operators then used an angiogram and an improved cone-beam CT (CB-CT) scan to identify the PSAs and the affected artery location. To superselectively access the target arteries, a 2.7 Fr Progreat microcatheter was used. Notably, trans-arterial catheterization could not be achieved in any of the participants in our series due to the aforementioned anatomical characteristics.

The PSA diagnosis was performed through imaging processes such as ultrasound (US) and fluoroscopy, and defined as a pooling of contrast agent in the lumen of the affected arteries. The operator used a 22-gauge Chiba needle to get percutaneous access to the lesion. Subsequently, a sacculography was performed before every injection to ensure that the needle location was accurate, using US and fluoroscopic supervision and sometimes performing numerous angiography examinations in different projections to improve needle progression. The embolic agents of choice were either a mixture of N-butyl cyanoacrylate (NBCA) and lipiodol or coils and polymer. NBCA and lipiodol were used at a 1:2 ratio respectively, and a total 0.2–0.6 mL of the resulting liquid mixture was injected once or twice if deemed necessary by the researchers. The Chiba needle was

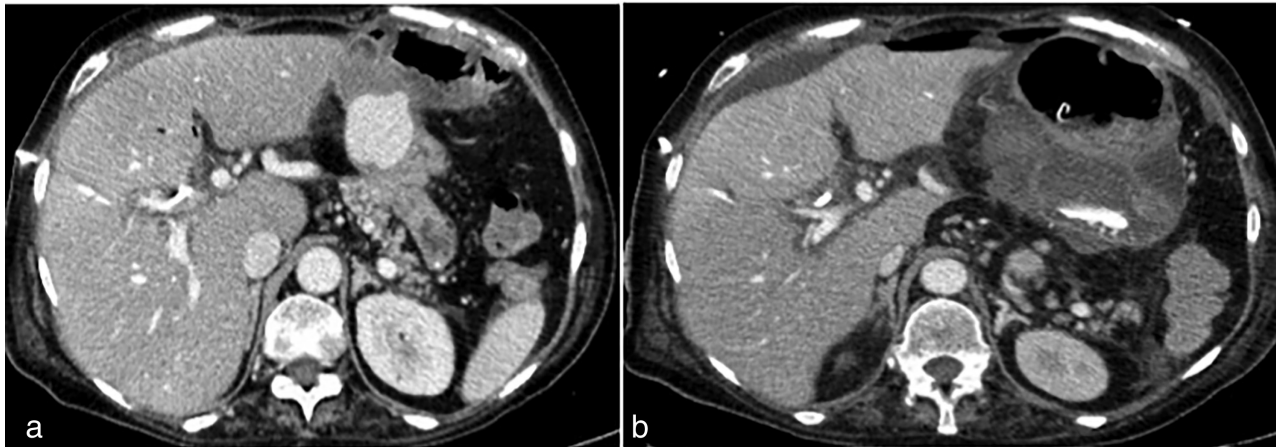


Figure 1 PSA acute bleeding. **(a)** a 40 mm PSA of the pancreatico-dorsal artery in a patient who underwent duodenocephalopancreasectomy with consequent anastomotic dehiscence. **(b)** Active contrast agent extravasation demonstrates acute bleeding from the PSA.

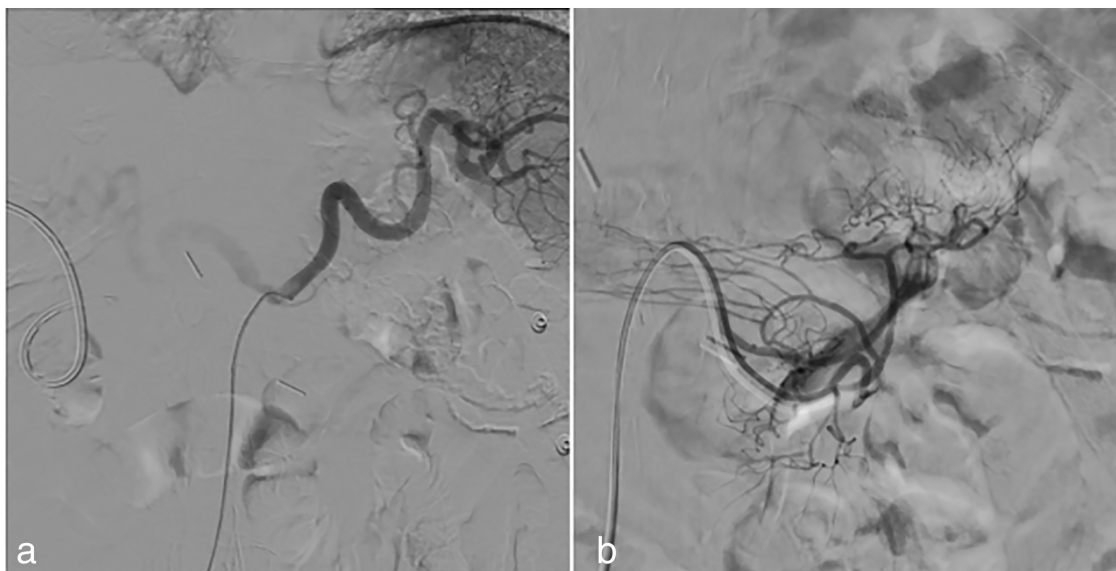


Figure 2 Angiogram. **(a), (b)** Selective angiogram did not show a PSA.

periodically cleaned with a 5% dextrose solution prior to the administration of the NBCA glue; the administration of the glue was guided through fluoroscopy and only stopped when the PSA was filled or when slight extravasation of glue was noticed. Regardless of the embolic agent utilized, the Chiba needle was removed after embolization was complete, performing a final assessment through US or angiography to ensure the correct exclusion of the PSA from circulation and therefore confirming technical success.

In a single case, coils and polymer were used to fill a PSA characterized by the exceptionally large diameter of 40 mm (Figure 1*a,b*); arteriograms did not reveal the PSA (Figure 2*a,b*); in this case, a sheath, a diagnostic catheter and a microcatheter (Progreat 2.7 Terumo)

were used. Polymer (Onyx 18, Medtronic) and coils were used to completely fill the PSA (Figure 3*a-d* and Figure 4).

Experiment Findings

The total embolization of the PSAs was observed at the end of the percutaneous procedures in all of the patients, proving a technical success of 100% in our sample. Primary and secondary clinical successes were obtained in all of the patients as well.

The maximum monitoring period was 72 months and, throughout that period, major and minor complications were recorded; the incidence of bleeding recurrence and embolic material migration were monitored.

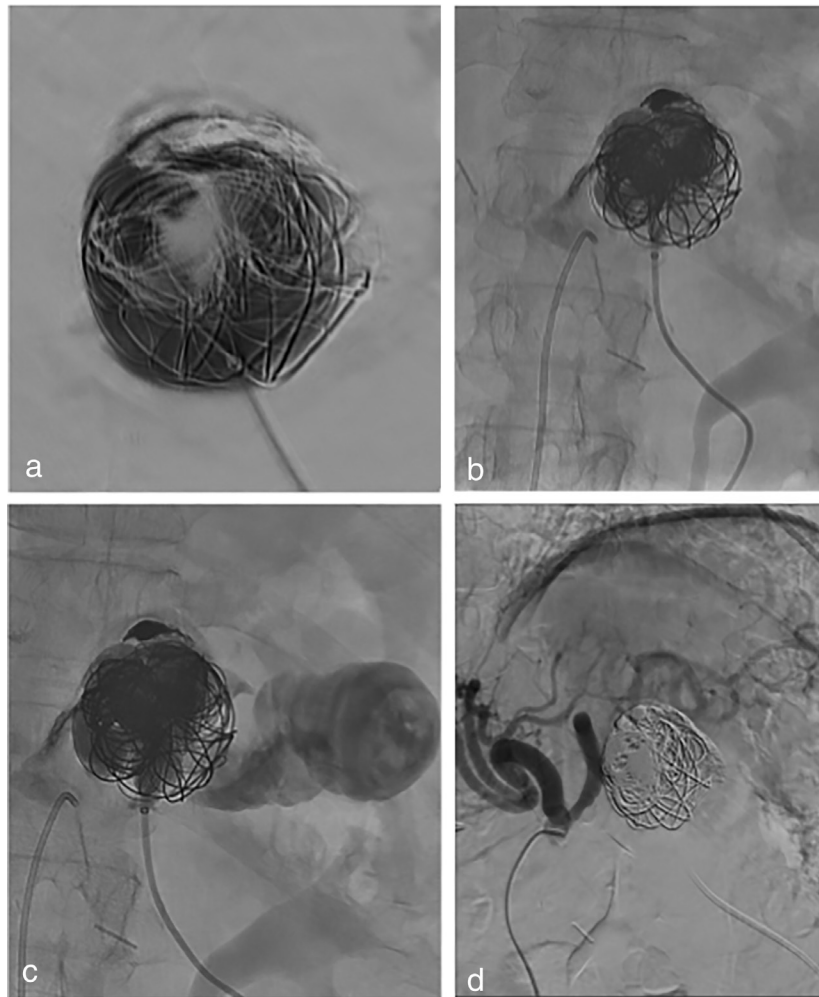


Figure 3 Percutaneous PSA embolization. (a), (b), (c), (d) Percutaneous puncture of the PSA and embolization with coils and non-adhesive fluid (Onyx).

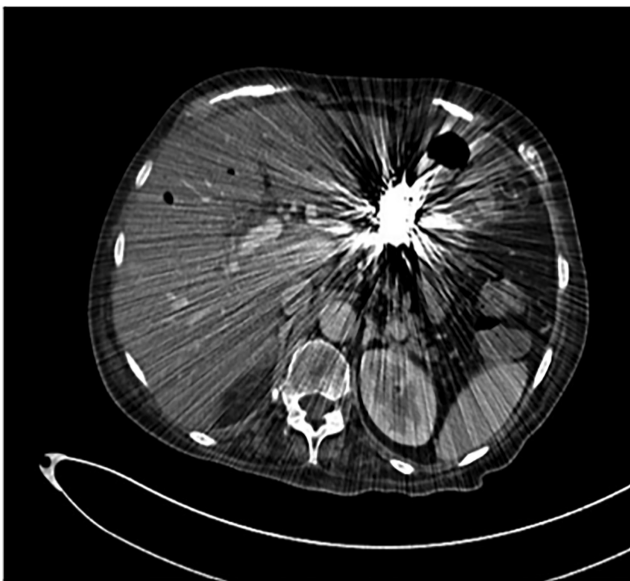


Figure 4 Control CT scan. The CT scan showed no signs of vascularization within the treated PSA and absence of active bleeding.

Ethical Approval and Informed Consent

The study was conducted in compliance with the Declaration of Helsinki, a set of ethical principles regarding human experimentation and data collection. Prior to the beginning of the study, informed consent forms were obtained from patients or relatives if patients were deemed incapable of rational decision-making.

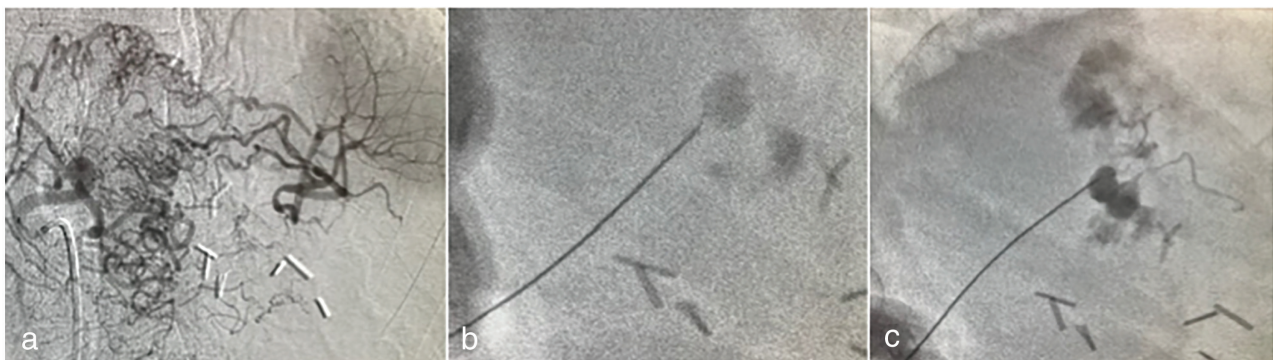
RESULTS

The five participants in this study had a median age of 52 years, and the mean PSA size was 27.2 mm. The etiology related to the development of PSAs among the patient population was heterogeneous and included biliary procedures, surgery, trauma, and pancreatitis.

Using CE-CT imaging, the location of each of the PSAs was determined: the vessels involved were the right hepatic artery, the left gastric artery, the digiunal artery, the first jejunal artery, and the pancreatic artery, as shown in Table 1.

Table 1 Patient characteristics and embolization information.

Patient ID	Gender	Age	Cause	PSA-Affected Area	PSA Diameter (mm)	Embolic Agent	Developed Complication
1001	M	38	Biliary operation	Right hepatic	22 mm	22G, glue	No
1002	F	51	Pancreatitis	Left gastric	30 mm	22G, glue	No
1003	F	56	Surgical procedure	Digiunal	24 mm	22G, glue	No
1004	M	60	Trauma	First jejunal	20 mm	22G, glue	Asymptomatic embolic material migration
1005	M	55	Surgical procedure	Pancreatic artery	40 mm	Microcath coils + onyx	No

**Figure 5** Left gastric PSA percutaneous embolization. **(a)** Left gastric PSA unreachable via transarterial. **(b)** Percutaneous fluoroscopic guidance puncture with 22G needle. **(c)** Embolization with glue.

The analysis revealed that the maximum and minimum PSA diameters were 40 mm and 20 mm, respectively. In the study, four patients received a mixture of NBCA and lipiodol in a 1:2 ratio (80%, $n = 4$) (Figure 5a–c), and only one participant received the coils + polymer combination. Primary clinical success was 100%, as normal hemoglobin levels were reported in all patients after the embolization. As a result, embolization was not repeated in any cases, and no more blood transfusion was required during their hospital stay. Notably, no life-threatening secondary conditions were observed during the treatment; no major complications were observed throughout the follow-up period; in one patient an asymptomatic embolic agent migration was reported.

Secondary clinical success was also obtained in the current study, as evidenced by both the absence of re-bleeding over the 72-month outpatient monitoring period and the complete pseudoaneurysm embolization. One patient died during the follow-up period, but the death was caused by cancer-related complications, unrelated with the subject of this study. None of the remaining four participants experienced re-bleeding episodes or any procedure-related problems, proving the procedures' potential in excluding PSAs from the circulation in subjects where trans-arterial approaches cannot be deployed

or have already been tried unsuccessfully. Ultimately, those results show that the procedure is feasible, safe, and useful as a treatment option in this subcategory of patients.

DISCUSSION

Pseudoaneurysms are caused by a disruption in the continuity of the arterial walls, resulting in the formation of a sac that communicates with arterial lumen [1]. Causes of PSAs include invasive surgery, intravenous drugs delivery, perivascular inflammation, and trauma to the artery wall [7].

In the past, PSAs were almost exclusively treated through invasive surgical procedures. However, literature linked such interventions with higher morbidity and mortality rates, highlighting the need to explore efficient but less invasive procedures [8].

This resulted in the discovery and widespread adoption of a broad array of endovascular approaches that have seen a constant growth in the variety of treatment options, their efficacy, and their safety [1].

Less invasive procedures are popular because they can be deployed to eliminate PSAs that could be surgically difficult to correct and to treat patients that have been deemed unfit for open surgery.

The endovascular approach, despite having a high success rate, can be unfeasible in treating PSAs in some patients. Notably, percutaneous embolization requires the adoption of imaging modalities as guidance during percutaneous therapy (including US, CT, and fluoroscopy). All of these imaging methods can be used on their own or they can be combined in various ways to make the approach both easier and more accurate [9]. Contextually, the current study examined the effectiveness of percutaneous imaging guided puncture in cases where trans-arterial approaches were not feasible in the treatment of PSAs, such as, for instance, when the artery affected by the PSA is inaccessible.

Our study's clinical and technical success rates were 100%, with no cases of recanalization, re-bleeding, or the development of debilitating secondary conditions.

In our small series, the rate of minor complications was so low that it can be considered almost negligible. However, caution must be adopted when performing percutaneous puncture. As mentioned above, our study's limitations include its small sample size and the heterogeneity of etiology behind the PSAs of patients in the sample.

CONCLUSION

Our study demonstrates that percutaneous embolization of visceral PSAs is a safe and effective treatment alternative that should be considered when the trans-arterial method is not feasible. Nonetheless, the procedure should be performed by experienced operators and in selected cases, as more extensive studies in terms of population size are still lacking.

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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Author Contributions

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

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Prone Zone 3 REBOA Rescue for Postoperative Hemorrhagic After Sacrococcygeal Tumor Resection

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In this report, we describe a 41-year-old man who underwent resection of a large chordoma. During his postoperative recovery, he experienced delayed-onset non-compressive pelvic hemorrhage in the surgical resection bed resulting in nerve root compression. Zone 3 REBOA was prepositioned intra-operatively prior to placing the patient in the prone position for hematoma evacuation and exploration for surgical hemostasis. The balloon was completely inflated to facilitate exposure to the site of hemorrhage in this patient with a high risk for neurologic injury during this operative re-exploration.

Keywords: Resuscitative Endovascular Balloon Occlusion of the Aorta; REBOA; Hemorrhagic Shock; Postoperative Hemorrhage; Chordoma

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INTRODUCTION

The use of resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for management of hemorrhagic shock from blunt or penetrating trauma is well described [1,2]. However, fewer reports exist on the use of REBOA in management of postoperative hemorrhage from non-compressible sites. Traditionally, the treatment of postoperative hemorrhage has entailed balanced blood product resuscitation, correction of coagulopathy, and surgical or endovascular control of the bleeding source [3,4]. In many cases, even when

rapid operative or endovascular options are readily available, REBOA can serve as a bridge to definitive hemostasis. Here, we describe the deployment of a Zone 3 REBOA in a patient with major postoperative hemorrhage following resection of a large sacral chordoma.

CASE REPORT

A 41-year-old man with morbid obesity (body mass index 44) presented for evaluation of significant sacral swelling. He reported a remote pilonidal cyst incision and drainage, and a family history notable for ulcerative colitis (mother) and prostatic cancer (father, grandfather). He underwent several years of outpatient management with oral prednisone for a working diagnosis of chronic coccydynia. Differential diagnosis included lumbar disk herniation or sacroiliitis secondary to inflammatory bowel disease. Eventually, a gluteal soft tissue ultrasound revealed a 18 cm left gluteal soft tissue mass with internal vascular flow. Magnetic resonance imaging (MRI) and computed tomography (CT) of the pelvis further characterized a 18 cm × 17 cm × 14 cm

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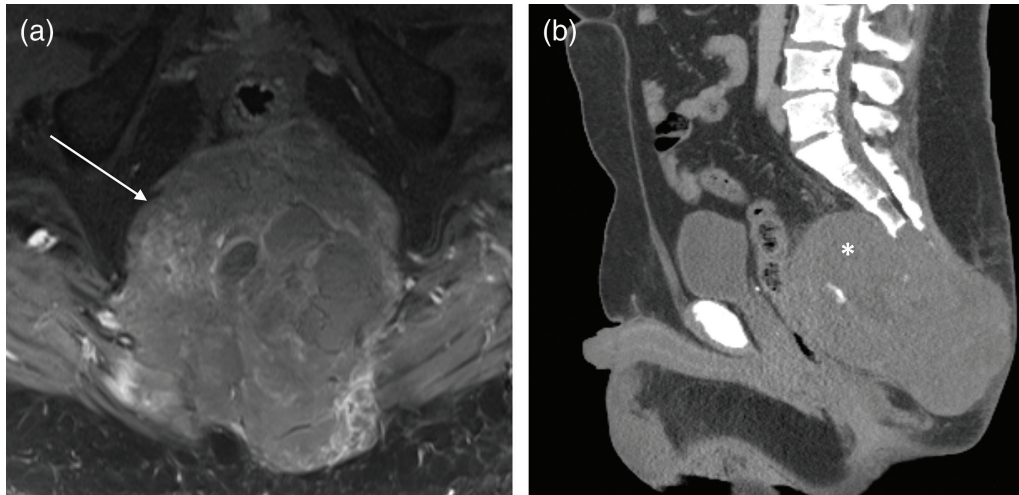


Figure 1 Representative axial MRI image (a, arrow) and sagittal CT image (b, *) showing the large sacral chordoma.

well-circumscribed pre-sacral mass involving the coccygeal tip, extending posteriorly to involve the sacral nerve roots (Figure 1a,b). He was then referred to our tertiary medical center for surgical evaluation and management.

Image-guided core biopsy of the mass confirmed the diagnosis of a chordoma. He underwent open excision of the sacral chordoma with bilateral S2 nerve sacrifice and sacrectomy by a multi-specialty team using the StealthStation surgical navigation system (Medtronic, Minneapolis, MN, USA). The chordoma was adherent to the distal rectum, so this was resected and repaired intraoperatively with subsequent laparoscopic diverting loop ileostomy. The total operative time was 10 hours with estimated blood loss of 1.5 L. The patient received 14 U packed red blood cells, 12 U fresh frozen plasma, and 2 U of platelets. He was transferred to the neurosurgical intensive care unit (Neuro ICU) postoperatively and was extubated on postoperative day (POD) 1.

The patient continued to recover expectedly until POD 8 when he was diagnosed with an acute deep venous thrombosis of the right gastrocnemius vein as well as a left upper lobe segmental pulmonary embolism. An unfractionated heparin infusion was initiated. On POD 9 the Neuro ICU team noted increased sanguineous drain output; CT angiography revealed a 15 cm × 15 cm × 8 cm hematoma in the surgical resection bed but no active extravasation. Later, while being turned in bed, the patient became acutely hypotensive, with increased sanguineous output noted from the pelvic Jackson-Pratt drains along with frank bleeding from the incision and per rectum. He also endorsed new severe right lower extremity radiculopathy, raising concern for neural element compromise.

The patient was tachycardic and hypotensive requiring vasopressors, but he remained interactive. Blood

product transfusion was initiated, and the massive transfusion protocol was activated. Given new neurologic symptoms and ongoing rapid blood loss, open surgical exploration was deemed necessary to relieve any compression on the neural elements and to achieve hemostasis. While the operating room was being prepared, early femoral arterial access was obtained for placement of a REBOA catheter as a bridge to definitive surgical hemostasis. Consent was waived in the emergency setting, and a 7 French (Fr) arterial access sheath was placed in the patient's left femoral artery under ultrasound guidance. The femoral sheath was secured in place using silk suture and a clear, sterile surgical dressing.

The patient's hemodynamics improved with resuscitation, so Zone 1 REBOA was deferred. We decided instead to use Zone 3 REBOA to facilitate surgical exposure and hemostasis during prone positioning. After induction of general anesthesia in the operating room, a REBOA catheter (Prytime Medical Devices, Inc., Boerne, TX, USA) was introduced through the left femoral sheath and advanced to the 30 cm corresponding with distal aortic positioning. The balloon was inflated with a small volume of saline and the catheter was seated at the aortic bifurcation with an attendant decrease in pulsations on the arterial line tracing from the access sheath. The balloon was then deflated to minimize inflation time during positioning. The catheter was anchored with multiple sutures including one in the bifurcation between the balloon and pressure monitoring ports. A surgical team member was dedicated to monitoring the catheter during all positioning maneuvers.

Following hematoma evacuation in the prone position the patient's hemodynamics worsened and the source of bleeding was confirmed to be adjacent to multiple nerve roots, presumably from the pudendal artery. To facilitate visualization and operative hemostasis near



Figure 2 Intraoperative vital signs showing the abdominal aortic pressure above (109/61) and below (49/41) the Zone 3 balloon. Complete occlusion was confirmed with the lack of pulsatile flow distal to the balloon.

multiple nerve roots, the balloon was inflated to achieve distal aortic occlusion for a total time of 34 minutes (Figure 2). After hemostasis was achieved with a combination of bipolar cautery and ligation of the pudendal artery, the patient was returned to the supine position and the catheter was removed, with both catheter tip and the balloon intact. Total operative time was approximately 4 hours, estimated blood loss was 1.5 L, preoperative hemoglobin concentration was 10.1 g/dL and postoperative hemoglobin was 10.7 g/dL, postoperative platelet count was 152, and the international normalized ratio was 1.2 following intraoperative administration of 3 U packed red blood cells, 5 U fresh frozen plasma, 1 U cell saver, and 1.5 g calcium gluconate. The 7 Fr access sheath was removed several hours later in the Neuro ICU once hemostasis was assured with no evidence of continued coagulopathy.

Following this procedure, systemic anticoagulation was held, and an inferior vena cava (IVC) filter was placed to mitigate the risk of further venous thromboembolic events. Unfractionated heparin infusion was resumed on POD 8 after the REBOA procedure. On POD 12 once assured that the patient was neurologically stable while on therapeutic anticoagulation, he was transitioned to low molecular weight heparin.

In the subsequent weeks, the patient underwent embolization of a pudendal and inferior gluteal artery

pseudoaneurysms, completion abdominoperineal resection with ileostomy take-down and end-descending colostomy, and complex wound closure with an omental flap. He was discharged to an acute rehabilitation facility in stable condition on hospital day 68.

Ethical Approval and Informed Consent

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

DISCUSSION

The safety of REBOA for use in civilian and military trauma systems as an adjunct for the control of non-compressive truncal hemorrhage has been well established [1,2,5,6]. Here, we describe the novel use of REBOA as a bridge to definitive surgical hemostasis in a non-compressible pelvic hemorrhage following resection of a large sacrococcygeal chordoma. Pre-positioning the REBOA catheter in Zone 3 prior to prone positioning afforded maximal flexibility with our hemostatic options on exploring the surgical site. Once the area of hemorrhage was exposed, it became clear proximal vascular control was needed to permit hemostasis without risking nerve injury. We thus inflated the balloon and were then able to control the site of hemorrhage from the pudendal artery precisely.

The indications and benefits for the use of REBOA as an adjunct for managing acute non-traumatic exsanguination are still emerging. Several case series describe the use of REBOA in postpartum hemorrhage and upper gastrointestinal bleeding [7,8]. A recent multi-institutional review of 37 patients with acute non-traumatic hemorrhage in which REBOA was deployed (43% gastrointestinal bleeding, 22% Zone 3) found its use was associated with an improvement in hemodynamics in 80% of cases in which the balloon was inflated, with a mean inflation time of 35 minutes [9]. None of the Zone 3 deployments resulted in patient death, whereas Zone 1 deployment was associated with a 50% mortality rate. This presumably correlates with the more acute nature of gastrointestinal bleeding events (i.e. variceal hemorrhage or bleeding secondary to peptic ulcer disease), complications (i.e. aspiration), as well as the patients comorbidities (i.e. cirrhosis and portal hypertension). Interestingly, seven (19%) of the REBOA insertions in this series were prophylactic and did not result in balloon inflation [9].

Additional case series cite similar instances in which the use of REBOA may prove advantageous, such as in obstetric emergencies, upper gastrointestinal hemorrhage, ruptured aortic aneurysms, and even in non-traumatic cardiac arrest. In one series of 11 patients in which REBOA was utilized to help control non-traumatic

hemorrhage, there were no complications directly related to vascular access, and the overall in-hospital mortality was 65% [10]. Partial balloon occlusion has also been described as an adjunct to achieving hemodynamic stability while potentially sparing the risk of reperfusion injuries [11].

CONCLUSIONS

In this case report, we describe REBOA as a bridge to surgical hemostasis in a patient with severe, life-threatening postoperative hemorrhage following resection of a large sacral chordoma. Zone 3 REBOA insertion in this case allowed for more precise localization of the source of hemorrhage near multiple nerve roots. This report provides further evidence for expanded applications for REBOA in non-traumatic hemorrhagic shock. Larger studies are warranted to quantify the potential morbidity or even mortality benefits in these patients.

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 of this publication have no disclosures nor conflicts of interest relevant to the topic of this publication.

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Author Contributions

All authors have substantially contributed to the study and manuscript.

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Prolonged Partial REBOA: A Practice Paradigm for Managing Hemorrhage from Abdominal Gunshot Wounds

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Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a valuable tool for management of life-threatening truncal hemorrhage. However, prolonged use of REBOA is limited by the ischemia that it causes distal to the occlusion. Partial REBOA (pREBOA) is a developing technique to inflate the balloon partially to allow for a variable degree of distal blood flow and mitigate some of the complications of prolonged occlusion of the aorta while also ameliorating ongoing blood loss. We describe a case of a patient who presented with a gunshot wound to the right upper quadrant of the abdomen with significant liver, kidney, and colon injuries. The patient was successfully treated with pREBOA for 20 hours without ischemic sequelae. This is the longest reported use of prolonged pREBOA and suggests that this technique may offer a means for hemorrhage control in the pre-/intra- and postoperative settings.

Keywords: *Resuscitative Endovascular Balloon Occlusion of the Aorta; REBOA; pREBOA; Penetrating Trauma; Hemorrhage Control*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a technique that can be utilized to assist with temporary control of noncompressible truncal hemorrhage [1]. It involves placement of a balloon catheter into the descending thoracic aorta (Zone 1) or just proximal to the aortic bifurcation (Zone 3) in order to arrest distal blood flow and ongoing hemorrhage. However, its use is associated with a range of possible complications such as liver failure, intestinal ischemia and limb loss due to ischemia downstream of the occlusive balloon [2]. Studies have demonstrated occlusive times beyond 60 minutes for Zone 1 and 90 minutes for Zone 3 are almost universally fatal [3]. Partial REBOA

(pREBOA) has been proposed as a means to allow for control of life-threatening hemorrhage while maintaining some distal perfusion with encouraging results in animal models [4]. The time limits of partial aortic occlusion are not yet completely elucidated.

We present a case in which an ER-REBOA Plus catheter remained in place for 20 hours while the occlusive balloon was variably deflated without any ischemic complications following a gunshot wound to the right upper quadrant of the abdomen.

CASE REPORT

A 57-year-old man presented after a single high-velocity rifle wound to the right upper quadrant of the abdomen. On arrival at the hospital, he was lethargic and had abdominal tenderness with guarding. Initial blood pressure and pulse were 116/54 mmHg and 73 beats per minute, respectively. Bedside ultrasound showed free fluid in the abdomen and chest x-ray showed shrapnel in the right upper quadrant with a retained bullet in the mid back near L1. Computed tomography (CT) scan of the abdomen and pelvis showed a grade V injury to the right kidney, grade IV right hepatic lobe injury with active hemorrhage and a right colon injury (Figure 1a,b).

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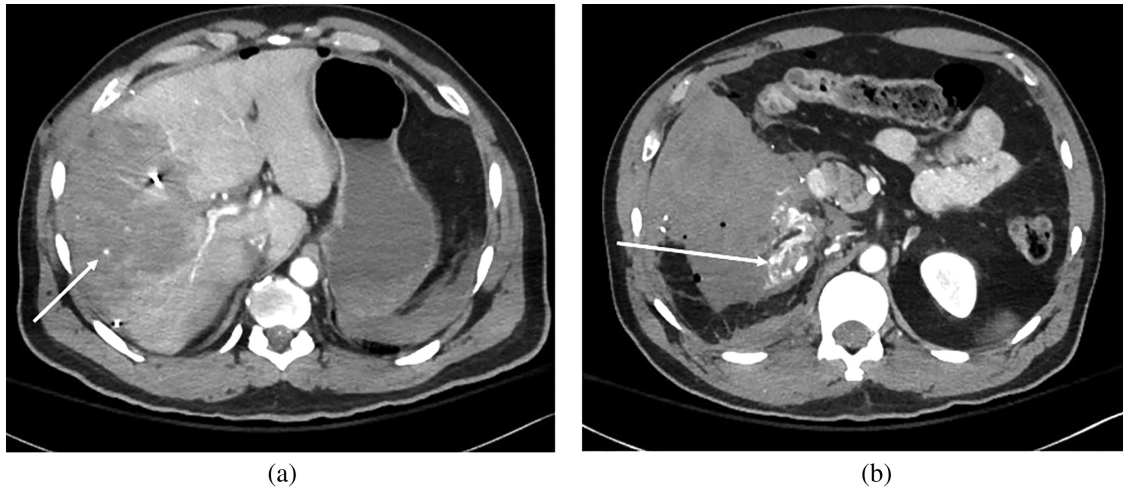


Figure 1 CT images showing (a) a grade 4 right hepatic lobe injury and (b) a grade 5 injury to the right kidney with active hemorrhage, and a right colon injury at the hepatic flexure. The arrows point to areas of active arterial hemorrhage.

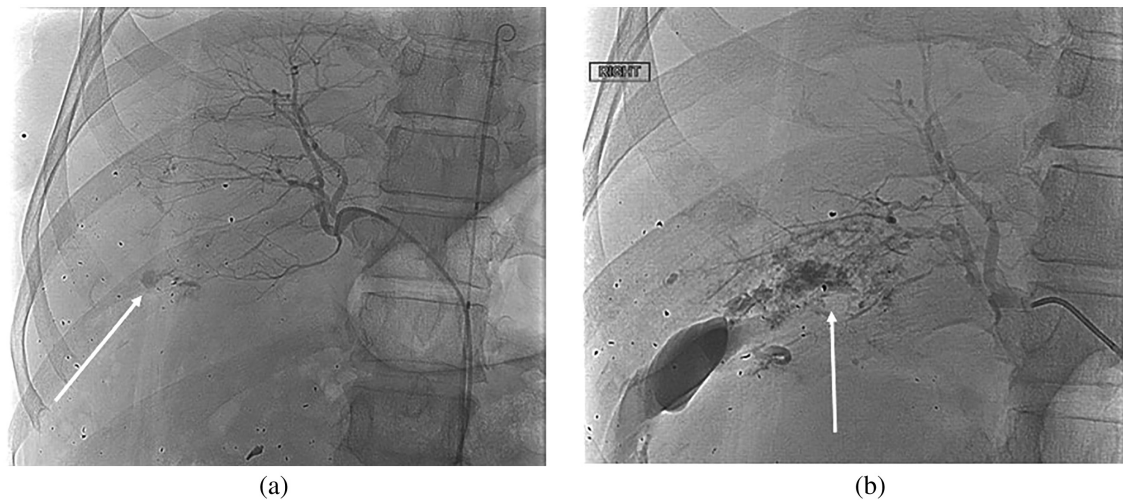


Figure 2 Selective angiography of the liver showing (a) hemorrhage from the area of segment 8 and (b) the right kidney showing multifocal arterial hemorrhage. Shrapnel is seen throughout the right upper quadrant of the abdomen, predominantly over the liver. The arrows point to areas of active arterial hemorrhage.

Interventional radiology was consulted for embolization of the right hepatic and right renal arteries, massive transfusion was started and the patient received tranexamic acid. His blood pressure decreased to 90/50 mmHg shortly after CT scan. Therefore, right common femoral arterial access was obtained, and an ER-REBOA Plus catheter with full balloon inflation (8 ml) was placed in Zone 1 with improvement in the patient’s blood pressure to 102/46 mmHg prior to transport to interventional radiology. He underwent embolization of the right hepatic and right renal arteries (Figures 2a,b and 3a,b), which took 70 minutes and received 3 units of packed red blood cells and 3 units of plasma during this time. The balloon was deflated during the interventional radiology procedure.

He was then taken to the operating room for a nonanatomic right hepatectomy and perihepatic packing, right

nephrectomy, right colectomy, and placement of temporary abdominal dressing. Throughout the 147-minute operation, the REBOA balloon was intermittently partly deflated to 3–5 ml volume and re-inflated to 8 ml (100%) occlusion to allow perfusion of the abdominal viscera while minimizing ongoing blood loss from the liver. There were no overt signs of bowel ischemia, but the team was concerned about the ramifications of prolonged ischemia on the remaining kidney, liver, lower extremities as well as the alimentary tract. At the conclusion of the case, the REBOA balloon remained inflated with 4 ml of fluid. He received a total of 39 units packed red blood cells, 28 units plasma, 5 units platelets, 10 units cryoprecipitate and was maintained on a continuous plasma infusion for the next 4 hours in the intensive care unit (ICU) due to ongoing severe

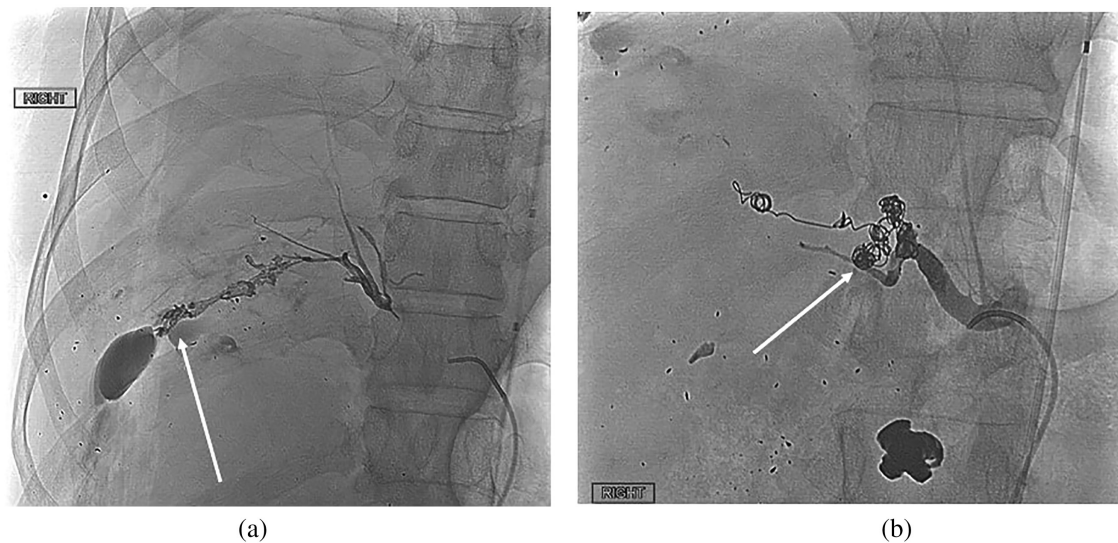


Figure 3 Angiography images following selective coil and ethylene vinyl alcohol copolymer Onyx (Medtronic, Minneapolis, MN). **(a)** Embolization of the right hepatic and right distal renal arteries. **(b)** The retained bullet fragment is seen overlying the vertebral body at the bottom of the image.

coagulopathy. The REBOA balloon remained inflated with 4 ml of fluid for 6 additional hours in the ICU and then was sequentially deflated, first to 3 ml of fluid for 2 hours and then completely deflated. In total, the REBOA catheter was in place and variably inflated from 0% to 100% for 20 hours while the femoral sheath remained in place for a total of 24 hours. Twenty-four hours after arrival, he returned to the operating room for repair of a diaphragm laceration, creation of an end ileostomy, placement of perihepatic drains, and abdominal closure. Intraoperatively, there was no evidence of bowel necrosis or ischemia. Post-intervention, there were also no access site-related complications or ischemia to the extremity.

His hospital course was complicated by transient renal failure and a bile leak, which was treated with biliary stent and sphincterotomy. He was ultimately discharged neurologically intact to rehabilitation after a 25-day hospitalization. He is now home, off dialysis, and on a regular diet.

Ethical Approval and Informed Consent

The study was deemed to be exempt from IRB review and the need to obtain informed consent.

DISCUSSION

The most common cause of preventable death following injury is hemorrhage. Control of hemorrhage within the torso requires urgent embolization and/or operative intervention. Hemorrhage control from the liver is particularly difficult due to its dual blood supply from the portal vein and hepatic artery as well as inability to resect the organ entirely. Embolotherapy offers a means

to control solid organ arterial bleeding, but requires time and is relatively contraindicated in hemodynamically unstable patients. REBOA offers a means to control aortic blood flow using an endovascular approach and pREBOA offers a means to allow some ongoing blood flow to the body while minimizing blood loss [5]. Zone 1 placement involves balloon positioning in the mid descending thoracic aorta to control blood loss in the abdomen. pREBOA offers the ability to control distal blood flow dynamically based on a patient's hemodynamics and ongoing blood loss. In this case, placement of a REBOA catheter with partial inflation afforded us the time and hemodynamic stability necessary to proceed with embolotherapy. We also embolized the kidney despite knowing that the patient would require nephrectomy in order to minimize blood loss. This procedure required little additional time. By initially embolizing the injured organs, we mitigated the risk of uncontrolled arterial hemorrhage at the time of laparotomy. We were able to titrate the degree of balloon occlusion based on the patient's blood pressure without rapid exsanguination from injured organs, and could restore full aortic occlusion when blood loss was excessive while transfusion was ongoing. As time elapsed, we partly deflated the balloon to allow for distal flow and titrated the degree of deflation based on the impact this had on his blood pressure. Even following operation, the patient required prolonged partial aortic occlusion due to his severe hepatic injury, blood loss, and shock which resulted in a severe coagulopathy.

Studies on REBOA have not consistently found a mortality benefit [6]. Mortality may not be the appropriate endpoint to assess this modality. Rather, time to and degree of hemorrhage control, which are highly

associated with death, may be better measures of efficacy. In this case, we were able to slow ongoing hemorrhage, which was initially due to organ injury and then due to coagulopathy, to allow time for embolotherapy, operative intervention, and repletion of coagulation factors while simultaneously allowing for distal aortic blood flow. Deflation of the balloon during operation and shortly after arrival to the ICU resulted in recurrent, severe hypotension. We suggest that this supports our belief that prolonged partial REBOA was necessary.

This is the first report of prolonged use of a REBOA catheter with partial aortic occlusion. Current guidelines recommend maximum 30–60 minute Zone 1 aortic occlusion to avoid organ ischemia. However, these guidelines are based on complete aortic occlusion. pREBOA allows for partial occlusion and thus a variable degree of distal blood flow [7–9]. A flow rate of 0.5 L/min has been shown to be effective at preventing ischemia while minimizing hemorrhage in swine [10]. The current pREBOA catheter, which is not the catheter used in this case, allows for measurement of aortic pressure across the balloon. Studies are now needed to compare pREBOA with direct (open) hemorrhage control in terms of blood loss/transfusion need and organ ischemia as well as to correlate distal aortic pressure with actual flow and ischemic threshold. Use of prolonged pREBOA may represent a minimally invasive means to slow down hemorrhage in order to offer endovascular means for definitive hemorrhage control and/or to minimize intraoperative and postoperative blood loss following severe injury in select cases.

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

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Author Contributions

All authors contributed equally to the project.

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A Prospective Meta-Analysis (PMA) Could Harmonize the Studies Focusing on Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)

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With the rapid development of novel surgical devices such as Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) and the eagerness of clinicians to use them, there is a risk that their usage in clinical practice exceeds the evidence-based principles required for their introduction. This might be truer in the fields, such as trauma surgery, where the patient population and the disease (injury) burden are very heterogeneous and time-sensitive, and thus not fitting for the more gold standard investigation methods. The studies that are currently being published considering the use of REBOA in clinical settings have significant limitations and raise concerns in terms of the risk of biases that might influence the gold-standard evidence-based synthesis. This paper elaborates on the merits of a Prospective Meta-Analysis (PMA) in reducing such biases.

Keywords: *Prospective Meta-Analysis; Resuscitative Endovascular Balloon Occlusion of the Aorta; Surgery; Trauma; Wounds; Injuries*

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DEAR EDITOR,

With the rapid development of novel surgical devices and the eagerness of clinicians to use them, there is a risk that their usage in clinical practice exceeds the evidence-based principles required for their introduction. This might be truer in fields such as trauma surgery, where the patient population and the disease (injury) burden are very heterogeneous and time-sensitive, and thus not fitting for the more gold standard investigation method where patients are randomized to a treatment. This has led to retrospective or prospective non-randomized analyses of different treatments in the

trauma setting. However, new-generation statistical methods have given the opportunity to tackle this challenge by using these non-randomized data to gain high-quality evidence synthesis.

In a recent publication by Castellini and colleagues, the authors investigated the effectiveness of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in the management of major bleeding from torso injuries due to trauma by using a comprehensive systemic review and meta-analysis [1]. Exsanguinating hemorrhage is still the leading cause of preventable deaths after traumatic injury [2]. During the last decade, there has been a rapid development in REBOA devices and techniques as well as educational efforts for their use to get temporary hemorrhage control [3]. However, their role in clinical practice has been questioned and, to a large extent, compared to Resuscitative Thoracotomy (RT). The aforementioned study compares REBOA vs RT with/without REBOA, and REBOA vs non-REBOA. The results of the meta-analysis showed a significant decrease in mortality in the REBOA compared to RT subgroups, which was consistent with previous systematic reviews [4,5]. Nevertheless, as the

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authors do declare in their manuscript, there are several limitations with their investigation in terms of study design, participant selection bias, survival bias, and also heterogeneity and selection bias in reporting the results in the included studies in the meta-analysis.

To overcome these limitations, prospective collaborative methods with the use of Prospective Meta-Analysis (PMA) that has the capability of enhancing the breadth of evidence synthesis could be of value. In a PMA compared to a conventional retrospective meta-analysis, the studies are identified and evaluated to be eligible for inclusion before the results of these studies are released. To find the planned and ongoing studies, a systematic search in clinical trials and cohort registries and, subsequently, early contact with the investigators should be undertaken [6]. The cornerstone of a PMA is that the analysis strategies are determined before any results to the research question are known [7]. Therefore, a PMA has the capability of reducing the risk of publication bias and selective outcome reporting bias by agreeing on a standard set of core measures and time-point outcomes with the investigators in advance. In addition to its benefits in harmonizing the key outcomes, it has the capability of collecting studies with varied participants, selection criteria, and intervention design, which is the superiority of PMA over a multi-center study [8].

Apart from the conventional method of conducting a PMA (using the summary of results), it can also be designed in the context of a network meta-analysis or an individual patient data analysis. Through a network meta-analysis, instead of comparing two interventions with a narrow research question, the investigators can visualize and interpret all treatments for a given condition or disease, and all the possible comparisons between them, such as REBOA, partial REBOA, RT, and no-REBOA, can be included in the network meta-analysis to compare and assess their effectiveness. In a meta-analysis of individual patient data, instead of using summary data of each published paper, the raw data of each individual and participant can be collected and analyzed [9].

Although conducting a PMA could decrease several potential sources of bias, it may have some difficulties in terms of collaboration and forming a research network. Some investigators may not cooperate to contribute their data. A paradigm shift in moving from conventional retrospective systematic reviews and meta-analyses has its challenges since there is an innate tendency against changes in how individual physicians practice medicine, and also between healthcare systems. Here, the involvement of surgical societies or organizations is of great importance, as they could play a leading role.

In conclusion, the number of studies investigating the role of REBOA in trauma, especially in early hemorrhage control, is increasing. Most of these studies have limitations in their methodology that raise

concerns for the conclusions drawn. Here we propose PMA as a new-generation statistical method. The role of leading surgical societies as stakeholders to increase collaboration for PMA is of importance. Although PMA is no magic wand to fix all the methodological limitations that arise in clinical studies where randomization is not feasible, it has the potential to harmonize the studies included in the meta-analysis to a greater extent.

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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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Author Contributions

MHT and SM developed the presented idea. MHT and RB prepared the first draft of the paper. All authors contributed to the final version of the manuscript.

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Supporting Cardiac Perfusion by pREBOA with Reduced Visceral Ischemia Despite Extended Occlusion

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Keywords: pREBOA; Partial REBOA; Trauma, Hemorrhage, Shock, Proximal Control, REBOA, Zone 1, Zone 3; Partial or Intermittent REBOA; Ischemia-Reperfusion Injury; REBOA, Trauma, Aortic Occlusion, Injury, Hemorrhage

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INTRODUCTION

Partial resuscitative endovascular balloon occlusion of the aorta (pREBOA) has been shown to have less distal organ injury when compared to complete occlusion, thus safely allowing longer occlusion times. Its use is gaining momentum as an adjunct for patients with noncompressible truncal hemorrhage. Current clinical guidelines recommend avoiding REBOA in polytrauma where proximal chest injuries are suspected [1]. However, there is an increasing interest in the use of REBOA as an adjunct to surgical treatment in polytrauma patients due to the nature of their injuries. The objective of this case report was to present the successful use of pREBOA to Zone 1 in a patient with hemorrhagic shock secondary to a blunt cardiac injury that did not result in visceral ischemia despite an extended partial occlusion time of 3 hours.

CASE REPORT

A 28-year-old male restrained driver was involved in a motor vehicle collision with multiple traumatic injuries. Systolic blood pressure (SBP) was unattainable on arrival

and thus the massive transfusion protocol (MTP) was activated and pREBOA was placed at 48 cm in Zone 1. A left chest tube was placed after chest X-ray and large volume bloody output immediately returned. The patient was not stable enough for imaging and he was taken directly to the operating room for surgical exploration. A median sternotomy was performed and an injury to the left ventricle was found and repaired. Partial REBOA remained in Zone 1 for a total of 3 hours (proximal SBP 80s, distal SBP 30–60s). The patient had on-going hypotension when the REBOA balloon was deflated, and subsequently an exploratory laparotomy was performed which revealed hemoperitoneum from a mesenteric injury. The abdomen was packed and the REBOA balloon was deflated followed by catheter removal in the Operating Room. The patient was transferred to the Intensive Care Unit for on-going resuscitation and eventual abdominal closure two days after his initial surgery. No lab marker indications of renal hypoperfusion were found post-operatively, nor any other markers of ischemic sequelae to viscera were noted in the post-operative period.

Ethical Approval and Informed Consent

Ethical approval was not required. Informed consent was not possible because of the retrospective nature, the information has been anonymised.

DISCUSSION

For patients with impending cardiac arrest from circulatory collapse, REBOA offers a less invasive alternative to the traditional resuscitative thoracotomy, with aortic cross clamping as a temporizing measure to increase

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coronary and cerebral perfusion pressures, decrease the workload on the heart, and get the patient to definitive repair [2].

While aortic occlusion increases coronary and cerebral blood flow, this also means increased blood flow to any injury above the point of REBOA deployment, thus worsening hemorrhage and hemodynamic collapse [3]. This can be detrimental if not quickly followed by a definitive intervention, and thus current recommendations do not support the use of REBOA in the management of proximal thoracic injuries.

Our findings challenge this recommendation, as the hemodynamic support provided by pREBOA allowed the patient to be taken for definitive repair of his proximal injury that otherwise would not have been possible. Furthermore, partial occlusion to Zone 1 was safely utilized in our patient for an extended time of 180 minutes without any resultant hypoperfusion-related injury to downstream viscera as previously described with complete occlusion.

CONCLUSION/LEARNING POINTS

We present the successful utilization of pREBOA in Zone 1 to bridge a critically ill polytrauma patient to the operating room for definitive management after blunt injury. Use of pREBOA supported coronary perfusion throughout the operation, and controlled bleeding from a mesenteric injury without causing any resulting ischemic damage. Our findings suggest that pREBOA can be sustained for as long as 180 minutes without negative distal sequelae and can be used as an adjunct to surgery in the management of proximal blunt thoracic injuries.

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

Dr Smith is on the advisory board for Prytime Medical. The authors have no other disclosures nor conflicts of interest.

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Author Contributions

All authors have substantially contributed to the case report.

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A Case Report of Partial Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Non-Traumatic Gastrointestinal Hemorrhage

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Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a tool used in the management of hemorrhagic shock in trauma patients. REBOA has also been proposed as an option for non-traumatic hemorrhage, such as gastrointestinal (GI) hemorrhage. In this case report, the use of a partial REBOA (p-REBOA) for a patient with an acute upper GI hemorrhage is presented as a management strategy to temporize bleeding.

Methods: Case information was obtained from the electronic medical record at the University Medical Center in New Orleans.

Results: A 46-year-old woman presented to the Emergency Department with concern for an upper GI bleed. The patient was tachycardic on presentation and then quickly became unresponsive. Massive transfusion protocol was initiated and a p-REBOA catheter was placed in Zone 1. After the REBOA was inflated 20 mL in 2 mL increments, the patient's blood pressure improved, while maintaining distal perfusion. An exploratory laparotomy, with an angiogram once the patient had been stabilized, was planned. Despite resuscitative efforts for more than 2 hours, the patient progressed to cardiac arrest and did not have return of spontaneous circulation.

Conclusions: This case report describes the use of p-REBOA in Zone 1 to control hemorrhage in a patient with a suspected upper GI bleed. This strategy could be utilized in patients with suspected non-traumatic hemorrhage in order to control bleeding temporarily and allow for ongoing resuscitation and stabilization of a patient prior to definitive treatment.

Keywords: REBOA; GI Bleed; Hemorrhage; Massive Transfusion; Bleeding Control

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INTRODUCTION

Hemorrhagic shock is estimated to be the cause of more than 1.9 million deaths per year, worldwide, and more than 60,000 deaths per year in the United States [1]. Non-traumatic causes of bleeding are often overshadowed by traumatic etiologies. Gastrointestinal (GI)

bleeding, more specifically peptic ulcer disease, encompasses a large proportion of those deaths. GI bleeds are responsible for more than 1,800 deaths per year in the United States and more than 140,000 worldwide [1].

During the Korean War, occlusion of the aorta to temporize major bleeding was first described in the 1950s for the management of hemorrhage, and is now gaining favor as an alternative to resuscitative thoracotomy in the setting of refractory hemorrhagic shock [2,3]. Resuscitative endovascular balloon occlusion of the aorta (REBOA) was initially designed to control traumatic intra-abdominal or pelvic hemorrhage [4]. However, more experience with the use of REBOA for the management of non-traumatic hemorrhagic shock has emerged [1,2]. A newer generation of REBOA, the partial REBOA (p-REBOA), has been studied more recently with the goal of decreasing the risk of ischemia-reperfusion injury to distal organs, as it allows a small amount of blood to flow past the balloon while inflated [5].

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REBOA deployment can act as a stabilizing measure until definitive control of bleeding can be achieved. However, REBOA use remains infrequent – one postulation to its limited use is due to less familiarity with deploying REBOA [2]. One of the most common indications for REBOA deployment in the setting of non-traumatic hemorrhage is GI bleeding. However, use in non-traumatic settings has not been well established, with limited case numbers and even more limited studies performed [2,3]. The objective of this study is to present a case report on the use of p-REBOA to temporize a suspected non-traumatic upper GI bleeding in a hemodynamically unstable patient, and improve the management of hemorrhagic shock.

CASE REPORT

A 46-year-old woman with no significant past medical history presented to the Emergency Department of a Level 1 Trauma Center with altered mental status. The patient was tachycardic and normoglycemic on initial evaluation, but quickly became unresponsive. Advanced Cardiac Life Support Protocol was initiated, the patient was intubated, and an orogastric tube was placed with return of approximately 1 L of bright red blood. Trauma Surgery was emergently consulted given the concern for GI bleeding.

Massive transfusion protocol was initiated and a p-REBOA was placed in an attempt to temporize the patient's ongoing hemorrhage. The existing femoral arterial line was exchanged for a 7.5 French arterial sheath and the p-REBOA catheter was inserted to Zone 1. The balloon was inflated to a maximum volume of 20 mL in 2 mL increments. Pressures were intermittently detected distal to the balloon following inflation. The p-REBOA remained inflated throughout resuscitation efforts. In order to obtain definitive control of the suspected GI hemorrhage, an exploratory laparotomy and angiogram were planned in the hybrid operating room. Interventional Radiology was also consulted for the angiogram. Despite more than 2 hours of maximum resuscitation efforts, the patient progressed into pulseless electrical activity before any definitive intervention could be performed. Further resuscitative efforts were terminated.

Ethical Approval and Informed Consent

Ethical approval was not required. Informed consent was not possible given the retrospective nature of the report, and any personal information has been anonymized.

DISCUSSION

The causes of hemorrhage are many, including but not limited to trauma, postpartum hemorrhage, GI hemorrhage,

perioperative hemorrhage, and aneurysmal rupture; they are major causes of death worldwide annually [1]. Improving mortality secondary to hemorrhage requires a multi-faceted approach including prevention of hemorrhage, early control of hemorrhage, and reduction of time to definitive hemostasis [1]. One such advancement on the front of early hemorrhage control has been REBOA and p-REBOA.

REBOA has been used for over 70 years, primarily in the setting of acute traumatic hemorrhage. It has gained favor in settings of refractory hemorrhage in which the alternative would be resuscitative thoracotomy [3]. With advancements in endovascular technology, REBOA has been used in a wider range of patients in the emergency setting of acute, non-traumatic hemorrhage [2,6]. More recently, p-REBOA has been studied to reduce the risks of ischemia-reperfusion complications to tissue distal to the balloon [5]. While the mortality rate in this patient population is high, there have been low incidences of access site-related complications [6].

Future research would be beneficial in determining appropriate patient selection for REBOA deployment. Furthermore, in scenarios such as the one presented in this case report, in which REBOA/p-REBOA is used as a temporizing measure, an important variable to account for would be time to deployment of REBOA. Studies focused on efficacy of REBOA/p-REBOA should be directed at scrutinizing outcome measures other than mortality directly related to deployment, to determine better potential scenarios in which REBOA/p-REBOA would be most helpful. Given its potential as a temporizing measure in the setting of acute hemorrhage, REBOA/p-REBOA could be a powerful tool in the arsenal of the surgeon during resuscitation efforts.

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, MD, PhD is a paid consultant for Aroa Biologics and on the advisory board for Prytime Medical.

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Education



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

One of the main EVTMS-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 EVTMS 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 EVTMS-ST case discussions,
please email: david.mcgreevy@regionorebrolan.se

Coming Meetings

Satellite International Conference “Modern Management of Severe Orthopaedic Injuries in War, Mass Casualty Situations and Humanitarian Disasters”, 31 March 2023, Riga, Latvia
<https://rw2023.rsu.lv/events/satellite-international-conference-modern-management-severe-orthopaedic-injuries-war-mass>

ECTES European Congress 2023, 7 May 2023, Ljubljana
<https://estes-congress.org/general-information/welcome-note>

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

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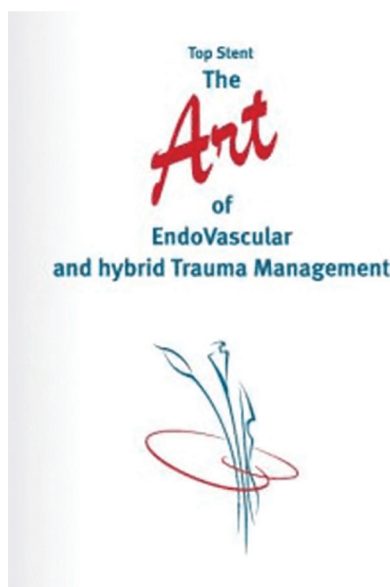
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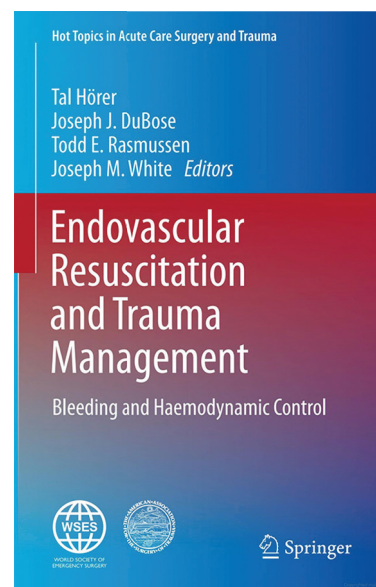
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ESTES CONGRESS 2023 – LJUBLJANA, SLOVENIA

**EVTM Guest symposium – a paradigm shift
in management of bleeding patients**



**Date: 2023-05-07
Time: 08:30–10:00**

The European Society for Trauma and Emergency Surgery (ESTES) yearly conference (ECTES) is this year going to be held in Ljubljana, Slovenia between the 7-9th of May. They are planning an attractive and exciting congress with many interesting topics to be presented and discussed. We are happy to inform all EVTSM Society members that as a result of very fruitful cooperation with the ESTES president and board of directors, EVTSM has been invited to host a guest symposium during the conference. We hope that as many as possible can take part and attend this congress and the EVTSM guest symposium. Please spread this information and hope to see you all in Ljubljana.

Best regards,
EVTSM president
Boris Kessel

