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Issue Highlights

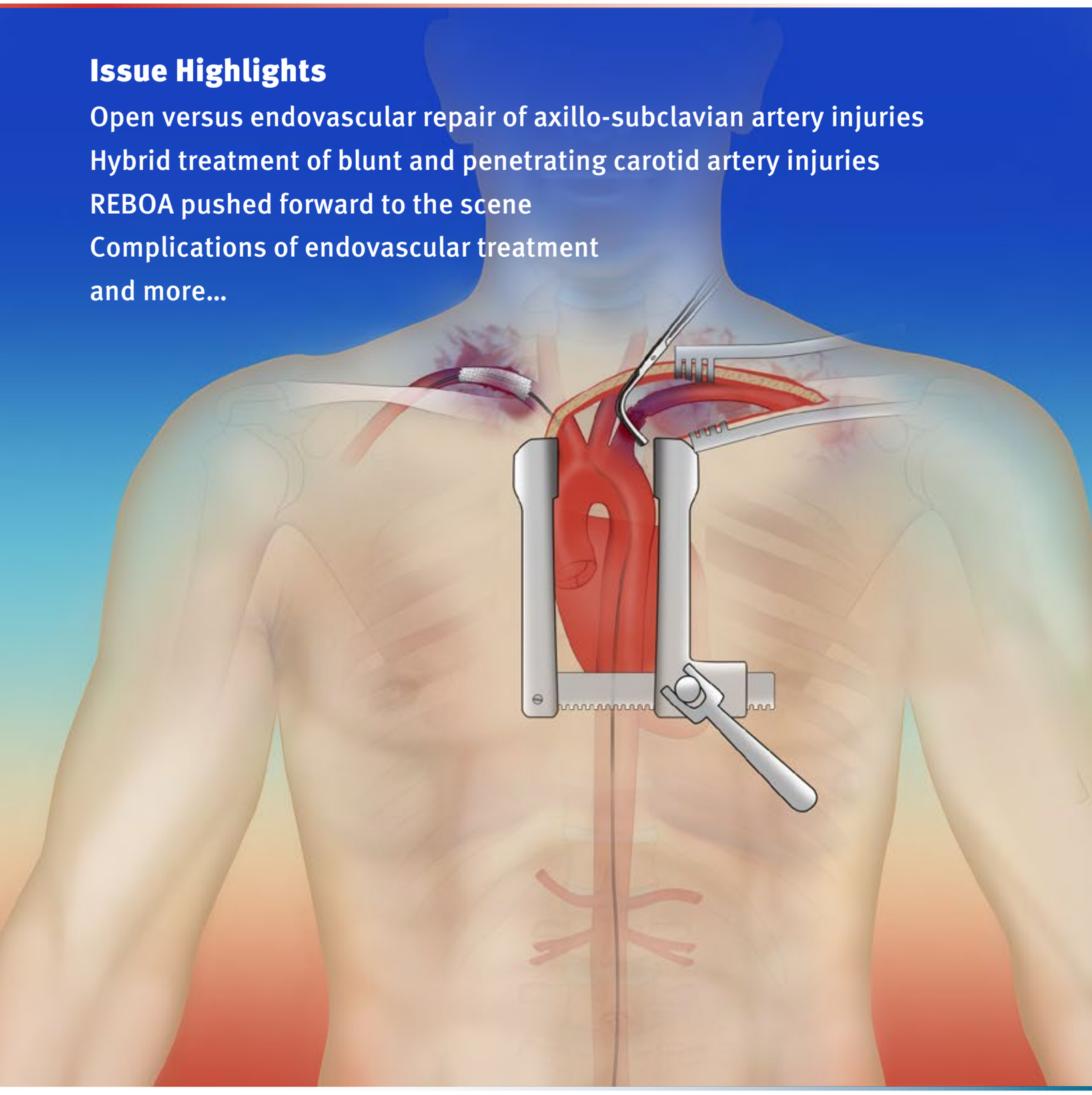
Open versus endovascular repair of axillo-subclavian artery injuries

Hybrid treatment of blunt and penetrating carotid artery injuries

REBOA pushed forward to the scene

Complications of endovascular treatment

and more...



Official publication of the Society of Endovascular Resuscitation and Trauma Management

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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 Örebro University Hospital Research Unit.

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 quarterly 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 and Web Of Science.

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

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)

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.

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, along with highest academic degree.
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- Author Contributions: All authors are expected to have substantially contributed to the study and manuscript writing.
- Funding Declaration: Any grant funding should be listed.
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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
Sub-Heading Bold and Italicized
Sub-sub-heading Italicized

Abstract
The abstract should be a maximum of 250 words and consist of the following headings:

Background
Methods
Results
Conclusions

Original Studies
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. 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.

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, 1the advice and opinion of actively practicing clinicians is of great importance. Both solicited and unsolicited submissions are reviewed, both on major or minor components on endovascular techniuqes . This can be presented in the context of â€œevidenceâ€ or just as an opinion. The use of quality images and diagrams is encouraged. The submission should be a maximum of 1500 words.

Author Guidelines

Images of Interest
Rather than accept case reports, the Journal will prefere 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.

Resident Corner
Short article managed and written by residents (no senior authors) with educational value (max word count 1500)

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.

References
References should follow the Vancouver Style and should be noted in the text numerically in sequence within the text using square brackets, eg: [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.
Where there are more than six authors, the first three should be included followed by et al .

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.

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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 is 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 in this section.

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 reractions or corrections of mistakes after 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). Please follow the ethical guidlines as explaied also in the "intractuins for authors" section.

Detailed ethical guidelines

Maintaining integrity of the research and its presentation is helped by following the rules of good scientific practice, which is 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.

Author Guidelines

(continued)

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.

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Patient Anonymity and Informed Consent
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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 documenting animals studies, might be the ARRIVE reporting guidelines (PLoS Bio 8(6), e1000412,2010). We encourage 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 as possible if a waiver of regulatory requirements for obtaining and documenting informed consent applies.

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.

The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained it should be indicated in the published article.
– International Committee of Medical Journal Editors ("Uniform Requirements for Manuscripts Submitted to Biomedical Journals") — February 2006

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 Endoascular 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 two 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.

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

Contents

Original Article

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Contemporary Management of Axillo-subclavian Arterial Injuries Using Data from the AAST PROOVIT Registry

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Background: Endovascular repair has emerged as a viable repair option for axillo-subclavian arterial injuries in select patients; however, further study of contemporary outcomes is warranted.
Methods: The American Association for the Surgery of Trauma (AAST) PROspective Observational Vascular Injury Treatment (PROOVIT) registry was used to identify patients with axillo-subclavian arterial injuries from 2013 to 2019. Demographics and outcomes were compared between patients undergoing endovascular repair versus open repair.
Results: 167 patients were identified, with intervention required in 107 (64.1%). Among these, 24 patients underwent open damage control surgery (primary amputation = 3, ligation = 17, temporary vascular shunt = 4). The remaining 83 patients (91.6% male; mean age 26.0 ± 16) underwent either endovascular repair (36, 43.4%) or open repair (47, 56.6%). Patients managed with definitive endovascular or open repair had similar demographics and presentation, with the only exception being that endovascular repair was more commonly employed for traumatic pseudoaneurysms ($p = 0.004$). Endovascular repair was associated with lower 24-hour transfusion requirements ($p = 0.012$), but otherwise the two groups were similar with regards to in-hospital outcomes.
Conclusion: Endovascular repair is now employed in >40% of axillo-subclavian arterial injuries undergoing repair at initial operation and is associated with lower 24-hour transfusion requirements, but otherwise outcomes are comparable to open repair.

Keywords: *Axillo-subclavian Injury; Endovascular Repair; Vascular; Trauma*

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Presentation: This paper outlines work that was associated with data accepted for a poster presentation for the 2020 Annual American Association for the Surgery of Trauma meeting, that was held virtually in September 2020.

*A full list of Study Group members and their affiliations appears at the end of the paper.

BACKGROUND

Injuries to the axillary and subclavian arteries account for approximately 5–10% of civilian and military vascular injuries[1,2]. These injuries are, however, associated with challenging open exposures and reported morbidity and mortality rates ranging from 5% to 39%[3,4]. In this study, axillary and subclavian artery segments are grouped together since these two close segment neighbors are located in the junctional region of the forelimb that requires similar exposure considerations.

Traditional management of axillo-subclavian arterial injuries requiring intervention mandated open surgical exposure and repair. More recently, however, endovascular management has emerged as a viable alternative for treatment in select patients. When compared to open repair (OR), endovascular repair (ER) has been shown to be associated with decreased operative time, lower estimated blood loss, fewer iatrogenic injuries in the area of trauma, lower in-hospital mortality, and decreased rates of sepsis[5–7]. As endovascular technologies continue to evolve and their utilization continues to increase, there remains an important need to review subsequent outcomes. The purpose of this study was to compare in-hospital outcomes of ER and OR using a contemporary prospective vascular trauma registry.

METHODS

After Institutional Review Board Approval, the American Association for the Surgery of Trauma (AAST) PROspective Observational Vascular Injury Treatment (PROOVIT) registry was used to identify patients with axillo-subclavian arterial injuries from 2013 to 2019. This voluntary registry allows for collection of data from collaborating trauma centers and is open to all vascular injuries occurring at participating trauma centers. Patient demographics included age, gender, mechanism of injury, admission vital signs, Injury Severity Score (ISS), and Abbreviated Injury Scale score for each body region. Interventional data included operative procedures. Recorded outcomes included blood products transfused during hospital admission, complications of repair (thrombosis/stenosis, delayed amputation), hospital length of stay (LOS), and mortality. Patient demographics and in-hospital outcomes were compared between patients undergoing ER versus OR. Categorical variables were compared using Chi-square or Fisher exact tests, and continuous variables were compared using Student's *t*-test or Mann–Whitney rank-sum test. Significant results were designated with *p*-values less than 0.05.

Ethical Approval and Informed Consent

Ethical approval to report these cases was given by the Institutional Review Board. Informed consent was not required.

RESULTS

At the time of the data pull for the present article, the PROOVIT registry contained 4357 patients. Among these, upper extremity injuries (subclavian, axillary, brachial, radial, and ulnar arteries) accounted for 1038 injuries, for a total of 23.8% (1038/4357). Among the upper extremity arterial injuries, axillo-subclavian accounted for 16.1% (167/1038) of upper extremity injuries (subclavian, axillary, brachial, radial, ulnar). From 2013 to 2019, there were 167 patients who sustained injuries to the axillary and subclavian arteries. Nonoperative management was used in 60 patients (35.9%), and 24 patients were managed with initial open damage control. These groups of patients were not included in the comparison between patients who received either definitive ER or OR (Figures 1 and 2). In the 24 patients who received initial open damage control, there were eight who died (33.3%) and three (12.5%) who underwent amputations. Management in the remaining 21 patients included four (16.7%) with vascular shunts, nine (37.5%) with ligation, and eight (33.3%) with initial ligation followed by delayed repair at a subsequent operation (Figure 2).

In the remaining 83 patients, definitive repair was by ER in 36 (43.4%) and by OR in 47 (56.6%) (Figure 1). Among the patients who received definitive treatment, there were 55 (66.3%) with penetrating injuries. The types of injuries included 33 (39.8%) transections, 21 (25.3%) occlusions, 16 (19.3%) pseudoaneurysms, and 19 (22.9%) partial transections/flow-limiting defects (Table 1).

In patients treated with ER, the average age was 24.5 ± 11 years, and 94.4% were males. At admission, 14.3% ($n = 5$) of the patients were hypotensive (systolic blood pressure <90 mm Hg) and 68.8% ($n = 22$) had an ISS ≥15 (Table 1). In patients treated with OR, the average age was 27.5 ± 16 years, and 89.4% were males. At admission, 11.4% ($n = 5$) of the patients were hypotensive (systolic blood pressure <90 mm Hg) and 60.0% ($n = 24$) had an ISS ≥15 (Table 1).

When outcomes were compared between patients who underwent ER and OR, there was a significant difference with regard to total 24-hour transfusion requirements (1.0 ± 6 units for ER vs 2.5 ± 9 units for OR; $p = 0.012$). There were no deaths in the OR group and one in the ER group (mortality = 2.8%). There was a need to intervene in 8.3% of patients ($n = 3$) undergoing ER and 8.5% of patients ($n = 4$) undergoing OR ($p = 1.00$). There were two (5.6%) delayed amputations in the ER group and one (2.1%) in the OR group ($p = 0.576$) (Table 2).

DISCUSSION

With a total of 167 patients, this study is one of the largest in the trauma field comparing the use of ER and

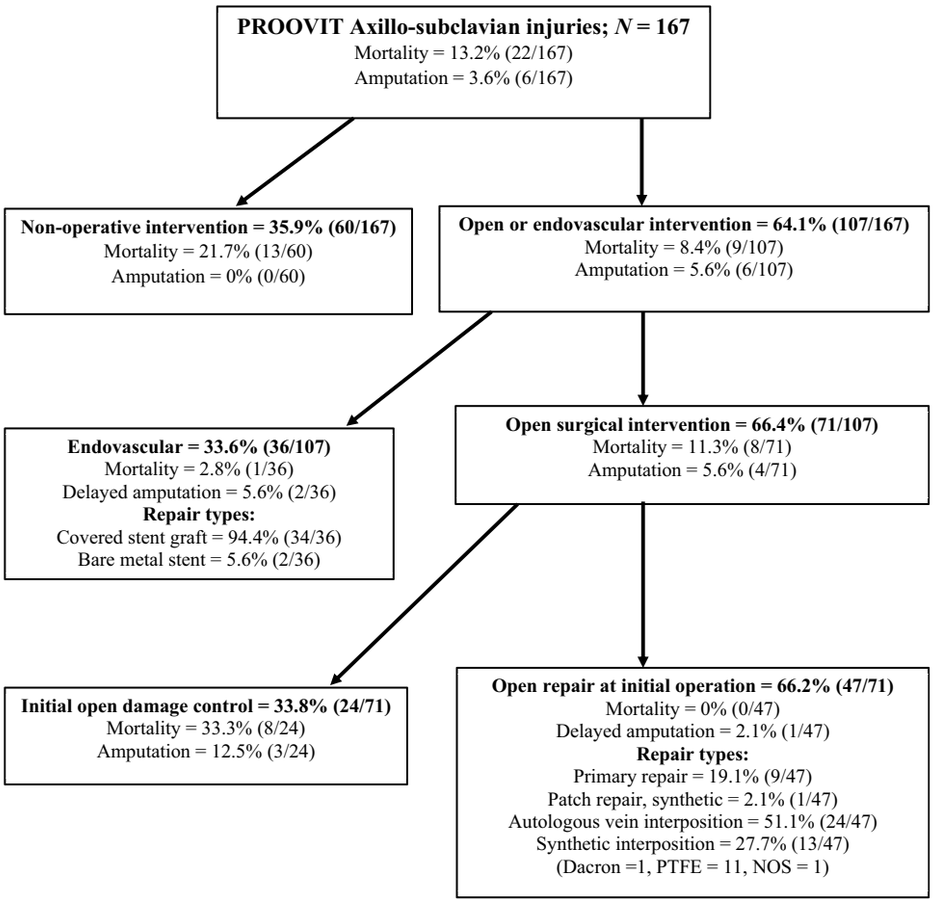

Figure 1 Breakdown of all patients used from PROOVIT data. *N* = 167 represents total number of patients used in this study. Mortality rate and amputation rate are represented in each group of patients. NOS, not otherwise specified; PTFE, polytetrafluoroethylene.

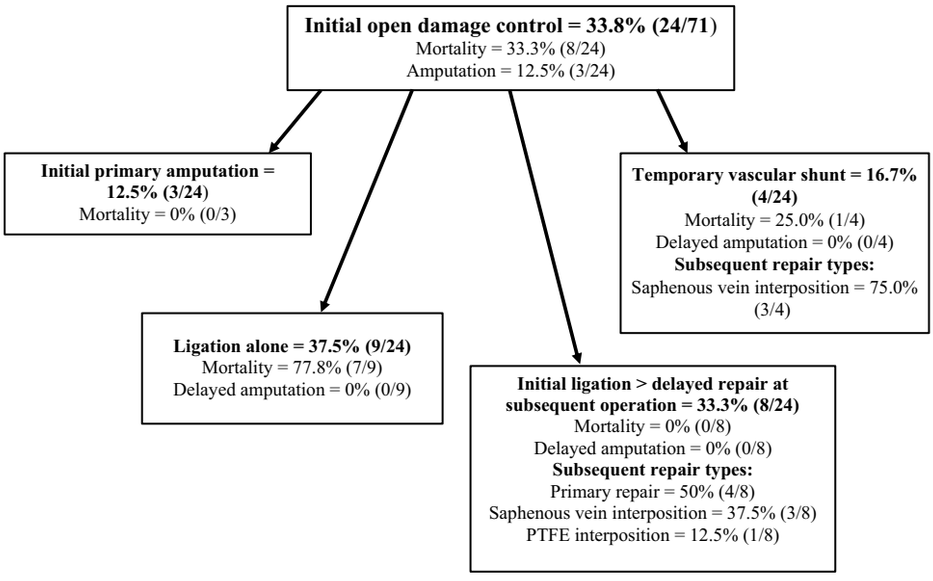

Figure 2 Breakdown of patients who underwent initial open damage control. Mortality rate and amputation rate are represented in each group of patients. PTFE, polytetrafluoroethylene.

Table 1 Demographic and clinical data of patient groups.

	Total (N = 83)	*Open Repair (N = 47)*	*Endovascular Repair (N = 36)*	*p-value*
Age, years (median ± IQR)	26.0 ± 16	27.5 ± 16	24.5 ± 11	0.979
Male, % (*n/N*)	91.6% (76/83)	89.4% (42/47)	94.4% (34/36)	0.341
Penetrating, % (*n/N*)	66.3% (55/83)	66.0% (31/47)	66.7% (24/36)	0.976
Transection, % (*n/N*)	39.8% (33/83)	44.7% (21/47)	33.3% (12/36)	0.295
Occlusion, % (*n/N*)	25.3% (21/83)	21.3% (10/47)	30.6% (11/36)	0.335
Partial transection/flow-limiting defect, % (*n/N*)	22.9% (19/83)	27.7% (13/47)	16.7% (6/36)	0.237
Pseudoaneurysm, % (*n/N*)	19.3% (16/83)	8.5% (4/47)	33.3% (12/36)	0.004
SBP on admission (median ± IQR)	123 ± 51	128 ± 49	119 ± 53	0.596
Hypotension on admission, % (*n/N*)	12.7% (10/79)	11.4% (5/44)	14.3% (5/35)	0.743
ISS (median ± IQR)	18 ± 14	17 ± 17	20 ± 15	0.163
ISS ≥ 15, % (*n/N*)	63.9% (46/72)	60.0% (24/40)	68.8% (22/32)	0.442
Head AIS ≥ 3, % (*n/N*)	20.6% (13/63)	22.9% (8/35)	17.9% (5/28)	0.626
Chest AIS ≥ 3, % (*n/N*)	71.4% (50/70)	63.2% (24/38)	81.3% (26/32)	0.095
Abdomen AIS ≥ 3, % (*n/N*)	9.4% (6/64)	5.6% (2/36)	14.3% (4/28)	0.391
Extremity AIS ≥ 3, % (*n/N*)	41.2% (28/68)	50.0% (19/38)	30.0% (9/30)	0.096

Data is represented as either median ± IQR or percentage (n/N). p-value < 0.05 is considered significant. AIS, Abbreviated Injury Score; IQR , interquartile range; n, number of patients with each clinical characteristic; N, number of patients in total, in the OR group or in the ER group.

Table 2 In-hospital outcomes of patients in ER and OR groups.

	Total (N = 83)	*Open Repair (N = 47)*	*Endovascular Repair (N = 36)*	*p-value*
Total PRBCs first 24 hours, units (median ± IQR)	2.0 ± 7	2.5 ± 9	1.0 ± 6	0.012
Need to re-intervene on initial repair, % (*n/N*)	8.4% (7/83)	8.5% (4/47)	8.3% (3/36)	1.000
Thrombosis of repair, % (*n/N*)	4.8% (4/83)	4.3% (2/47)	5.6% (2/36)	1.000
Flow-limiting stenosis, % (*n/N*)	1.2% (1/83)	0% (0/47)	2.8% (1/36)	0.434
Infection resulting in need to re-operate, % (*n/N*)	0% (0/83)	0% (0/47)	0% (0/36)	N/A
Delayed amputation, % (*n/N*)	3.6% (3/83)	2.1% (1/47)	5.6% (2/36)	0.576
Stroke related to vascular injury or repair, % (*n/N*)	2.4% (2/83)	2.1% (1/47)	2.8% (1/36)	1.000
Hospital LOS (median ± IQR)	8.0 ±13	7.5 ± 13	9.0 ± 15	0.864
ICU LOS (median ± IQR)	3.0 ± 5	3.0 ± 5	2.0 ± 4	0.629
Mortality, % (*n/N*)	1.2% (1/83)	0% (0/47)	2.8% (1/36)	0.434

Data is represented as either median ± IQR or percentage (n/N). p-value < 0.05 is considered significant. IQR, interquartile range; n, number of patients with each clinical characteristic; N, number of patients in total, in the OR group or in the ER group. PRBC, packed red blood cells; LOS, length of stay; ICU, Intensive Care Unit.

OR for axillo-subclavian arterial injuries. The PROOVIT registry includes multicenter data specific to vascular injury which captures variables and outcomes not available in previous retrospective studies utilizing dual center or NTDB data. By using data from the PROOVIT registry over a seven-year period, this study assessed the outcomes of axillo-subclavian injuries after ER or OR.

The historic approach to axillo-subclavian injuries has been OR, and successful treatment relies on recognition of the severity of the injury and rapid control of hemorrhage or restoration of flow[8,9]. To date, ER has been reserved for patients who are more hemodynamically stable, but it is becoming more widely used in other patients as more advantages are discovered. These have been documented in multiple reviews of injuries to the carotid artery, abdominal aorta, iliac artery, femoral artery, and the axillo-subclavian arteries[10-14].

Furthermore, there have been studies showing improved outcomes with ER for axillo-subclavian arterial injuries. In 2011, Shalhub et al.[15] performed a retrospective review of 34 patients with blunt thoracic outlet arterial injuries in which 12 were managed with endovascular repair. They demonstrated that patients treated with ER had shorter operative times, less blood loss, and less morbidity. Similarly, a retrospective study by Branco et al.[16] in 2016 reviewed 153 patients with axillo-subclavian injuries over an 11-year period. There were 72 patients matched based on demographics and clinical data, with 18 patients managed with ER and 54 with OR. Patients who underwent ER had significantly lower in-hospital mortality and lower rates of surgical

site infections and sepsis. Another study by Matsagkas et al.[17] investigated the use of ER in seven patients with blunt trauma to the axillary and subclavian arteries. They found that endovascular technique for blunt injuries was reliable with no procedure-related complications during the median hospital stay of 22 days and there was a 0% mortality rate. Finally, a retrospective review by Waller et al.[18] found that, while axillary and subclavian artery injuries still require open exposures and repairs, endovascular repairs are more effective for pseudoaneurysms.

The current review documents a continuing increase in the use of ER for axillo-subclavian injuries. In the group of 83 patients who received definitive treatment, 36 (43.4%) were managed with ER. This is similar to other studies over the past decade in which 60% and 42.9% of patients with axillo-subclavian injuries were managed with ER[15,19].

Overall mortality in this review was 13.2%. Patients who were hemodynamically unstable underwent initial open damage control and had a mortality rate of 33.3%. In the remaining patients who received definitive treatment with either ER or OR, the mortality rate was only 1.2% as previously noted. In addition, there was a low number of amputations in both treatment groups. The only significant outcome of this review was that there were less blood transfusions in the ER group; however, it is clear that ER is comparable to OR for axillo-subclavian artery injuries when considering mortality, thrombosis of repair, flow-limiting stenosis, infection rates, amputation rate, stroke, and LOS.

As with every study, there were a number of limitations. First, this was a retrospective review of data from the PROOVIT registry. Databases such as the PROOVIT registry have some limits in information provided for individual patients and in the variability in contribution from the patients enrolled in this unfunded and voluntary effort. Furthermore, patients had definitive treatment with either ER or OR based on their hemodynamic stability and feasibility of intervention in this nonrandomized review. In addition, these patients were not matched based on demographic or clinical variables such as age, type of injury, severity of injury, and blood pressure on admission for statistical analysis. Also, data on whether patients needed a thoracotomy, sternotomy, or laparotomy and on procedural times, longer term outcomes outside of the hospitalization, out of hospital outcomes, estimated blood loss from all injuries, precise amount blood loss from the axillo-subclavian injury, and Acute Respiratory Distress Syndrome (ARDS) were not available. This restricts the ability of the results in this review to be compared to those in previous studies[1,15,16]. Finally, indications for initial damage control and exact outcome metrics were not available, which prevented this subset of patients from being compared to the endovascular treatment group.

CONCLUSION

The current review documents a continuing increase in the use of ER for axillo-subclavian arterial injuries. In the group of 83 patients who received definitive treatment, 36(43.4%) were managed with ER. Overall mortality in this review was 13.2%. Patients who were hemodynamically unstable underwent initial open damage control and had a mortality rate of 33.3%. In the remaining patients who received definitive treatment with either ER or OR, the mortality rate was only 1.2% as previously noted. The only significant outcome of this review was that there were less blood transfusions in the ER group; however, it is clear that ER is comparable to OR for axillo-subclavian arterial injuries when considering mortality, thrombosis of repair, flow-limiting stenosis, infection rates, amputation rate, stroke, and LOS. Additional studies will be required to assess specific management techniques depending on location of vascular injury and accessibility of injury.

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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Original Article

Zone III REBOA and the COBRA-OS™: Safety of Inadvertent Iliac Artery Device Deployment

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Background: Resuscitative Endovascular Balloon Occlusion of the Aorta is an emerging technique in trauma. However, inadvertent iliac artery balloon inflation can lead to complications. This study aims to investigate the safety characteristics of the COBRA-OS™ compared with a 7-Fr commercially available device during purposeful iliac artery balloon overinflation.
Methods: In vitro: the COBRA-OS™ was inflated in explanted porcine iliac arteries and intentionally overinflated until balloon or vessel rupture occurred. In vivo: the COBRA-OS™ and 7-Fr device were deployed in the iliac arteries and intentionally overinflated until rupture of the balloon or blood vessel.
Results: In vitro: an average volume of 1 ml was required for occlusion using the COBRA-OS™ and the mean balloon rupture volume was 32.5 ml. The COBRA-OS™ partially migrated into the aorta in all cases. In vivo: the COBRA-OS™ and 7-Fr device occluded the iliac arteries with a mean volume of 3.5 ml. Overinflation resulted in no iliac ruptures with the COBRA-OS™ (mean balloon rupture volume = 10 ml). Overinflation with the 7-Fr device resulted in 1 iliac rupture at 5 ml. The other two 7-Fr devices had a mean balloon rupture volume of 5 ml. All COBRA-OS™ devices moved partially up into the aorta during inflation while all 7-Fr devices remained in the iliac artery.
Conclusions: The COBRA-OS™ allows for significant overinflation when deployed in the common iliac artery of a porcine model due to its unique design. This ultimately may help to prevent balloon and blood vessel rupture during clinical use; however, further studies are required.

Keywords: *REBOA; Iliac; Safety*

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INTRODUCTION

Non-compressible torso hemorrhage (NCTH) can be temporized by the use of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) prior to definitive management in the operating room [1]. Broadly speaking, REBOA is a minimally invasive procedure that entails introducing a balloon catheter through the femoral artery into the aorta, providing temporary aortic occlusion and a bridge to definitive surgical hemostasis. Aortic occlusion is normally intended for Zone I (left subclavian to the celiac artery) or Zone III (renal arteries to iliac bifurcation). The zone of deployment decision is generally based on the location of the injury and the hemodynamic status of the patient [2].

There are a number of known complications associated with the use of REBOA [3]. One complication that may arise with Zone III occlusion is the inadvertent deployment of the REBOA device in the iliac artery instead of the intended infrarenal aorta, which can lead to iliac artery rupture or ineffective aortic occlusion. This complication is mainly due to the relatively short

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length of Zone III (median 8.7 cm) [4] and the clinical desire to stay below the renal arteries to avoid Zone II deployment (para-visceral occlusion) with the inherent risk of mesenteric and renal ischemia, especially during prolonged inflation times [3]. It can also happen when the device is cycled through inflation and deflation, with subsequent distal migration of the device.

The COBRA-OS™ is a novel 4-Fr REBOA device [5] that has been designed to provide an increased safety profile, including: (1) the ability to tolerate significant overinflation; and (2) the propensity for retrograde migration into the aorta in the case of inadvertent iliac artery deployment. This study investigates these safety characteristics using an in vitro porcine model and further examines them in a comparative study with a commercially available 7-Fr REBOA device in an in vivo porcine model.

METHODS

The COBRA-OS™

The device used for aortic occlusion in this study was the COBRA-OS™ (see Figure 1). The COBRA-OS™ is a large vessel balloon occlusion system designed to be inserted through a 4-Fr sheath. A 4-Fr Custom Sheath Introducer Kit (0.018-inch guidewire) that accompanies the device is used to gain access to the common femoral artery in the groin. The COBRA-OS™ is designed to occlude the aorta in the descending thoracic aorta (Zone 1; solid black marker; indicating 48-cm depth) or to occlude the aorta below the renal arteries (Zone 3; three black markers; indicating 28-cm depth). Its overall working length and therefore maximal reach is 55 cm. The device consists of a stiff stainless-steel inner guidewire with an atraumatic floppy distal J-tip that is housed in a compliant occlusion balloon with proximal and distal necks. The balloon is off-set upwards towards the J-tip and has a maximum diameter of 25 mm. No other guidewires are required and this is not an over-the-wire device. A reusable J-tip straightener is preloaded on the distal neck to facilitate the introduction of the device into the 4-Fr introducer sheath hemostasis valve. There is no arterial line monitor associated with the device. There is a unique Safety Shoulder Reservoir™ that was designed to allow the balloon to preferentially grow in length once the balloon has reached full occlusion instead of continued diameter increase. This is meant to help prevent rupture of the balloon or vessel by offloading the additional inflation volume into the "reservoir".

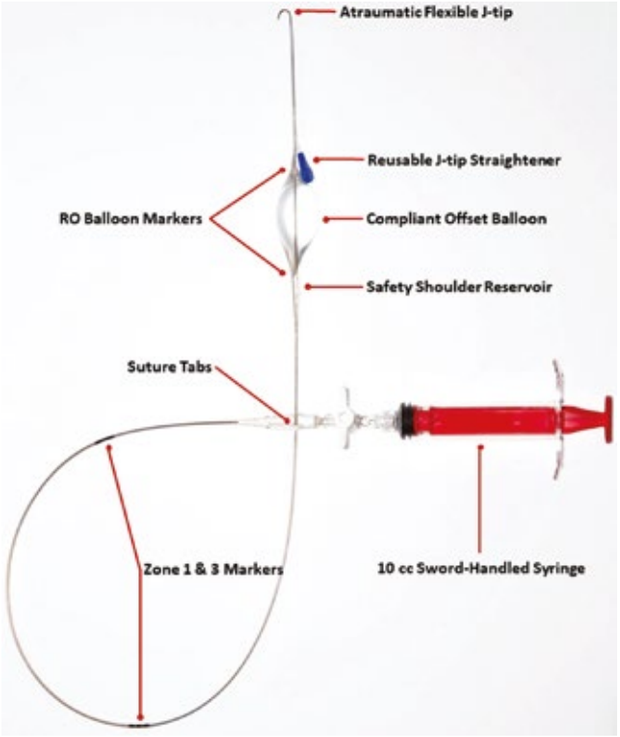

Figure 1 Image of the COBRA-OS™ with syringe attached and features labelled. RO, radiopaque.

In Vitro

Three explanted porcine aortas with attached iliac arteries were obtained from a local abattoir (Mount Brydges Abattoir, Mount Brydges, ON, Canada). Testing was performed using the COBRA-OS™ (Front Line Medical Technologies Inc., London, ON, Canada) on fresh and untreated tissue.

A total of three iliac arteries were deemed viable for testing based on visual inspection. Baseline diameter and length measurements of the usable iliac arteries were recorded. The COBRA-OS™ was inserted through the lumen of the artery and inflated with saline until vessel occlusion occurred based on direct visualization. We ensured that the point of maximum diameter of the balloon was centered along the entire length of the iliac artery (including external and common iliac artery). Saline was then continuously injected to observe the device response to overinflation and volume was monitored until either rupture of the balloon or blood vessel was observed. The position and location of the balloon were also monitored and documented for any migration. Upon rupture of the balloon or artery, the vessels were opened to expose the intima at the treated site. The device was removed and discarded in order to enable assessment for damage where the balloon was inflated. The vessel was inspected both internally and externally to assess for any macroscopic arterial damage and photographic images were taken.

In Vivo

Under an animal use protocol obtained from Western University, three adult female pigs with a mean weight

of 67 kg were tested in this study, enabling the use of six iliac arteries in total. One device was deployed per iliac artery: three using the COBRA-OS™ and three using a commercially available 7-Fr device.

Under ultrasound guidance, a 4-Fr introducer sheath was placed in the left common femoral artery percutaneously for introduction of the COBRA-OS™ and a 7-Fr introducer sheath was placed in the right common femoral artery for introduction of the 7-Fr device. A lower midline incision was performed to expose both iliac arteries and the aorta for visualization. Both devices were advanced into the common iliac arteries, which was confirmed by direct arterial palpation and visualization of radiopaque marker bands of the devices under X-ray guidance. We ensured that the points of maximum diameter of both test devices were centered along the length of the common iliac artery. Note that, because of this, the safety shoulder reservoir of the COBRA-OS™ was partially contained within the 4-Fr sheath due to the porcine anatomy. The devices were inflated with saline consecutively until vessel occlusion occurred based on loss of arterial pulse below the devices. Volume was recorded and inflation was continued to intentionally overinflate the balloon until either rupture of the balloon or blood vessel occurred. The position and location of the balloon were also monitored and documented for any migration and X-ray images were taken. Upon rupture of the balloon or artery, the vessels were opened to expose the intima at the treated sites and were inspected both internally and externally to assess for any macroscopic arterial damage.

The primary endpoints of this study were rupture of the balloon or blood vessel and the final position of the balloon in the vessel.

Ethical Approval and Informed Consent

As this was an animal study, no research ethics board approval was required.

RESULTS

In Vitro

A total of three iliac arteries were used in this in vitro study, with a mean common iliac diameter of 10 mm and mean length of 7.7 mm. All testing resulted in balloon rupture and no occurrence of iliac rupture. An average volume of 1 ml was required to occlude the artery using the COBRA-OS™ and the mean balloon rupture volume with overinflation was 32.5 ml (see Figure 2*a*). The COBRA-OS™ partially migrated into the aorta in all three cases and migration occurred at an average inflation volume of 15 ml. Visual inspection and photographic images showed no evidence of gross arterial damage at the treatment sites (see Figure 2*b*).

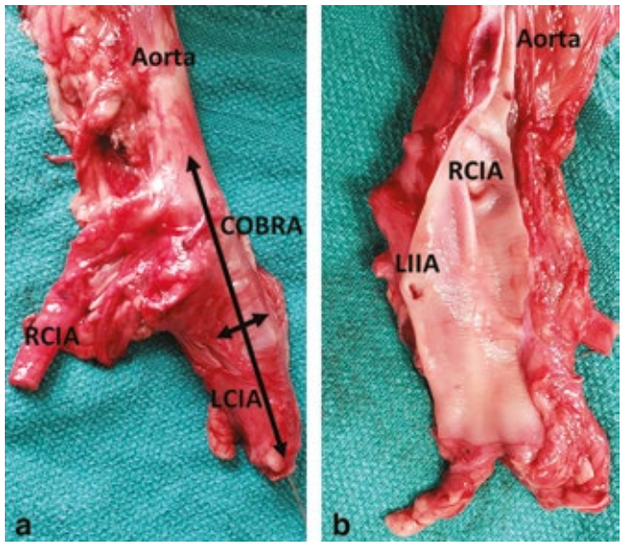

Figure 2 In vitro images. **(a)** In vitro deployment of COBRA-OS™ (COBRA) in left common iliac artery (LCIA) with migration into aorta and subsequent occlusion of right common iliac artery (RCIA). **(b)** Left common iliac artery and aorta opened up post-rupture of COBRA-OS™ with right common iliac artery (RCIA) and left internal iliac artery (LIIA) orifices shown and no intimal damage seen.

In Vivo

A total of six iliac arteries were used in this in vivo study, with a mean common iliac diameter of 7.7 mm on the left and 7.3 mm on the right. Both the COBRA-OS™ and the 7-Fr device occluded the common iliac artery with a mean volume of 3.5 ml (range 3–4 ml). Overinflation in the COBRA-OS™ resulted in three balloon ruptures at a mean balloon rupture volume of 10 ml (range 9–11 ml, 280% overinflation) and no iliac ruptures. Overinflation with the 7-Fr device resulted in two balloon ruptures with a mean balloon rupture volume of 5 ml (40% overinflation) and one iliac rupture at 5 ml. All COBRA-OS™ devices moved partially up into the aorta during inflation (after the maximum diameter of the balloon was centered along the length of the common iliac artery), while all 7-Fr devices remained in the common iliac artery, as shown by X-ray images. Figure 3 shows both devices deployed simultaneously for demonstration purposes. Visual inspection showed no evidence of gross arterial damage at the treatment sites in the non-ruptured iliac arteries.

DISCUSSION

The benefits of REBOA in NCTH as a surgical adjunct are offset by the potential complications of the technique and devices used. Blind insertion and inflation are often necessary, which can increase these risks further [6]. Improving the safety of REBOA is important in reducing

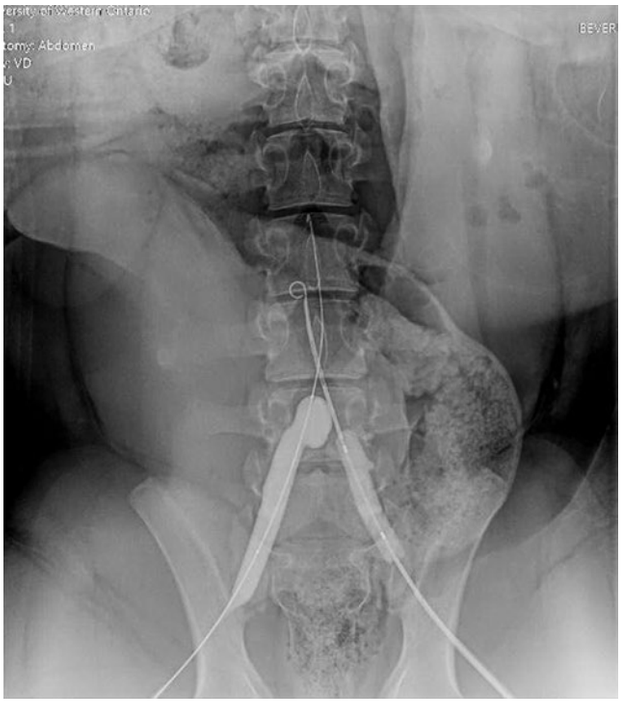

Figure 3 COBRA-OS™ deployed in the right iliac artery with migration into the aorta; 7-Fr device deployed in the left iliac artery.

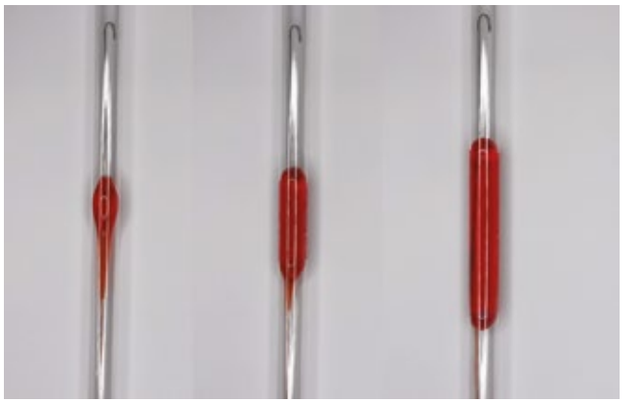

Figure 4 COBRA-OS™ with full occlusion in a stiff plastic 13-mm tube on the left and two subsequent overinflation images for demonstration purposes of the Safety Shoulder Reservoir™. The length of the balloon on the far right is approximately 10 cm.

the associated risks but also to increase the overall adoption of this potentially life-saving tool.

This study evaluates the behavior of the COBRA-OS™ during inadvertent iliac artery deployment in a pig model. The potential increased safety can primarily be attributed to both the off-set eccentric shape of the balloon and secondarily due to its Safety Shoulder Reservoir™. During over-inflation of the COBRA-OS™ with intentional iliac artery positioning and deployment in this study, the off-set nature of the balloon made it grow "upwards" towards the aortic bifurcation and allowed for the balloon to migrate into the aorta once the point of maximum diameter of the balloon rose above the bifurcation, with a "water-melon seeding" effect. The provision for the COBRA-OS™ to migrate preferentially into a larger space of the aorta may seem intuitive and inevitable; however, we have demonstrated that this is not an intrinsic feature of all devices. The design of the COBRA-OS™ facilitates and allows for this migration to occur, potentially decreasing the risk of vessel rupture. During this study, it proved difficult to keep the COBRA-OS™ balloon in the iliac artery to test rupture, and physical retraction had to be employed to obtain correct rupture data. There are scenarios beyond iliac artery deployment in which this safety characteristic could be potentially useful. For example, if the COBRA-OS™ was theoretically deployed from the brachial artery, the same principles would apply to the subclavian artery.

The ability of the COBRA-OS™ to sustain overinflation is due to the compliant nature of its balloon material and its unique Safety Shoulder Reservoir™. This unique reservoir allows for preferential longitudinal growth once occlusion has occurred as opposed to increased radial pressure being applied to the artery. The compliant balloon material can expand up to approximately 10 cm in length, with the superior 5 cm being the functional balloon occlusion region and the inferior 5 cm being the tapered shoulder reservoir region (see Figure 4). These safety characteristics are more pronounced in a porcine model, representing an extreme case of the small arterial sizes that may be seen in an adult patient population. The COBRA-OS™ has been shown in our study to possess significant overinflation capabilities even in these exaggerated circumstances with no incidence of arterial rupture despite intentional overinflation.

The significantly smaller overinflation volumes of the in vivo study versus the in vitro study are likely due to the fact that the safety shoulder reservoir was partially contained within the 4-Fr sheath in the in vitro study. If the three black markers (indicating Zone 3) are used in practice and positioned at the 4-Fr sheath valve, then no part of the safety shoulder reservoir would be contained within the sheath.

The limitations of this study included a small sample size and the potential for human error with visual measurements. We are also unable to determine if the same results would be applicable to human arterial anatomy.

In conclusion, the COBRA-OS™ possesses unique safety characteristics that allow for significant overinflation and safe migration into the aorta when inadvertently deployed in the common iliac artery of a porcine model. Further studies are required, but this study demonstrates that the COBRA-OS™ may help prevent balloon and iliac artery rupture during clinical use.

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

A Power and A Parekh are co-founders and have an equity stake in Front Line Medical Technologies Inc. LJM is Chair of the Scientific Advisory board, has an equity stake, and receives consulting fees from Front Line Medical Technologies Inc.

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Author Contributions

A Power and A Parekh were involved in the study design. A Power, A Parekh, TB, and AG were involved in data collection. All authors were involved in data analysis, data interpretation, and critical revisions.

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Narrative Review Article

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A Practical Approach to Introducing Pre-hospital Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA), the Problems Encountered and Lessons Learned

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Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is an endovascular procedure which utilises a catheter-based balloon device to achieve aortic occlusion. The aim of this resuscitative measure is to improve blood pressure proximal to the occlusion site and therefore preserve cardiac and cerebral perfusion to prevent cardiac arrest. In addition, there is a relative reduction in arterial flow to the site of injury distal to the balloon. Endovascular techniques are gaining acceptance for the in-hospital management of haemorrhage; however, their use in pre-hospital care is still limited. This is due to several factors including the technical challenges, training and skill sets of pre-hospital care teams and the potential for harm of REBOA, particularly with extended balloon occlusion times. However, non-compressible torso haemorrhage is associated with a mortality of approximately 50% and a significant proportion of these deaths occur in the pre-hospital phase of care. In the exsanguinating patient, resuscitative thoracotomy with direct aortic compression is often the only means to control haemorrhage. This resuscitative measure is now a more established pre-hospital intervention which has significantly improved outcomes in the context of penetrating trauma, particularly thoracic injury. However, in the context of blunt injury and subdiaphragmatic haemorrhage, the outcomes from pre-hospital resuscitative thoracotomy remain poor. We present our initial technique for successfully introducing REBOA for the pre-hospital management of exsanguinating pelvic or groin haemorrhage following trauma, our indications for REBOA and comments on the problems and limitations encountered, as well as the lessons learned .

Keywords: *REBOA; Resuscitation; Trauma; Haemorrhage; Pre-hospital Care; Endovascular*

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INTRODUCTION

Non-compressible torso haemorrhage (NCTH) is the leading cause of potentially preventable trauma deaths [1]. Junctional vascular injuries and pelvic fractures resulting from blunt and penetrating mechanisms of injury form a major part of NCTH. These injuries can lead to exsanguinating haemorrhage resulting in traumatic cardiac arrest with reported mortality rates of up to 50% [2–4]. A peak in mortality is observed in these patients at around 30 minutes from injury which, for a large proportion of patients, occurs in the pre-hospital environment [5]. London's Air Ambulance (LAA) is a physician-led pre-hospital service providing an advanced trauma team which aims to deliver effective treatment to critically injured patients as soon as possible following injury. Recent data show that mortality in shocked patients undergoing laparotomy is unchanged despite advances in trauma care [6]. Resuscitative thoracotomy and aortic compression (RT) is an open surgical technique which is well established in the hospital, and its

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use has been described in the treatment of traumatic cardiac arrest by non-surgeons in the pre-hospital phase of care [7,8]. It is effective for penetrating injuries with cardiac tamponade or a thoracic source of haemorrhage [9]. However, RT carries major surgical morbidity and has poor outcomes in blunt injury and subdiaphragmatic haemorrhage [10,11].

We recognised that for a meaningful reduction in mortality in patients with subdiaphragmatic exsanguination, novel resuscitation solutions were required. In 2013, LAA delivered the first known civilian pre-hospital resuscitative endovascular balloon occlusion of the aorta (REBOA) [4], and since then we have continued to successfully develop this intervention [12]. This was developed using 'off the shelf' and readily available equipment used for routine endovascular procedures. The aims of this article are to describe the practical technique which was initially adopted to successfully perform pre-hospital REBOA as a resuscitation adjunct following major trauma, to describe our indications for REBOA and to comment on the problems and limitations encountered. We also consider how this equipment and technique could be implemented as an endovascular resuscitation and haemorrhage control service in austere healthcare systems and its potential to be used in the management of postpartum haemorrhage [13] and out-of-hospital cardiac arrest [14].

REBOA IN PRE-HOSPITAL CARE

The use of endovascular techniques is becoming more prevalent in the in-hospital management of trauma haemorrhage [4,15–20]. REBOA involves inflation of a compliant balloon within the aorta to provide temporary occlusion and control of bleeding inflow to the site of injury prior to definitive haemostasis. This limits ongoing haemorrhage and preferentially supports myocardial and cerebral perfusion, albeit at the expense of distal ischaemia. These principles are in keeping with RT and aortic cross clamping but achieved in a less invasive manner in the already injured patient [20–25]. In traditional endovascular practice, vascular access is gained via the common femoral artery (CFA), ideally under ultrasound scan (USS) guidance or via direct surgical exposure, and devices are positioned and deployed under fluoroscopy in the controlled and sterile environment of an operating theatre, interventional radiology suite or hybrid theatre. However, the rapid onset of exsanguinating haemorrhage and expected mortality associated with NCTH has required REBOA to be performed in more austere conditions encountered in pre-hospital care and by physicians from backgrounds other than vascular surgery or interventional radiology. The aims of pre-hospital REBOA are to permit resuscitation, rapidly control exsanguinating haemorrhage and to transport to definitive care.

The aorta can be divided into three distinct zones [26]. Zone I extends from the origin of the left subclavian artery to the coeliac axis. Zone II extends from the coeliac axis to the most caudal renal artery. Zone III is distal from the most caudal renal artery to the aortic bifurcation. A multidisciplinary group with expertise from emergency medicine and pre-hospital care, trauma surgery, interventional radiology, anaesthetics and intensive care medicine began developing a standard operating procedure (SOP) for pre-hospital zone III REBOA in 2012. It was agreed that basic measures should be performed first including non-invasive haemorrhage control techniques such as minimal handling, pelvic splinting, limb splinting, tourniquets, transfusion of blood products and antifibrinolytics, and rapid transfer to a Major Trauma Centre (MTC). At the time of development, it was anticipated that balloon occlusion times would be in excess of 30 minutes from inflation to definitive haemorrhage control. For this reason, REBOA would be limited only to zone III in order to minimise the risk of visceral ischaemia. In addition to this, we felt that femoral puncture site morbidity should be limited by using an 8Fr sheath as a maximum. At this time, there was a lack of bespoke lower profile endovascular devices with a balloon large enough to occlude the aorta in zone I which were compatible with this sheath size, precluding more proximal balloon occlusion. These were the key factors in establishing the equipment required to safely implement a strategy for zone III REBOA in the pre-hospital environment.

At present there is no universally agreed definite indication for pre-hospital REBOA and the population most likely to benefit from the procedure has yet to be clearly defined. The in-hospital use of REBOA is currently the subject of an ongoing study [27]. We feel the use of pre-hospital zone III REBOA is indicated in the context of blunt or penetrating injury to the pelvis or groin, when a senior, experienced clinical team identify unequivocal signs of true exsanguinating haemorrhage and imminent risk of hypovolaemic cardiac arrest [28].

Ethical Approval and Informed Consent

Ethical approval was not required. No identifiable data is included.

LAA TECHNIQUE FOR PRE-HOSPITAL REBOA

The technical performance of REBOA can be challenging and becomes even more so when performed in time critical situations out-of-hospital in an austere environment. The layout of the REBOA pack carried by LAA initially focussed primarily on size and weight but also incorporated features to aid the clinician and assistant performing the procedure. The packs contained sections numbered from one to four, in the order that they were

to be used, and the equipment was chosen to be as minimal and intuitive as possible. With subsequent development this was improved with the introduction of bespoke REBOA packs. The equipment and technique described here was utilised for all patients in our initial case series [8].

Patient Selection and Positioning

Patient selection is based on decision making by senior experienced doctors as part of the LAA team according to previously established criteria suggesting exsanguinating pelvic haemorrhage [28] (Table 1). When establishing this service, no age limits were specified but our SOP was only to consider pre-hospital REBOA in adult patients. REBOA is only considered in cases where the impression of these senior clinicians is that the trajectory of presenting physiology is imminent cardiovascular collapse and traumatic cardiac arrest, with an injury pattern congruent with this physiology.

The patient should be positioned supine in an area with 360-degree access and all efforts made to calm, protect and optimise the immediate area around the clinician and assistant performing the procedure. Concomitant tasks, such as intravenous access and intubation/ventilation for example, should be performed by other members of the team and a separate team member should take over the role of team leadership while the intervening clinicians are task focussed. In patients with suspected pelvic fractures, clothing should be removed and a pelvic splint should be applied. It may be necessary to carefully move or modify the binder to allow femoral vascular access. Prepare the skin and place the drape over the patient, exposing the operative area of interest.

Arterial Access

Arterial access should be gained via the CFA. In patients with a suspected junctional vascular injury, the contralateral CFA should be used. The position of the CFA can be estimated at a point approximately 2-cm inferior to the mid-inguinal point.

The femoral vascular structures should be visualised under USS with pulsatile flow seen to confirm the CFA. Puncture the CFA under USS guidance using a percutaneous entry thin-walled needle (Cook, Indianapolis, USA) or in severely shocked patients using a Merit MAK mini access kit (Merit Medical, Utah, USA). Access is then established by passing an 0.035-inch guidewire into the needle followed by a 7Fr sheath (Cordis, California, USA) with its dilator on the wire. With a skin incision made this should advance into the artery without resistance. Ensure the sheath's side port is in the 'off' position. On completion of this step, there will be an 11-cm 7Fr sheath providing access to the CFA and external iliac artery providing a port through which REBOA can be performed.

Balloon Positioning and Inflation

Pass the Amplatz Extra-Stiff guidewire (Cook, Indianapolis, USA) with j-tip through the sheath to a depth of approximately 50 cm from the skin incision. The guidewire should pass without resistance if in the correct intraluminal position. Perform a test inflation of the balloon with the pre-loaded 2.5-ml syringe of saline provided. Load the balloon catheter (LeMaitre, Massachusetts, USA) onto the guidewire and advance to a depth of 40 cm from the skin. Take care to ensure the wire is not withdrawn and remains sterile. Inflate the balloon with 0.9% NaCl to a maximum of 2.5 ml or until resistance is encountered. This balloon will enlarge approximately to a 14-mm diameter when inflated with 2.5 ml. Clearly document the time of balloon inflation.

Once the balloon is inflated, aortic pulsation should push it towards the terminal aorta (if aortic pressure is high enough) and it will be supported at the bifurcation. Allow the balloon to migrate spontaneously or apply very gentle caudal traction if required. Confirm correct positioning with an improvement in central haemodynamic, absence of lower limb pulses and absence (or marked reduction) of pulsatile flow on USS distal to the balloon.

The sheath should then be sutured in position and the catheter, sheath and wire covered with an adhesive dressing. A team member should be tasked with maintaining the position of the device and wire.

After REBOA, all efforts should be concentrated on minimising balloon occlusion time. Practically speaking, this involves immediate transfer for definitive care at an appropriate MTC during which there is a focus on volume resuscitation.

Following balloon inflation, patients may become normotensive or even hypertensive as a result of the increased systemic vascular resistance and improved coronary perfusion. A return of cerebral perfusion may necessitate review of adequate analgesia or depth of anaesthesia. As resuscitation continues, increasing aortic pressures may now cause a balloon which had not migrated back to the bifurcation to do so. Therefore, careful attention must be paid at all times to ensure the endovascular device is secured.

On arrival in the Emergency Department, clear handover should be made to the receiving trauma team including the presence of REBOA, balloon inflation time and the need for prompt haemorrhage control emphasised. All processes should function to minimise the total time of balloon inflation and distal ischaemia.

Balloon Deflation and Sheath Removal

Balloon deflation and catheter removal should occur in a controlled environment in a planned coordinated manner under instruction of a trauma team leader and with input from anaesthetics and interventional radiology or

trauma/vascular surgery. It is important to be aware that profound haemodynamic instability may follow balloon deflation due to a sudden reduction in systemic vascular resistance, hypovolaemia, reperfusion and washout of metabolic products with hyperkalaemia, hypocalcaemia and acidosis. Blood products should be immediately available for resuscitation and consideration given to aggressive pre-emptive resuscitation with blood products, calcium bicarbonate and sodium bicarbonate.

Once REBOA is no longer required, the sheath should be flushed and removed once coagulation is normalised and according to local institutional procedure. Proactive thrombectomy or angiography for thrombus associated with the balloon catheter and femoral arterial sheath should be performed in all patients. Its presence is very likely in our experience and complications common if not appropriately managed [12]. Whether the femoral arterial sheath is removed or remains in-situ, careful regular limb vascular observations should be continued as there is a high likelihood of thrombus and delayed ischaemic lower-limb complications.

Scene Management and Human Factors

It is expected that the operator performing REBOA will become 'task focused'. A clear dialogue is essential between members of the pre-hospital team confirming the REBOA operator will be 'eyes down' on the procedure, leaving the remaining members to take charge of the scene. This is essential to ensure the many other vital and time critical interventions are being concurrently performed and the team is working efficiently. The procedure packs are organised in such a way that an untrained assistant who is unfamiliar with the technique should be able to provide useful assistance. We have learnt, however, that the procedure is quicker and more likely to succeed when performed by a trained operator and a trained assistant. We aim to complete the procedure with needle in skin to balloon inflation within 4–6 minutes, although this is case dependent. The clinician running the scene should also be wary of procedure and scene time and communicate appropriately if delays occur.

GOVERNANCE AND TRAINING

This is a procedure which is performed on rare occasions in critically injured patients and therefore requires considered application. LAA team members are required to go through rigorous assessment before they are permitted to perform REBOA and then undertake regular simulation-based training. The Institute of Pre-hospital Care has developed the Pre-hospital and Emergency Endovascular Resuscitation (PEER) course which consolidates a formal two-day education programme in endovascular resuscitation theory with practical training. This is then cemented by a period of time working in the service and an assessment of competency including knowledge of our SOP, relevant literature and anatomy and a 'real-time' high-pressure practical scenario.

The introduction and development of this technique was subject to a stringent and multi-level governance process involving all members of the multi-disciplinary working group. This ensures that indications and response to the procedure are reviewed regularly, any complications detected early and that any lessons learned are acted on, continually evolving the process.

LESSONS LEARNED USING THIS INITIAL TECHNIQUE

LAA was the first known trauma service to use REBOA in the pre-hospital phase. At the time this strategy was being developed, the equipment available for REBOA was limited, with a relative lack of bespoke devices. The technique described here was developed using expertise in endovascular practice drawn from other applications. However, this equipment is relatively cheap and readily available.

Securing rapid, safe vascular access is a primary and essential step in any endovascular procedure. This has been shown to be a practically challenging and rate limiting step in performing REBOA [29] with an associated morbidity [30]. Performing USS guided percutaneous vascular access in hypovolaemic patients in the pre-hospital phase presents a unique set of challenges. These motor skills can be improved with practice [31] and we aim to increase proficiency with this skill formally through the PEER course and with a focus on regular training. One great advantage of this technique is that it can be performed using a 7Fr sheath which has lower puncture site morbidity compared with devices requiring a larger access sheath [32].

Not using a bespoke device for REBOA results in this initial method being a multistep process. These steps all add to the time taken to perform the procedure. It also makes learning the process more difficult and requires familiarity with more steps and more individual pieces of equipment. Transporting, preparing and using each piece in the correct order all becomes more difficult and adds to the cognitive burden of the team in an already high-stress environment. Using stiff guidewires can present their own benefits and challenges. They carry a risk of an iatrogenic vessel injury or dissection, as well as potential misplacement with blind passing. However, using a wire does offer secure access once established, versatility in exchange of endovascular device and may offer technical familiarity to operators.

A practical point we experienced following balloon inflation is often there is a lack or even absence of balloon migration towards the aortic bifurcation if systolic pressure is low. This carries the risk of placing the balloon too proximally, or the desire to pull the balloon back, which can result in misplacement in an iliac vessel or potentially a vascular injury. This can be mitigated by

Table 1 Features of exsanguinating heamorrhage – *'the hateful eight'* [24].

Case Features	*Clinical Signs of Exsanguinating Pelvic Haemorrhage*
1. Mechanism featuring large energy transfer or penetrating injury to the pelvis or groin 2. Injury pattern compatible with vascular injury and major haemorrhage 3. Rapid evolution of physiological shock state	1. Pallor 2. Clammy 3. Venous collapse 4. Air hunger 5. Hypotension (low volume/absent peripheral pulses) 6. Low/falling End Tidal CO_2 7. Tachy- or bradycardia 8. Altered mental state.

Table 2 Equipment required for Zone III Pre-hospital REBOA. Divided into four separate, labelled packs to facilitate performance and assistance on scene.

1. Preparation Pack
Sterile Drape 170 cm x 150 cm (3M)
Sterile gloves
Chloraprep
2. Access Pack
Percutaneous pink access needle (Cook 18G 7 cm)
7F Avanti + Percutaneous sheath introducer (Cordis)
Size 11 scalpel
10-ml syringe
Size 0 silk suture
Gauze swabs
3. Occlusion Pack
Amplatz Extra-Stiff guidewire with j-tip (Cook: 0.035 inch, 145 cm)
LeMaitre Over-the-wire Embolectomy Catheter x2, 6Fr, 40-cm, 13-mm balloon (includes 3-ml syringe for balloon inflation)
10-ml 0.9% NaCl flush
Drawing up needle
2.5-ml syringe
4. Securing Pack
Tegaderm film x5
Mini Access Kit
4F Merit MAK (21G /7 cm needle, 4Fr catheter, 0.018 inch guide wire)
Size 11 scalpel
Size 0 silk suture
Gauze swabs
Haemostatic valve
Red bung
10-ml syringe
Portable ultrasound scanner

using external landmarks and morphometry to estimate desired insertion distance.

In our experience, there appears to be some inherent partial occlusion property to this balloon, which is evidenced by the presence of computed tomography contrast distal to the site of occlusion in a small number of patients imaged in our case series [33]. There is no way to quantify or control this in real terms using the equipment described, but this may offer some degree of safety while familiarity is gained in establishing a service compared with less compliant and fully occlusive devices.

One major limitation with this strategy is that it only allows occlusion in zone III. We recognise that LAA sees patients who could potentially benefit from supracoeliac (zone I) occlusion. It is thought that some cases with haemorrhage amenable to zone III occlusion were missed due to diagnostic uncertainty. Clinicians found it hard, at times, to commit to the anatomical level of haemorrhage and therefore did not deploy REBOA due to diagnostic doubt. In some of these cases it was noted, retrospectively, that a zone III balloon may have prevented exsanguination. This was a recognised and accepted risk due to the safety considerations and equipment limitations mentioned previously. However, we have learned valuable lessons on careful, detailed assessment and considered the value of other diagnostic tools in differentiating the source of haemorrhage in these cases. We have now progressed to a procedure able to target zone I or III but with extreme caution and with the default that, if unsure of the source of haemorrhage, the clinician will begin with zone III occlusion, only progressing to zone I if the response is inadequate. This has followed our embedding of experience in the procedure, careful monitoring of results and as smaller profile devices capable of zone I occlusion have been developed [29]. More proximal occlusion is accompanied by greater risk with distal ischaemia, and the safest way to mitigate against this is an area of ongoing study. One recommended strategy is early partial REBOA [34, 35], which could not be accurately achieved using the described equipment.

In the evolution of pre-hospital REBOA within our service, progression to a more user-friendly device and technique giving the clinician versatility in occlusion zone and strategy has been key in our aim to replace the need for thoracotomy to treat exsanguinating subdiaphragmatic haemorrhage.

CONCLUSION

Hybrid endovascular techniques are becoming an increasingly accepted part of the management of critically injured patients. Pre-hospital REBOA provides temporary haemorrhage control and permits transfer for definitive care. We have described the first known technique for introducing pre-hospital REBOA, discussed the reasons why this was implemented and commented on the problems encountered with this approach. The technique described uses 'off-the-shelf' equipment which is familiar to many clinicians with endovascular practice. The relative availability and lower cost of this technique offers some versatility and could be applied in the management of bleeding in other areas such as high-risk labour or postpartum haemorrhage [13, 36], as well as use in austere healthcare settings [37] and in those with more limited budgets/resources, or in the management of out-of-hospital cardiac arrest [14].

It should be stressed that this article is not intended to simply be a guide to instruct clinicians on how to perform pre-hospital REBOA. The importance of experience in the recognition of true exsanguinating haemorrhage, the overall context being within a robust training programme supporting meticulous technique, and a multi-level governance programme as part of a prepared trauma system is imperative.

LAA has successfully implemented a pre-hospital zone III REBOA service and we describe how this was practically undertaken as well as reflecting on its strengths and limitations. We recognise that, in order to further develop pre-hospital REBOA, novel strategies and devices permitting zone I occlusion and refined occlusion strategies should be adopted and will be the subject of ongoing study and validation.

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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Images of interest

Chimney Grafts in Acute Endovascular Aortic Repair Due to Ruptured Abdominal Aorta Aneurysm

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Keywords: *Aorta Aneurysm; Rupture; Chimney; Parallel Graft*

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These photos show how a chimney graft (parallel graft) was used in an urgent case of ruptured abdominal aortic aneurysm to facilitate endovascular aortic repair. Procedure time was around 90 minutes with complete recovery of the patient. The parallel graft technique was used due to very short aortic neck and landing zone. A GORE Excluder system and B-graft as chimney graft were used in this case.

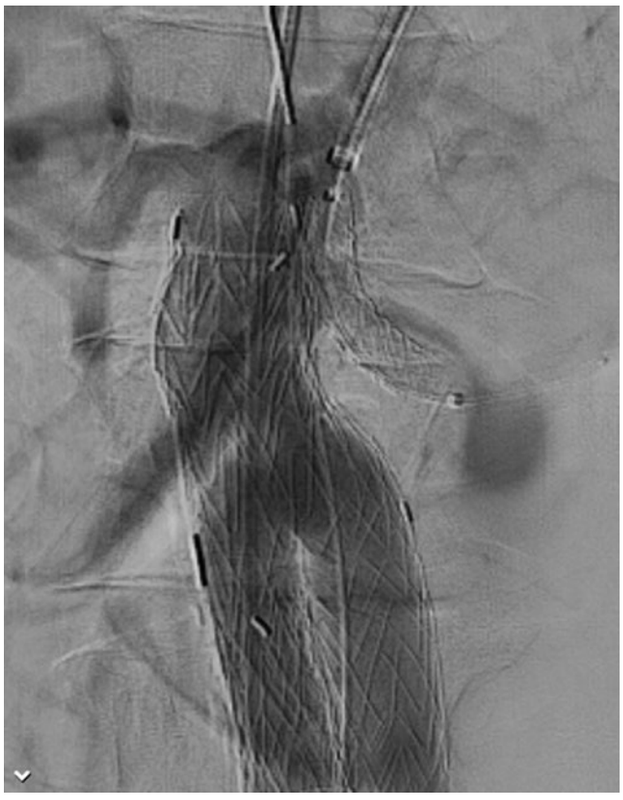

Figure 1 Peri-operative angiography showing the left kidney chimney graft position.

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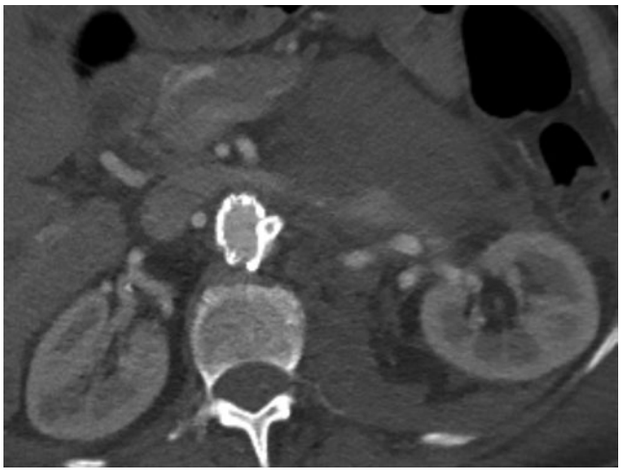

Figure 2 Axial view of computed tomography angiography (CTA) with chimney graft in the left kidney. No gutters seen and no endoleak on CTA.

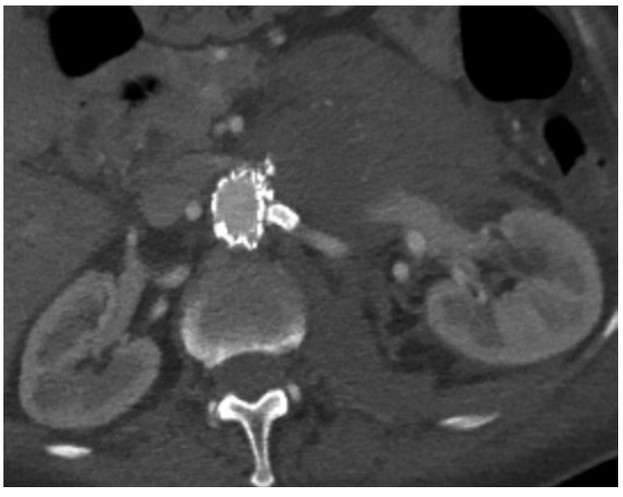

Figure 3 Axial view of the chimney graft parallel to the main graft body.

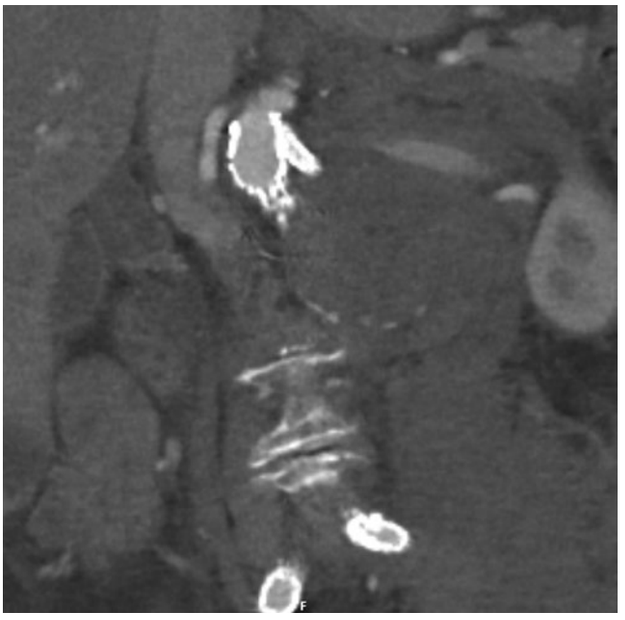

Figure 4 Coronal (frontal) view of the parallel graft on CTA.

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.
(3) The images were published with permission from the patient.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Case Report

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Central Venous Occlusion Caused by a Collapsed Stent: Endovascular Treatment in an Emergency

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Background: Stenosis and central venous obstruction are very serious and frequent complications in hemodialysis patients. The incidence of these complications is 30% and is due to an increase in venous flow that generates inflammation and proliferation of the endothelium. Causes of acute venous occlusion have rarely been described and the endovascular therapeutic options include percutaneous transluminal angioplasty (PTA) with or without the placement of a stent.
Methods: We report the clinical case of an acute occlusion of a covered stent in a right anonymous vein treated through a Bard Covera Plus recanalization and stent delivery procedure. We also performed a review of the scientific literature of the endovascular treatment of stenosis and occlusions of large venous vessels.
Results: The endovascular procedure has shown an excellent result of recanalization of a collapsed and acute occluded venous stent. PTA is always recommended as the first line of endovascular treatment of venous steno-occlusions. As far as we know, there are no studies with large case series describing the results analyzed in our clinical case.
Conclusions: Our experience suggests promising results of the use of the stent Covera Plus. However, it is essential to carry out safety and efficacy studies of the treatment on large series and in the long term.

Keywords: *Interventional Radiology; Interventional Nephrology; Venous Covered Stent; Phlebography; Vascular Treatment*

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BACKGROUND

Stenosis and central venous obstruction are very serious and frequent complications in hemodialysis patients. The incidence of these complications is 30% and is due to an increase in the flow and venous flow that generates inflammation and proliferation of the endothelium [1–3]. Causes of acute venous occlusion caused by stent collapse have rarely been described. We present the urgent treatment of an acute occlusion of a covered stent in a right anonymous vein through an endovascular interventional radiology procedure.

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CASE REPORT

A 57-year-old male patient was undergoing follow-up of a distal arteriovenous fistula right brachial-cephalic. About 7 months previous he developed central venous obstruction syndrome caused by severe stenosis of the anonymous right venous trunk and was subsequently treated via some percutaneous transluminal angioplasty (PTA) and covered stents. In the past 10 days, the patient had again developed worsening central venous occlusion syndrome. Interventional radiology consultancy was performed with phlebographic indication for possible endovascular treatment.

Upon physical examination, there was an increase in the size of the right arm compared with the contralateral. The presence of some aneurysms in the venipuncture sites of greater caliber than in the previous examination were observed. The cephalic vein was poorly compressible along the course and not collapsible on the Elevation Test. On palpation, the presence of pulsation was detected at the level of the surgical scar. On auscultation, there was a low systolic murmur, with low frequency and with normal intensity at the level of the surgical scar. The Eco-Color-Doppler examination

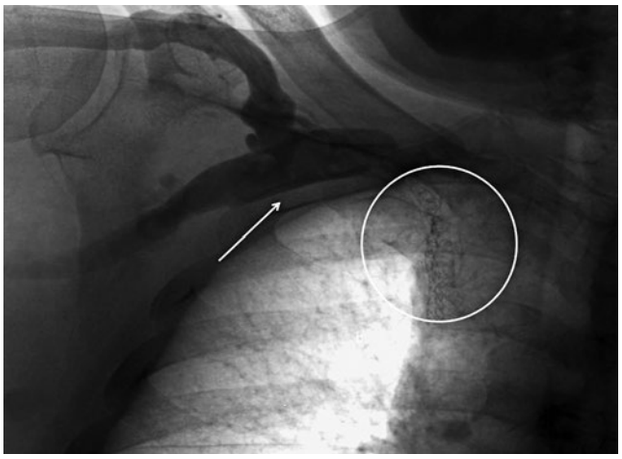

Figure 1 Upper limb phlebography (arrow) demonstrating complete occlusion and partial collapse of the stent (circle).

showed patency of the anastomotic chamber. The blood flow of the arteriovenous fistula was measured at the pre-anastomotic humeral artery with a result of 300 ml/min and with resistance indices within the limits. The post-anastomotic venous side showed regular development of the cephalic axis without narrowing. The vein was pulsating up to the outlet in the subclavian due to central stenosis.

Under local anesthesia, double access was performed at the level of the cephalic vein in the right arm and in the right common femoral vein by means of ultrasound fluoroscopic guidance. Phlebography performed through the introducer located in the right arm showed obstruction and partial collapse of the stent placed in the right anonymous vein. We had no information on the characteristics of the previously implanted stent. The stent was recanalized through combined access following the evaluation of the caliber of the venous vessel,

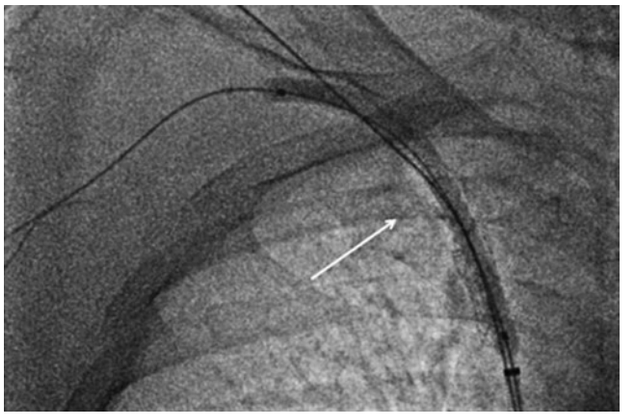

Figure 3 PTA for pre-dilation (arrow) of the occluded stent.

which was performed through the phlebographic images and based on the normal anatomy. After pre-dilation with an 8 × 80 mm Bard Ultraverse PTA catheter, the new covered stent Covera Plus 10 × 60 mm device was positioned in the lumen of the previous stent. Subsequently, further intra-stent dilation was performed through a 10 × 40 mm Bard Conquest PTA catheter. A total of 4,000 IU of intra-procedural enoxaparin sodium was administered. At the final phlebographic control, good patency of the venous lumen was found.

The patient was discharged without complications with complete re-functionalization of the arteriovenous fistula. Subsequently, double anti-aggregation was recommended (clopidogrel/acetylsalicylic acid 75/100 mg) for 3 months and then clopidogrel 75 mg for 9 months thereafter. In the following checks at 30, 60, and 90 days, complete resolution of the central venous syndrome was noted. At 12 months, there were no signs of stent occlusion. The patient is currently performing clinical instrumental follow-up and is in good physical condition.

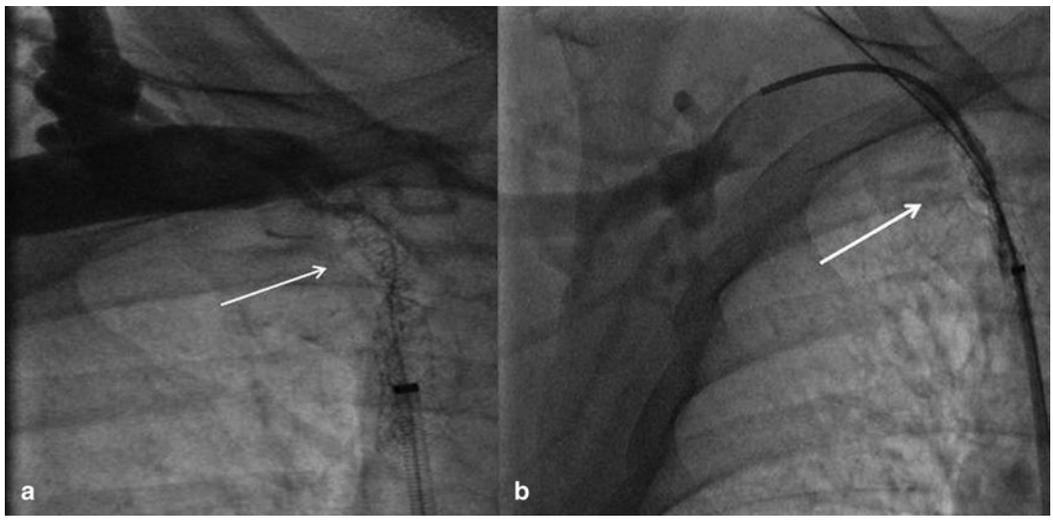

Figure 2 Recanalization (arrow) of the occlusion with phlebographic examination (**a**, **b**).

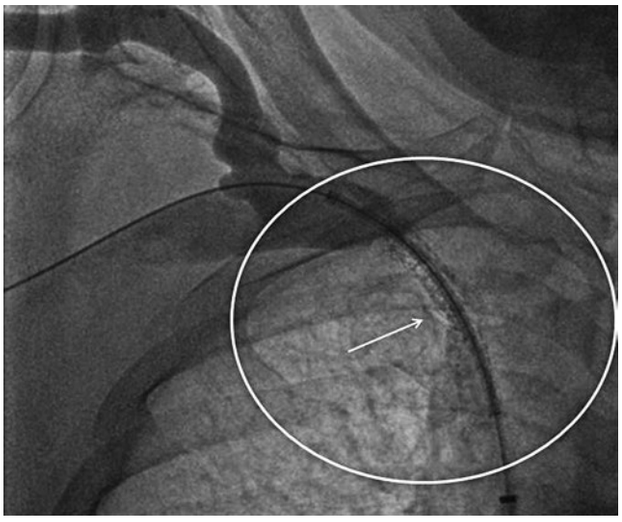

Figure 4 Localization of the new stent (circle).

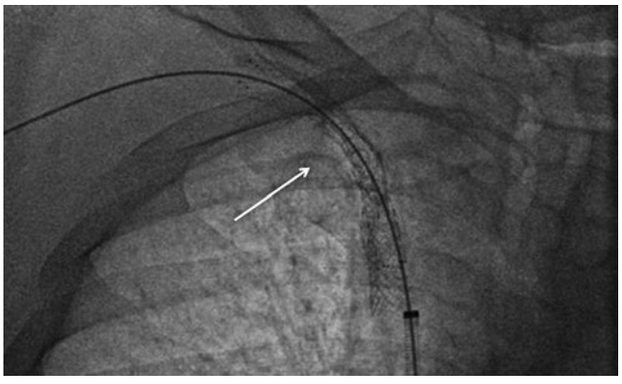

Figure 5 Release of the new stent (arrow).

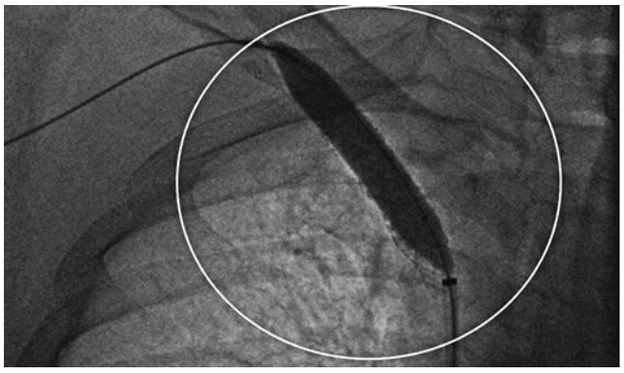

Figure 6 PTA of released stent (circle).

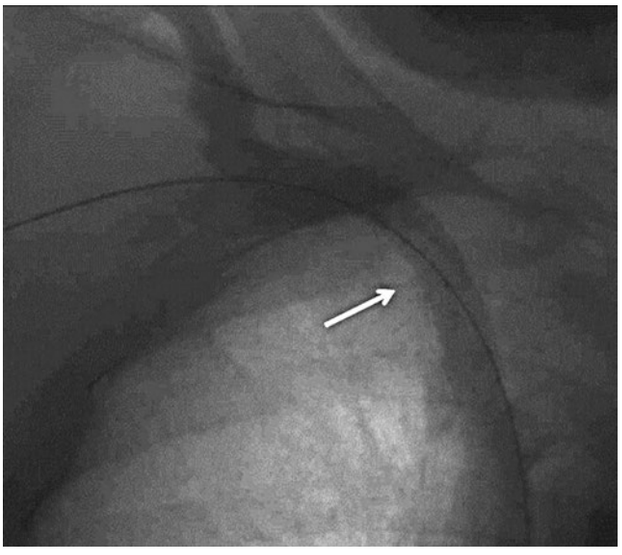

Figure 7 Phlebography demonstrating patency of the vessel (arrow).

Ethical Approval and Informed Consent

Ethical approval was not required. Informed consent was not possible due to the inability to contact the patient and the information has been anonymised.

DISCUSSION

The central venous obstruction for stent occlusion (CVD) can be asymptomatic [1,4,5]. Most occult CVDs become clinically evident after the development of a functioning arteriovenous fistula access. Symptoms of CVD depend on the site of venous stenosis or obstruction. As described in our paper, narrowing or occlusion of the central vein can lead to edema, venous hypertension, swelling, tenderness, pain, and erythema. In many cases, CVD can lead to aneurysmal dilation and tortuosity of the fistula for venous hypertension.

The development of venous collaterals that divert blood centrally are evident on physical examination of the neck, thorax, and ipsilateral extremity. Many patients present with low flow AV fistulas, and elevated venous pressure with prolonged bleeding from needle access sites after dialysis. Diagnostic imaging plays a central role in the diagnosis of acute central venous obstruction or occlusion. CVD can be diagnosed through ultrasound-detectable signs that consist of an absence of normal respiratory variation in central vein diameter and polyphasic atrial waves [3–6].

Phlebography is the gold standard for diagnosis [1,7,8] as it allows a complete evaluation of the entire vascular system [5]. In selected cases, ANGIO-RM could replace the phlebographic examination but there are still no scientific comparisons between the two imaging methods. There are many endovascular therapeutic options in use for stent venous central occlusion. These include PTA with or without the placement of an uncoated metal stent and, more recently, through the placement of covered stents. To our knowledge, there have been no randomized control studies comparing PTA and stents in hemodialysis

patients. The indication for stent implantation in previously implanted stents is recommended in conditions of acute thrombosis, collapse, and occlusion. The risks of stent implantation are related to the possibility that it may migrate, shorten, or fracture in a subacute or delayed manner after delivery [4,5,9]. The stent can cause intimal hyperplasia leading to relapsing stenosis [9]. The recommended stents are self-expanding stents. Balloon expandable stents are not routinely used as they can deform (squeeze) or migrate, especially in the subclavian and brachiocephalic veins [10]. Numerous scientific papers show a very high percentage of technical success.

As far as we know, in the literature there are no cases of the use of the stent Covera Plus in the emergency treatment of the occlusion of a central venous stent in hemodialysis patients. The advantages of the stents Covera Plus are that they are self-expanding and they form a relatively inert and stable intravascular matrix that promotes wall endothelialization and reduces the intimate hyperplastic response. The disadvantages of the stents Covera Plus are the costs and the coverage of venous collaterals.

CONCLUSION

As far as we know, there are no scientific articles in the literature describing the procedure for recanalization of acute occluded venous stents through the implantation of the stent Covera Plus. Although our experience suggests promising results, it is essential to carry out safety and efficacy studies of the treatment on large series and in the long term.

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

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Case Report

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REBOA-Assisted Resuscitation in Non-Traumatic Cardiac Arrest due to Massive Pulmonary Embolism: A Case Report with Physiological and Practical Reflections

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We present the case of a 36-year-old woman who suffered from and ultimately did not survive a non-traumatic out-of-hospital cardiac arrest (NTCA) likely due to massive pulmonary embolism. The resuscitation attempt included the use of a resuscitative endovascular balloon occlusion of the aorta (REBOA) catheter which resulted in a return of spontaneous circulation and distinct improvements in arterial blood pressure, end-tidal CO_2 and cerebral oximetry values. This suggests that the use of REBOA has the physiological basis and potential to improve the rate of both survival and favorable neurologic outcome and warrants further study.

Keywords: *REBOA; Cardiac Arrest; Resuscitation; Endovascular Techniques*

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A 36-year-old woman who sustained a non-traumatic out-of-hospital cardiac arrest presented to the emergency department of an urban community hospital. There was a considerable delay before transfer to hospital, due to the stretcher not fitting in the elevator at the patient's apartment complex. Upon arrival to the emergency department, she had already received cardiopulmonary resuscitation (CPR) for approximately 50 minutes, including an initial 10 minutes of chest compressions from her husband as instructed via telephone by the emergency operator.

The patient's cardiac rhythm was asystole and a mechanical chest compression device (MCCD) was used (Lucas2, Lund, Sweden). Focused bedside ultrasound ruled out cardiac tamponade, pneumothorax or a ruptured ectopic pregnancy, and revealed an extensively thrombosed right femoral vein. The patient was endotracheally intubated by the emergency physician, while a critical care physician inserted a resuscitative endovascular balloon occlusion of the aorta (REBOA) catheter in retrograde fashion via the left femoral artery under direct ultrasound guidance. Simultaneously, given the likely diagnosis of acute pulmonary embolism, the patient was given intravenous thrombolysis with 40 mg of Tenecteplase. Real-time monitoring of intra-arrest hemodynamic variables included arterial pressure measured from the intra-aortic catheter tip, end-tidal CO_2 ($EtCO_2$) from the endotracheal tube and cerebral tissue

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oxygen saturation ($SCTO_2$), which was measured with an Invos Somanetics device (Medtronic).

Resuscitative trans-esophageal echocardiography (TEE) was performed by a critical care physician to adjust chest compression position and confirm aortic zone 1 placement of the balloon (Figure 1).

TEE initially showed a lack of significant opening of the aortic valve during CPR both in mid-esophageal long axis and mid-esophageal aortic valve short axis views. The Lucas2 device was repositioned to improve the aortic valve opening during the rest of the resuscitation effort.

Return of spontaneous circulation (ROSC) was achieved within 10 minutes of aortic balloon occlusion, approximately 20 minutes after arrival in the emergency room. The MCCD was paused and adequacy of circulation assessed. The arterial line tracing revealed a systolic blood pressure of 105 mmHg and TEE demonstrated cardiac contractions. The aortic balloon was deflated over 10–15 seconds and an epinephrine infusion started. Clinicians subsequently noted a decrease in systolic blood pressure to approximately 40 mmHg, diastolic blood pressure levels at approximately zero mmHg, $EtCO_2$ from 27 mmHg to 15 mmHg and the onset of progressive bradycardia. In order to maintain perfusion, chest compressions were resumed with a resultant compression phase blood pressure of approximately 60 mmHg. The aortic balloon was then re-inflated with immediate improvement of compression-phase blood pressure to 115–125 mmHg, decompression-phase blood pressure at approximately 20 mmHg and return of $EtCO_2$ to 24–26 mmHg (Figure 2).

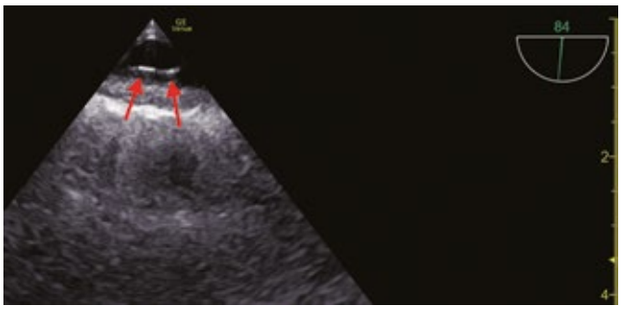

Figure 1 Tip of REBOA catheter (red arrows) in descending thoracic long axis view of the aorta. REBOA, resuscitative endovascular balloon occlusion of the aorta.

At this point, centers with capability to perform extracorporeal membrane oxygenation (ECMO) were contacted. However, because the patient's resuscitation efforts had lasted more than 70 minutes, combined with an initial s-lactate above 15 mmol/l, transfer was declined unless clinical improvement occurred. The clinicians at the bedside decided that due to the patient's young age, a positive outcome was still possible, and briefly conferred amongst themselves to optimize their resuscitation strategy. They determined that augmenting cardio-cerebral perfusion in the hopes of reaching sustainable cardiac performance would ideally lead to improved s-lactate measurements and sufficient clinical improvement to permit transfer to an ECMO center. Resuscitation efforts continued with the MCCD and aortic occlusion. A more detailed TEE examination revealed a dilated right ventricle and atrium as well as large mass on the tricuspid valve (Figure 3). In the clinical context, this was assumed to be a clot-in-transit, an echocardiographic finding that is near diagnostic for pulmonary embolism.

In an effort to prevent irreversible damage to splanchnic organs, the balloon was slowly deflated approximately every 10 minutes for about 1 minute, or until systolic blood pressure dropped below 50 mmHg, a level at which it was assumed that coronary perfusion pressure would be incompatible with maintaining cardiac activity and would likely devolve to asystole [1].

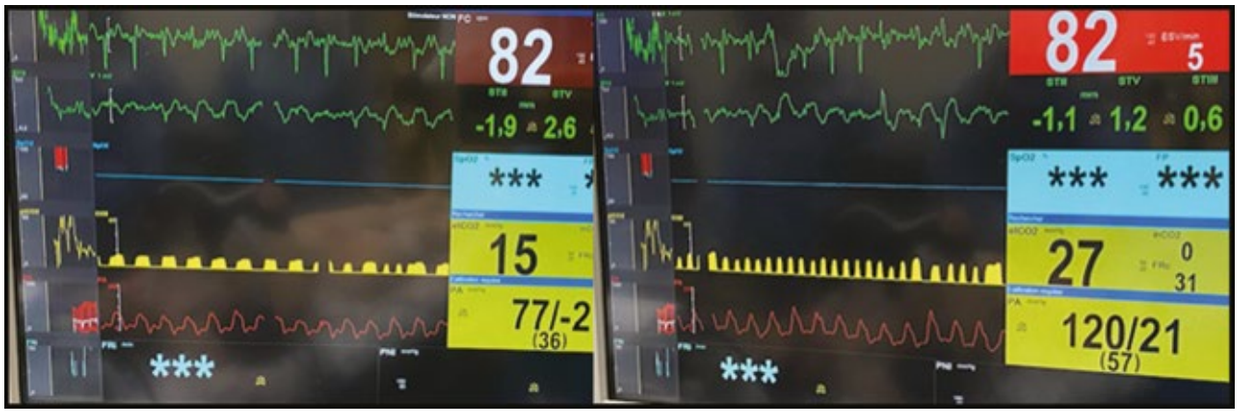

Figure 2 $EtCO_2$ and blood pressure values after REBOA deflation (left) and following re-inflation (right). $EtCO_2$, end tidal CO_2. REBOA, resuscitative endovascular balloon occlusion of the aorta.

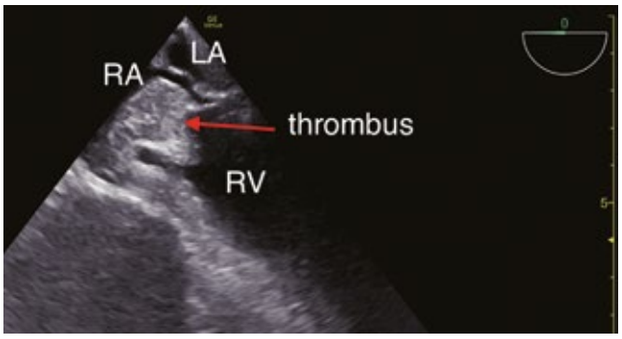

Figure 3 TEE view in mid-esophageal 4 chamber with rotation towards right sided chambers showing a large (>2 cm) mass attached to the tricuspid valve. TEE, trans-esophageal echocardiography.

In the ensuing 40 minutes, the 10:1-minute inflation:deflation cycles were repeated with serial reassessments of cardiac function by TEE, combined with a pause in chest compressions. In each of these deflation cycles, the blood pressure and $EtCO_2$ dropped and then responded to balloon reinflation (Figure 2). $SCTO_2$ dropped from 50–55% to 35–40% and responded to re-inflation. The s-lactate did not improve and remained above 15 mmol/l.

Resuscitative efforts were stopped after a total of approximately 110 minutes, in view of perceived futility and non-availability of ECMO support, and the patient passed away.

Ethical Approval and Informed Consent

The patient's next of kin provided informed consent for this case, including patient data and imaging, to be used for the purpose of science and teaching.

Given the nature of the case and extreme urgency, the critical care resuscitation physician decided that benefit outweighed risk and took the decision to perform REBOA cannulation. This was explained to the next of kin after the unsuccessful resuscitation, who was appreciative of the efforts made.

DISCUSSION

The last decade has seen a steady progress in ECMO-CPR (E-CPR) as an advanced adjunct to cardiac arrest resuscitation. As an example, the recent publication of the ARREST Trial by Yannopoulos et al. [2] has set a new standard for advanced resuscitation all over the world. Most importantly, the study highlights the possibility of better cardiac arrest outcomes, which have seen little improvement in the last two or three decades. However, there are many hurdles to overcome before E-CPR becomes widespread and available to most cardiac arrest patients.

Other interventions may significantly improve the quality of cerebral and coronary perfusion during resuscitation efforts. Optimizing circulation in these two vascular beds is the primary challenge in terms of both obtaining ROSC and a favorable neurologic outcome. Thoracic aortic occlusion with or without proximal perfusion have been the subject of several animal studies and human case reports and series, with human trials currently underway [3–6].

The physiology of aortic occlusion adjuncts is simple and elegant. It is well known that during optimal CPR, mechanical or manual, the cardiac output is only in the range of 25–40% of the pre-arrest values [7]. This low-flow state is often not sufficient to achieve adequate coronary and/or cerebral perfusion pressure. An increase in coronary perfusion pressure is associated with ROSC in humans [8]. The brain is susceptible to hypoxic injury – far more than rest of the body – and irreversible neurologic damage is hence the most common cause for post-resuscitation death [9]. Occlusion of the descending thoracic aorta decreases the vascular bed by more than two-thirds, thus increasing the perfusion of organs proximal to the occlusion, including heart, brain and upper extremities, via an increase in blood pressures in the aortic arch, coronary and cerebral arteries [10]. This is the rationale behind the use of REBOA to enhance CPR in non-traumatic cardiac arrest, as opposed to the original purpose and current indication, which is to control hemorrhagic shock. A recent case series by Brede et al. [4] showed that this procedure was feasible in the pre-hospital setting and resulted in an impressive rate of ROSC in patients with prolonged unsuccessful resuscitation efforts.

Another potential adjunct involves the infusion of oxygenated fluids, blood or saline, in a distally occluded aorta, termed the selective aortic arch perfusion technique [11]. This has been shown to work favorably in animal models but is not yet approved for use in humans.

The advantage of the REBOA approach is that it does not require the logistics and resources of E-CPR, nor the required level of training and experience in large gauge cannulation. Such competence is uncommon in community hospitals, where most cardiac arrests are managed. Physicians who regularly insert arterial lines or central vein catheters are familiar with the use of ultrasound and the Seldinger technique, and should be able to rapidly acquire the competence to insert a REBOA catheter. Structured training programs for this procedure are available [12].

Our institutional resuscitation team has been working towards E-CPR and advanced resuscitation techniques. While we do not routinely use REBOA in non-traumatic cardiac arrest, we decided to do so given the age of the patient and prolonged unsuccessful advanced cardiac life support (ACLS), in the hope of achieving ROSC.

While the outcome of this case was tragic, the observed dramatic improvement in physiological

parameters generated by a bedside technique that could be performed by most acute care physicians provides hope for the future. Our case achieved ROSC after balloon inflation despite a prolonged downtime, and demonstrated improvements in generated blood pressure and cerebral tissue saturation, as well as improved $EtCO_2$ similar to other studies [4].

This case also brings up some fascinating physiological questions and bedside clinical challenges. With the combination of MCCD and aortic occlusion, we obtained almost normal blood pressure. However, if the aortic balloon was deflated, ROSC was unable to be sustained, despite a high-dose epinephrine drip. While the team felt more comfortable with continuing the MCCD/REBOA approach despite ROSC, this would be at the cost of not perfusing the viscera and lower torso and limbs. One of the issues debated during this resuscitation was the feeling that since the liver was not perfused, lactate values were unlikely to improve. However, the clinicians determined that prioritizing coronary and cerebral flow to try to re-establish sustained cardiac performance took precedence over peripheral perfusion. The optimal balance between this can be debated. We empirically decided on a 10:1 time ratio for inflation:deflation, without real data to support this, only the assumption that cardiac perfusion had to take precedence, particularly given the diagnosis of pulmonary embolism.

REBOA-assisted circulation in massive pulmonary embolism has potential advantages, since coronary perfusion pressure is decreased by elevated right atrial pressure. Hence, a higher aortic pressure is required to maintain adequate right ventricular perfusion. The obstructive shock generated by massive pulmonary embolism occurs due to severe pulmonary hypertension and acute right ventricular failure. The combination of thrombolytics and REBOA may be a potential strategy to augment coronary perfusion pressure while thrombolysis, which is not instantaneous, relieves some of the obstruction and pulmonary hypertension. The optimal timing in relation to thrombolysis is unknown, but in our case happened almost simultaneously. We feel that either should not delay the other as thrombolysis is the only bedside therapy for massive pulmonary embolism, but that it should not be a contraindication for REBOA placement in arrest given the critical need for optimized aortic pressure due to the pathophysiology of pulmonary embolism.

At which point does the risk/benefit ratio tilt towards allowing distal perfusion at the cost of blood pressure and therefore coronary and cerebral perfusion pressures? The REBOA literature suggests 30–45 minutes as the upper margin of occlusion time, but can this easily translate to NTCA patients?

In the case series by Brede et al., the protocol mandated deflation when ROSC occurred, so as not to provide an increased afterload to the left ventricle and hinder cardiac output. However, if the cardiac output after ROSC is unable to maintain adequate arterial blood pressure, there may be an advantage in continuing aortic occlusion to maintain cardio-cerebral perfusion. This is a double-edged sword, with potentially improved myocardial perfusion due to increased aortic and subsequent coronary perfusion pressure on the one side, and increased afterload under which a stunned heart likely will succumb and lead to re-arrest on the other side. The best practice is currently not known. In our case, since TEE showed little difference in left ventricular function whether the REBOA was inflated or deflated, we assumed the issue was intrinsic rather than afterload related. The advent of REBOA catheters that allow for partial inflation may offer advantages and will certainly be the subject of further study, and whether a partial flow will extend the "safe" occlusion time is yet to be determined.

POSITION IN THE CHAIN OF RESUSCITATION

The recent development of endovascular resuscitation adjuncts raises organizational issues and challenges as well. The most important one is likely where they should fit in the chain of resuscitation.

In our opinion, the physiological benefit from REBOA-enhanced CPR would theoretically suggest it should be used in all non-traumatic cardiac arrest cases, as long as there is no delay to possible E-CPR treatment. REBOA-enhanced CPR may provide a bridge to a more definitive circulatory support such as ECMO or intra-aortic balloon pump (IABP) [3], or the introducer could easily be used to perform percutaneous coronary intervention, if appropriate. We propose a conceptual algorithm on how to introduce and position these interventions (Figure 4).

This assumes a patient who is a candidate for aggressive resuscitation including E-CPR but could also include other circulatory support strategies such as IABP or Impella-type devices, depending on availability and experience.

CONCLUSION

This case report describes the use of an adjunct treatment (REBOA) to cardiopulmonary resuscitation, which likely led to both ROSC and augmented objective parameters of resuscitation effect. E-CPR is not commonly available worldwide, even though it represents the highest quality of resuscitation and the best chance of survival, and REBOA-enhanced ACLS may provide the additional perfusion to obtain ROSC, or possibly a bridge to ECMO.

This case report additionally supports that more research is needed to answer many physiological and practical questions concerning the use of endovascular resuscitation in non-traumatic cardiac arrest.

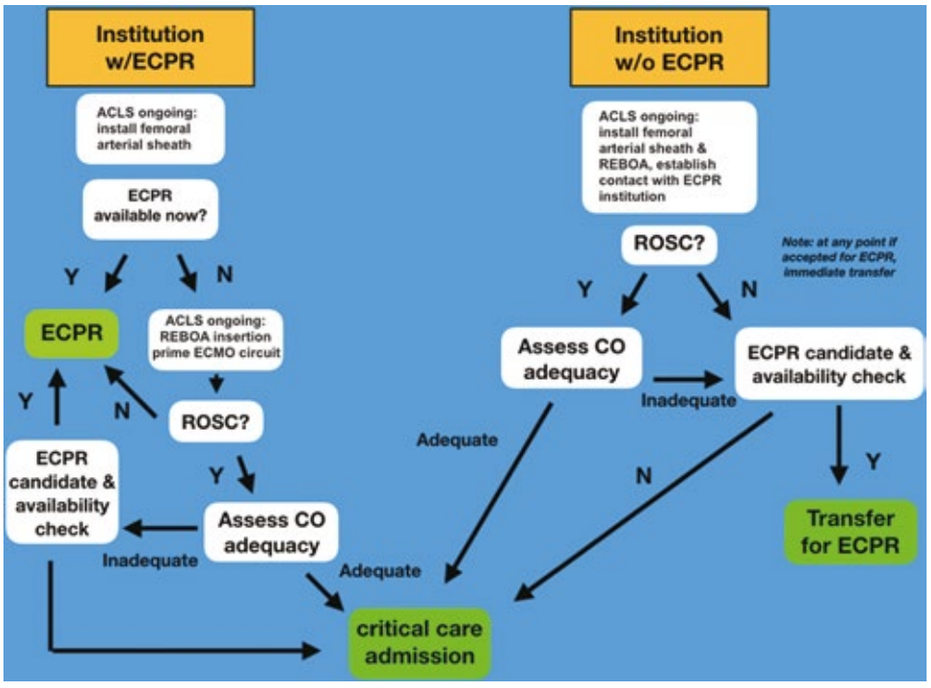

Figure 4 A proposed algorithm including REBOA-enhanced resuscitation. REBOA, resuscitative endovascular balloon occlusion of the aorta.

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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

All authors have substantially contributed to the article.

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Case Report

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Hybrid Open and Endovascular Management of a Gunshot Wound to the Carotid Artery

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In addition to standard open surgical techniques, major hemorrhage is increasingly being managed using hybrid (open and endovascular) surgery. We present a case of hybrid management of a carotid artery injury secondary to an oropharyngeal gunshot wound. After performing balloon catheter tamponade with an inflated intraoral Foley catheter, on-table transfemoral angiography demonstrated extravasation from the external carotid artery with arteriovenous fistulization to the internal jugular vein. An endovascular stent graft was deployed, spanning from the common carotid to the internal carotid artery. This facilitated surgical neck exploration and ligation of the external carotid artery and jugular vein injury in zone II/III of the neck while maintaining antegrade cerebral blood flow. The approach presented represents a feasible and effective means to manage these types of difficult-to-access injuries in the endovascular and hybrid surgical era.

Keywords: *Penetrating Trauma; Head and Neck; Wounds and Injuries; Noncompressible Hemorrhage; Angiography*

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INTRODUCTION

In addition to standard open surgical techniques, major hemorrhage is increasingly being managed using hybrid (open and endovascular) surgery [1–5]. Vascular surgeons were first to develop hybrid open-endovascular techniques for managing abdominal aortic aneurysms and peripheral artery occlusive disease [6–9]. However, along with increasing use of endovascular therapies for hemorrhage control (including embolization techniques, covered stent grafts, and resuscitative endovascular balloon occlusion of the aorta (REBOA)) has come a growing interest in the use of hybrid techniques in trauma [2,3,5,10–20].

Traditionally, upon leaving the trauma bay, surgeons needed to decide whether the patient should be transported to the computed tomography (CT) scanner, operating room, or interventional radiology suite. To avoid having to decide whether to take the patient to one of these three distinct, geographically separate environments, there has been an emergence of hybrid operating suites, in which surgeons may perform both open surgical and endovascular therapies depending on acuity, complexity, and evolution of the clinical scenario [21–24]. In these settings, traditional surgical and endovascular care can be delivered not only simultaneously (e.g., laparotomy for solid organ hemorrhage combined with embolization of a bleeding pelvic vessel), but also in sequence [23]. For example, temporary or partial control of bleeding can be obtained with endovascular stenting, making definitive hemorrhage control with open operative techniques more facile and limiting further blood loss in areas difficult to manage with operative exposure alone.

We present a case of hybrid open and endovascular management of an external carotid artery gunshot wound (GSW). The case demonstrates the utility of endovascular bleeding control in combination with traditional open operative exposure and provides a framework for future hybrid management of penetrating vascular injuries.

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Ethical Approval and Informed Consent

Ethical approval was not required. Informed consent for reporting of this case was obtained from the described patient verbally and via e-mail.

CASE

A 19-year-old male was brought to the Emergency Department of our regional trauma centre by paramedics after he sustained a GSW to the mouth and left neck. He was alert, oriented, moving all extremities, and vitally stable aside from being tachycardic (blood pressure 107/75, heart rate 118 bpm). There was significant hemorrhage coming from the oral cavity and a large expanding left neck hematoma. Initial resuscitation included an Emergency Department cricothyrotomy to secure the airway, oral packing with gauze sponges, placement of a right-sided femoral large-bore central venous access line (Cordis; Cardinal Health Inc., Santa Clara, California, USA), transfusion of packed red blood cells and fresh frozen plasma, and infusion of 1g of tranexamic acid. X-rays of the chest and neck were obtained and the patient was then transferred directly to the operating room (Figure 1).

In the operating room, the oral cavity was inspected revealing a penetrating injury to the proximal tongue and left posterior oropharynx. For immediate, temporary hemorrhage control, balloon catheter tamponade was performed by inserting a Foley catheter with a 20 cc balloon into the missile tract and inflating and repositioning it until external hemorrhage ceased. The patient was then prepped and draped in the supine position on a fluoroscopy-compatible table, such that the neck, torso, and groins were exposed. As the hemorrhage was completely controlled with balloon catheter tamponade, and a high, zone II/III carotid artery injury was suspected, we elected to proceed with a transfemoral angiogram prior to neck exploration.

We inserted a 6-French 90-cm long sheath into the left common femoral artery and used this to access the aortic arch and carotid arteries. A pigtail catheter was positioned in the aortic arch and used to perform angiograms of the left common, internal, and external carotid arteries (CCA, ICA, ECA, respectively). Initial imaging was difficult to interpret given the extravasation, drop-out artifact created by missile fragments, and presence of a high-flow arteriovenous fistula to the jugular vein. Selective angiography in the anterioposterior and lateral views with a portable C-arm demonstrated an intact left ICA and CCA. It also revealed contrast extravasation from the left ECA in distal zone II, approximately 3-cm distal to the carotid bifurcation, and an arteriovenous fistula between the ECA and internal jugular vein with retrograde filling of the cerebral sinuses (Figure 2).

After consideration of various options, we elected to proceed with hybrid open and endovascular surgical

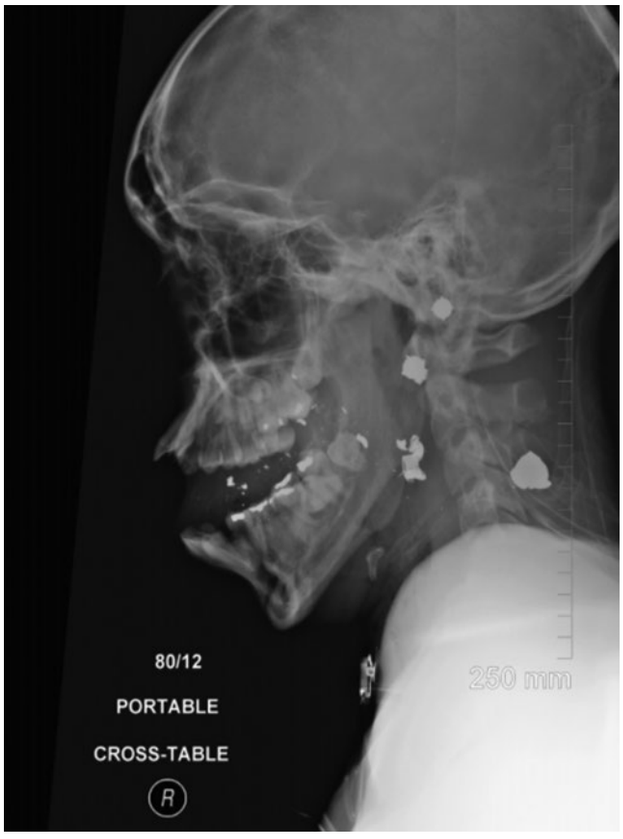

Figure 1 Location of missile fragments at junction of zone II and zone III of the neck.

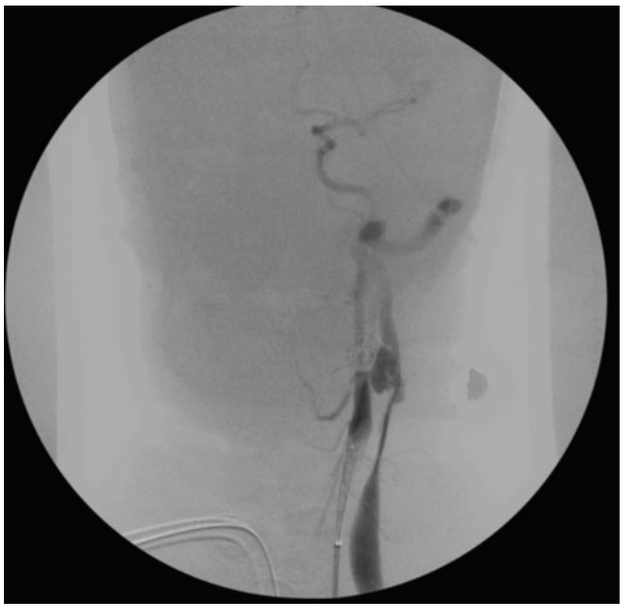

Figure 2 Left external carotid artery (ECA) injury with extravasation of contrast, as well as an arteriovenous fistula between ECA and internal jugular vein.

management. Following systemic heparinization, a 0.035 inch Rosen wire (Cook Medical LLC, Bloomington, Indiana, USA) was positioned in the distal ICA. Distal embolic protection was not used as the carotid bulb appeared patent and free of disease or clot. We weighed the risk of hemorrhage or prolonged cerebral ischemia with proximal CCA clamping during open surgical repair against that of poor stent patency in a young person and decided to proceed with endovascular stenting. A 7 mm x 5 cm Gore Viabahn self-expandable endoprosthesis (W. L. Gore and Associates Inc., Flagstaff, Arizona, USA) was deployed spanning from the distal left CCA to the proximal ICA. We subsequently post-dilated the endoprosthesis with a 7 mm × 40 mm Mustang balloon dilatation catheter (Boston Scientific Corporation, Marlborough, Massachusetts, USA). Angiography demonstrated stent patency with minimal antegrade flow into the ECA and arteriovenous fistula (Figure 3).

The left neck was then explored via a longitudinal incision along the anterior border of the sternocleidomastoid muscle with extension posterior and inferior to the left earlobe. The subcutaneous tissues were extensively infiltrated with blood and clot. With the vagus nerve protected, dissection of the proximal aspect of the CCA was undertaken in the retrojugular plane. As the dissection approached the carotid bifurcation, we encountered arterial and venous bleeding from the more distal portion of the incision underneath the mandible (distal zone II or proximal zone III). The bleeding was controlled with manual digital pressure until the dissection of the ICA and ECA was completed. The ECA was found to be completely transected with a large defect in the path of a missile fragment. The proximal end of the transected ECA was not bleeding and was subsequently surgically ligated just distal to the carotid bifurcation. The distal, actively bleeding branches of the ECA were surgically ligated. The high venous bleeding, presumably from a partially transected internal jugular vein, was not easily accessible for surgical exploration but was easily controlled by packing with Surgicel (Ethicon Inc., Cincinnati, Ohio, USA).

At this point, all bleeding had been controlled. Repeat completion angiography demonstrated stent patency with satisfactory opacification of the distal intracranial vasculature based on anterioposterior and lateral views (Figure 4). The ECA was successfully ligated with no further extravasation or arteriovenous fistula from antegrade or retrograde blood flow. The aero-digestive structures of the neck did not appear to be injured. A Jackson-Pratt closed suction drain was left in the operative field and tension-free closure of the wound was obtained by raising a small local advancement flap. Final exploration and repair of injuries to the oral cavity were then completed by an ear, nose, and throat (ENT) surgeon.

Post-operatively, the patient remained in hospital for 30 days. He was started on dual antiplatelet therapy,

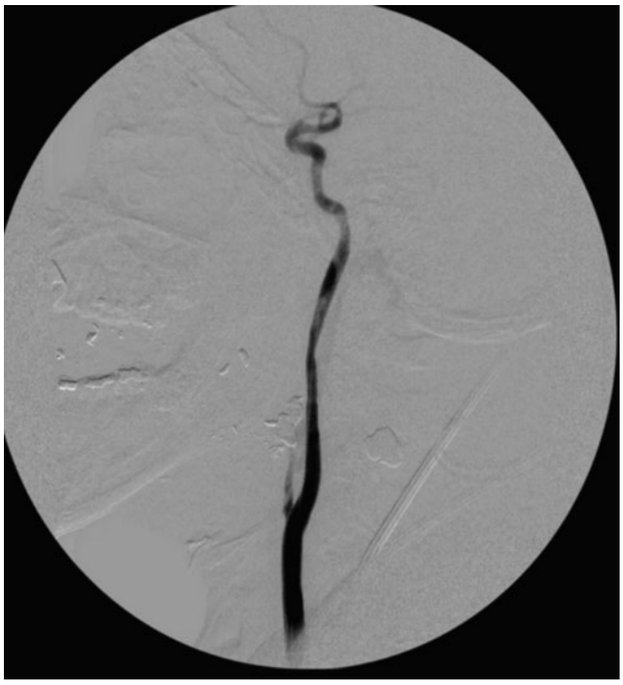

Figure 3 Patent stent deployed across external carotid artery (ECA) origin with minimal antegrade flow into the ECA and arteriovenous fistula.

which will be continued indefinitely. He underwent conversion of his cricothyrotomy to a formal tracheostomy, placement of a percutaneous endoscopic gastrostomy tube for feeding, and an external fixation device for management of associated mandibular fractures. Since discharge from hospital, follow-up CT imaging has revealed patency of the stent. Further, the gastrostomy tube and tracheostomy have been removed, and he is awaiting surgery for mandible reconstruction. Follow-up Duplex ultrasonography has revealed patency of the self-expandable carotid stent without stenosis or flow irregularities.

DISCUSSION

We have presented a case of hybrid management of a GSW to the oropharynx and neck. In this case, we elected to forego CT imaging given the hard signs of vascular injury. Appreciating the potential challenge of neck exploration for a high zone II/III injury, on-table angiography was performed after temporary hemostasis was achieved with balloon catheter tamponade with an intraoral Foley catheter. The angiogram demonstrated an ECA injury complicated by fistulization to the internal jugular vein. Various options were considered, including immediate neck exploration, neck exploration following CCA-ICA balloon occlusion, and neck exploration following CCA-ICA covered stenting to exclude the ECA. After intraoperative multidisciplinary consultation

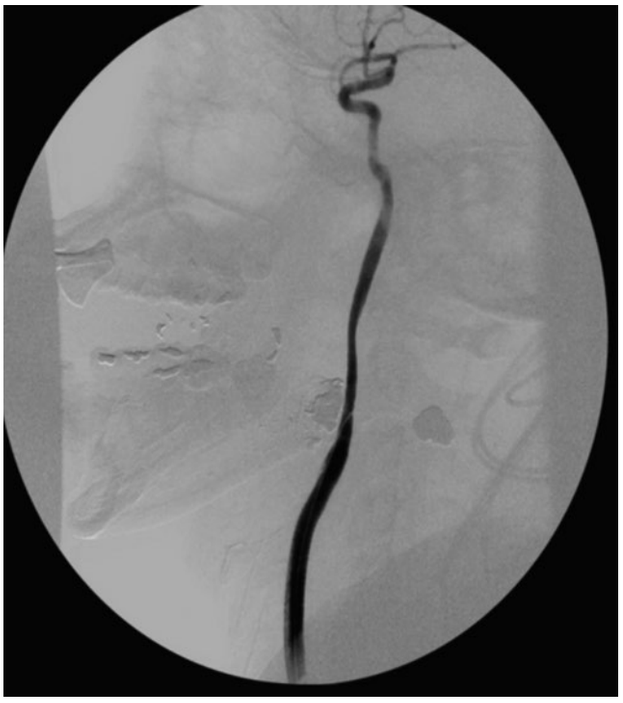

Figure 4 Patent stent with satisfactory opacification of the intracranial vasculature.

between vascular surgery, trauma surgery, interventional neuroradiology, neurosurgery, and ENT, it was determined that covered stenting would afford the best chance for hemorrhage control while maintaining antegrade cerebral blood flow. However, this may be offset by the potential short- and long-term sequelae of placing a carotid stent in the setting of a contaminated wound in a young individual, which was acknowledged. As it was suspected that the injury was high and potentially in zone III, availability of a hybrid operating environment capable of percutaneous and open vascular surgery was essential.

Hybrid surgical approaches in trauma are now well-described, and REBOA is a prime example of the utility of endovascular approaches as a bridge to definitive hemorrhage control [2–5,10–13]. Beyond the use of balloon occlusion of the aorta for pelvic injuries, much of the literature has focused on the use of balloon occlusion, embolization, or stenting in anatomic regions that are difficult-to-access with traditional open surgical techniques, such as the proximal groins and subclavian and innominate arteries [25–34]. Patients with zone III carotid artery injuries can present a specific challenge, in that obtaining proximal and distal control of the vessel may prove technically difficult and/or consequential with prolonged ischemic times. In such cases, angiography is a useful tool to identify the site of injury and may facilitate use of endovascular techniques better suited to gaining control of bleeding in this anatomic region, particularly in zones I and III of the neck [35–37]. Indeed, while REBOA is a useful bridge to definitive open surgical management, initial on-table endovascular techniques are useful not only for temporary balloon occlusion, but also for diagnosis of complex vascular injuries and may lead to potentially less morbid endovascular therapies such as the use of covered stents.

The use of covered stents to exclude an area of injury in the carotid arteries has been described elsewhere in the literature [38–40]. Duane et al. (2002) reported the case of a 31-year-old woman who developed a left ICA pseudoaneurysm following a stab wound, and of a 27-year-old woman who was shot in the right neck and was found to have a right ICA-to-internal jugular vein arteriovenous fistula [38]. In the first case, a CCA cutdown was performed and a 12-mm wall graft was placed. On follow-up angiogram, the graft had unfortunately become completely occluded. This is not necessarily a common complication, with one study of over 100 patients demonstrating 79.6% stent patency at 2 years [41]. The second patient underwent endovascular placement of a covered stent across the fistula with maintenance of cerebral blood flow and a favourable outcome. McNeil et al. (2002) similarly reported deploying a stent across an ICA pseudoaneurysm with a good neurologic outcome [39]. In the non-trauma literature, Marine and Sarac (2012) described deployment of a covered stent for an iatrogenic right CCA pseudoaneurysm and arteriovenous fistula [40].

Despite the success described in previous reports of endovascular stenting of carotid injuries, some have advocated for a primarily open surgical approach to penetrating carotid artery injuries, particularly in zone II [36]. Although there is a lack of morbidity associated with exposure in zone II of the neck and reasonable short- and medium-term outcomes have been reported with an exclusively open approach, the injury in our patient was felt to be high and potentially in zone III [36]. These factors, as well as the long-term sequelae of stenting were considered, especially given the young age of our patient. The need for lifelong antithrombotic therapy was acknowledged given that our patient was young. With respect to complications, infection was considered given that the stent was being placed in a contaminated field. While the consequences of graft infection could be devastating, carotid artery stent infections are rather rare in the literature, and this risk was weighed against the potential neurological effects of reduced cerebral blood flow and the risk of hemorrhage [42]. Occlusion or stenosis as well as leak have been reported in 10.6% and 5.3% of patients undergoing carotid artery stenting, respectively [41]. However, given the nature of the injury and the aforementioned risks of hemorrhage as well as the importance of maintaining cerebral perfusion, the benefits of stenting were felt to outweigh the risks.

Interestingly, the case we have presented represents a not-yet-explored intersection of the aforementioned

literature. First, while both open surgical and endovascular management of penetrating injuries have been reported, this is, to our knowledge, the first description of a hybrid open-endovascular approach to a penetrating ECA injury. Second, the means by which the covered stent was used to provide hemorrhage control has also not been previously described in this specific context to our knowledge . In the extant literature pertaining to endovascular management of penetrating carotid artery injuries, covered stents have been deployed across pseudoaneurysms and arteriovenous fistulas, or combinations thereof [38–40]. However, we are the first, to our knowledge, to report use of a covered stent to occlude the origin of the ECA prior to its ligation (i.e., to provide proximal control), minimizing blood loss during surgical exploration and maintaining cerebral blood flow in the setting of an unknown degree of collateralization.

Overall, while both open surgical and endovascular techniques can be successful in managing penetrating neck injuries, their simultaneous or staged use in a hybrid fashion represents an innovative approach with rapid proximal control of bleeding followed by definitive surgical hemorrhage control. In appropriate cases, endovascular techniques can be used as an adjunct to open surgery, reducing blood loss and the chances that open exploration devolves into significant, difficult-to-control bleeding and worsening instability, while maintaining antegrade perfusion to vital organs. Hybrid surgical techniques may also foster multidisciplinary, collaborative operative environments, creating space for different skill sets and potentially leading to the formation of novel surgical techniques.

The approach described above has some limitations. First, the patient's external bleeding could be controlled with a Foley catheter in the missile tract, allowing time to complete angiography and plan the hybrid approach. In patients with multiple areas of external bleeding or multiple significant injuries leading to instability, there would likely not be time to characterize the neck injuries with angiography prior to emergent surgical exploration. Second, placement of a synthetic graft in a potentially contaminated field is not extensively studied, and the role for long-term antithrombotic prophylaxis remains undefined. Nonetheless, where patient factors and injury patterns allow, the combination of angiography to characterize injuries, endovascular attainment of proximal bleeding control, and definitive repair with open surgery represents an attractive option for management of penetrating carotid artery injuries.

CONCLUSION

We present the case of a GSW to the left neck, with demonstration of a hybrid open-endovascular approach to manage an ECA injury and arteriovenous fistula. Hybrid surgery extends beyond simple balloon occlusion and bridging to open repair and allows for the consideration of more advanced endovascular techniques as well as multidisciplinary collaboration. The combination of diagnostic angiography and endovascular stenting to gain proximal control of the injured ECA while maintaining antegrade cerebral blood flow prior to open surgical neck exploration and ECA ligation represents a feasible and effective means by which to manage penetrating carotid artery injuries in the era of increasing use of endovascular and hybrid approaches.

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 have no relevant conflicts of interest to declare.

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Author Contributions

All authors had access to the relevant case information and were involved in manuscript preparation and final approval.

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Case Report

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Bioengineered Acellular Vessel Implantation in a Patient with Chronic Limb-Threatening Ischemia: A Case Report and Discussion of Implications for Trauma

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Keywords: *Bioengineered Blood Vessel; Vascular Reconstruction; Vascular Trauma; Novel Conduit*

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BACKGROUND

While the field of vascular surgery has seen major advances over the past few decades, options for vascular conduits in open bypass reconstruction remain largely unchanged. Current available conduits include autologous vein, synthetic grafts, and cadaveric and xenogeneic tissues. Autologous vein is frequently limited by availability, and vein harvest adds significant operative time to the procedure. Synthetic grafts suffer from an increased risk of infection, limiting use in an infected or contaminated field. Additionally, synthetic, cadaveric, and xenogeneic grafts have inferior patency when compared to autologous conduit [1]. The Human Acellular Vessel (HAV) (Humacyte, Inc., Durham, NC) is a bioengineered blood vessel that can be obtained "off the shelf" and has shown promise in the areas of durability, tissue incorporation, and resistance to infection [2–4]. A conduit with these properties carries substantial potential for use across the spectrum of vascular disease. We describe a case in which the HAV was utilized for revascularization in a patient with chronic, limb-threatening ischemia (CLTI) who lacked alterative reconstructive options. The case is followed by a brief discussion of potential broader applications of the HAV, specifically for use in vascular trauma.

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CASE PRESENTATION

A 70-year-old male with a complex vascular history to include previous endovascular repair of an infrarenal abdominal aortic aneurysm and peripheral arterial disease (PAD) presented with CLTI of the right lower extremity. Examination was notable for non-palpable popliteal and pedal pulses with a monophasic dorsalis pedis artery (DPA) signal, and an ankle-brachial index (ABI) of 0.1. Arterial duplex ultrasound (DUS) demonstrated patent right superficial femoral artery (SFA), totally occluded right popliteal artery at Hunter's canal, and lack of flow through the anterior tibial, peroneal, and posterior tibial arteries. Diagnostic angiography was completed and demonstrated chronic total occlusion of the above knee popliteal artery with proximal reconstitution of the peroneal artery and distal reconstitution of the

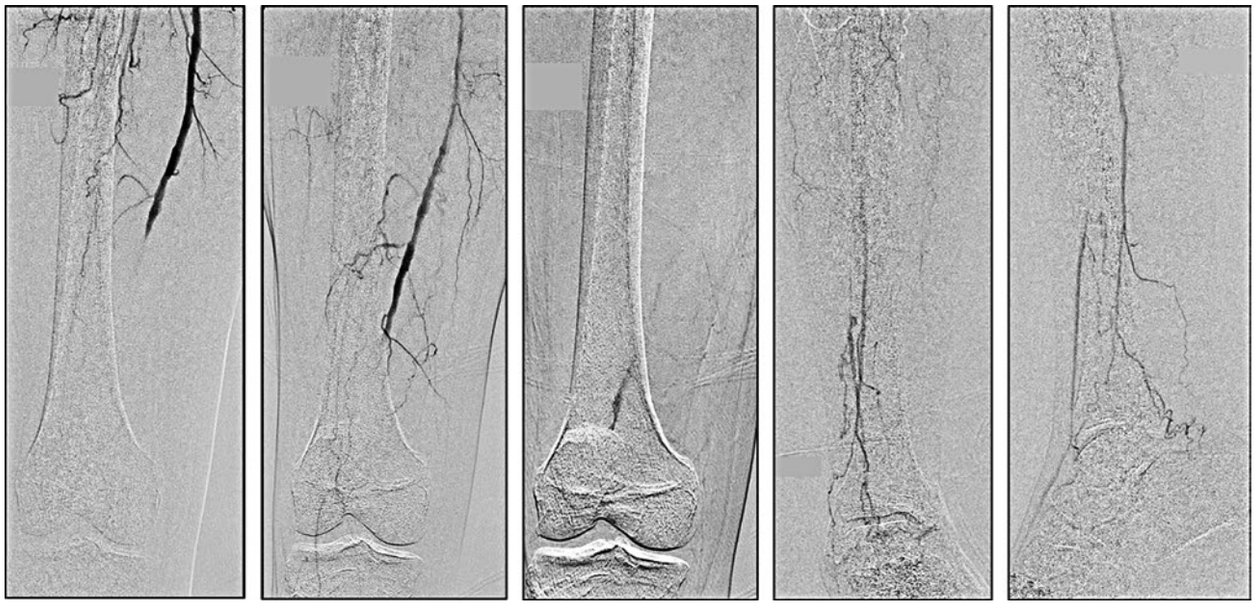

Figure 1 Preoperative angiography demonstrating total occlusion of the above knee popliteal artery with distal reconstitution of the peroneal and anterior tibial arteries.

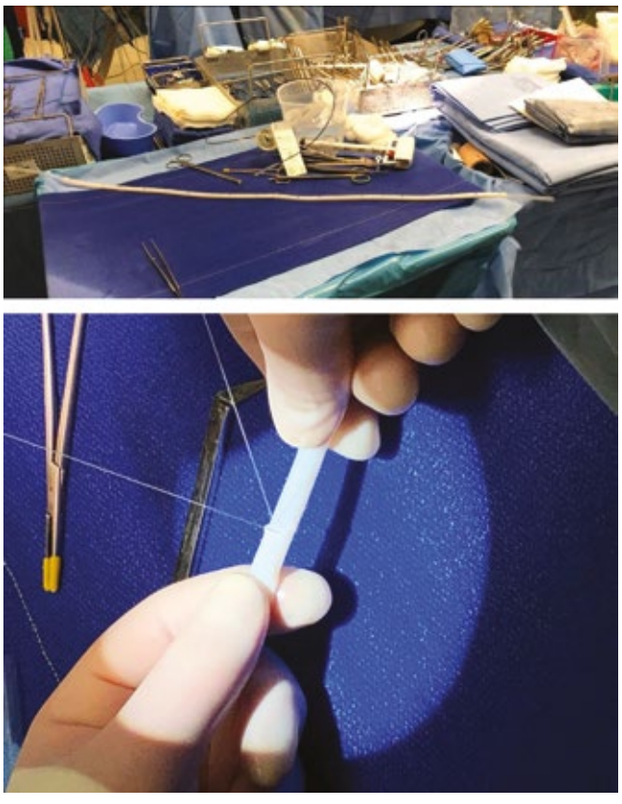

Figure 2 Intraoperative images of the human acellular vessel (HAV).

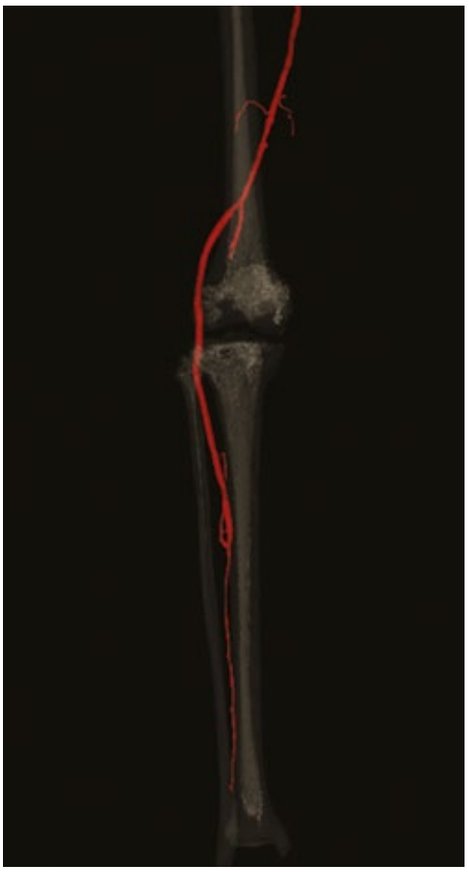

Figure 3 Three-dimensional reconstruction of right lower extremity computed tomography angiography (CTA) at 9 months postoperatively, showing patent right distal superficial femoral artery to proximal peroneal artery bypass with HAV.

anterior tibial artery and dorsalis pedis artery (Figure 1). The lesion was not amendable to endovascular treatment.

Vein mapping was performed and showed no suitable autologous vein for conduit. Compassionate use of the

HAV was requested via the U.S. Food and Drug Administration (FDA) Expanded Access Pathway, and the patient underwent an uncomplicated distal SFA to proximal peroneal artery bypass with a single 6 mm × 40 cm HAV implant creating an approximately 30 cm bypass (Figure 2). Anastomoses were performed with Gore-Tex™ (Gore, Newark, DE) suture, and the implant was tunneled anatomically. Postoperatively, the patient did well with return of a distal pulse and resolution of his rest pain. A right lower extremity computed tomography angiography (CTA) at 9 months (Figure 3), angiogram at 11 months (Figure 4), and DUS at 20 months postoperatively demonstrated primary patency of the implant. The patient has not sustained an infectious complication or immune rejection of the HAV implant. With the exception of chronic right lower extremity neuropathy and paresthesia, which had been present prior to the reconstruction and remain stable, the patient has continued to do well and is now over 22 months from surgery.

Ethical Approval and Informed Consent

Ethical approval and informed consent were not required for this retrospective case report. All information has been anonymised.

DISCUSSION

We describe a case in which the HAV was implanted for reconstruction in CLTI. The HAV has been studied in above-knee reconstruction for PAD [2]; however, to the authors' knowledge this is the first report of a successful bypass to a tibial artery using HAV. FDA emergency authorization for compassionate use allowed timely, effective restoration of blood flow to the patient's limb, and nearly two years later the patient has continued flow through the implant.

Intraoperative handling of the HAV was favorable. HAV mimics the properties of autologous vein more closely than those of synthetic conduits. Tunneling and creation of anastomoses using standard techniques was uncomplicated. No unanticipated technical challenges were encountered during surgical implantation.

While the indication for HAV implantation in this patient was CLTI, utility of the conduit may extend to multiple disease processes within vascular surgery. In particular, an "off-the-shelf", infection-resistant conduit is of significance to military vascular trauma. Epidemiologic analyses of injuries sustained in Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) have demonstrated rates of vascular injury of up

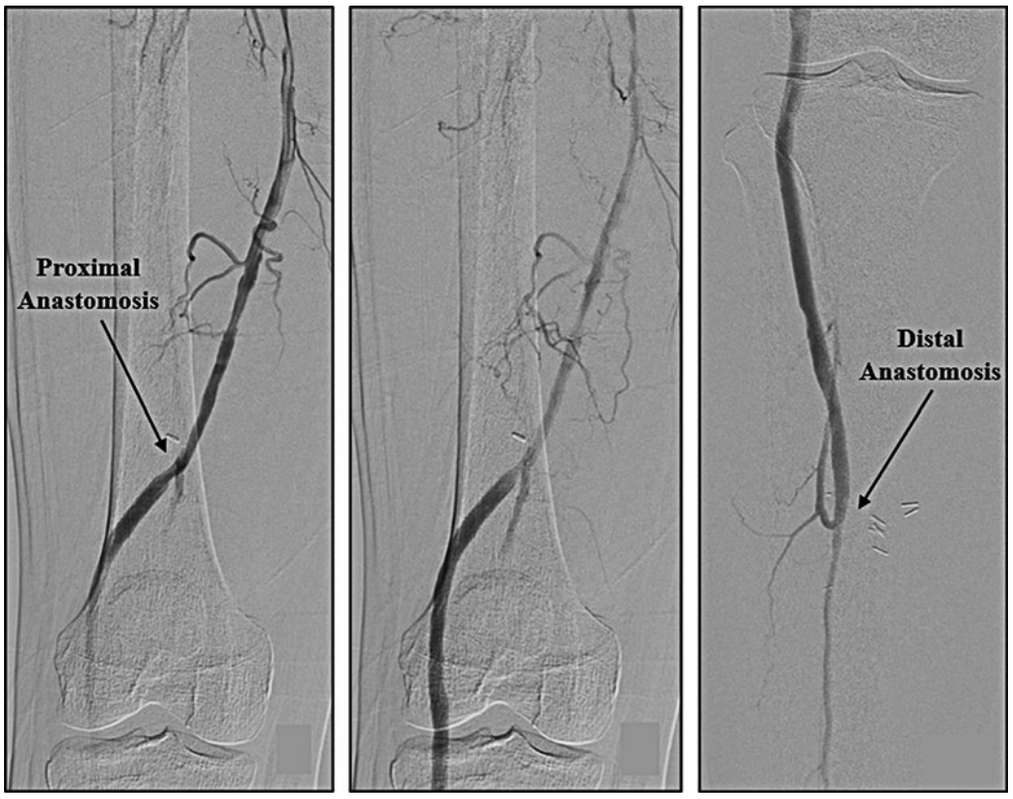

Figure 4 Right lower extremity angiogram performed at 11 months postoperatively demonstrating widely patent bypass.

to 18%, which is nearly five times that reported in previous wars, with extremity vascular injuries being most common (70–80%). Additionally, reconstructive procedures are performed more frequently, in up to 57% of cases, with the highest rates of reconstruction seen in the second half of the Global War on Terrorism (GWOT) [5–7].

The Joint Trauma System Clinical Practice Guidelines (JTS CPG) recommend autologous vein for reconstruction of injured extremity arteries, with prosthetic graft as a last resort and preferably only in wounds with minimal contamination [8]. However, in combat-associated wounds, significant contamination frequently occurs amidst complex explosive mechanisms with secondary blast injury. These injury patterns limit conduit options as autologous vein may be damaged or, if available, time required to harvest vein may preclude its use in soldiers in critical condition with multiple concomitant injuries [1]. While prosthetic grafts offer availability and sizing options, and may allow for short-term revascularization, the risk of thrombosis or subsequent infection requiring explanation remains high [9]. Additionally, high rates of graft rupture with subsequent life-threatening hemorrhage have been reported with vein grafts in infected wounds [10]. A conduit with long-term durability that can be expediently placed for extremity revascularization in extensive, contaminated wounds would be a step forward for successful limb salvage in the young, military population.

The HAV, an "off-the-shelf", infection-resistant conduit may be limb-saving in cases where autologous vein or prosthetic use is limited. Continued real-world experience with the HAV and ongoing clinical trials [11] may lead to significant improvement in the management of vascular disease and trauma.

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

TER and JMW were responsible for conception and design. ALL carried out the data collection and article drafting. TER, JMW, PWW, ALL and AJK performed the critical revisions.

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7th EVTM Symposium

HOT TOPICS in EndoVascular resuscitation and Trauma Management

in collaboration with European Society of Vascular Surgery

Welcome to Örebro, Sweden, December 3-5 2021

www.jevtm.com

Preliminary program & information about the symposium

INFO

INFORMATION ABOUT THE CONFERENCE

FEES & REGISTRATION

Early registration fee
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EVTM Symposium - Member of the EVTM or ESVS Society: 2 400 SEK
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Deadline for abstracts: **October 29th, 2021**
Author notification: **November 5th, 2021**

You will find the registration form, abstract submission and more information on our website:

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INFO

WELCOME!

It is a great pleasure to welcome you to the 7th EndoVascular rescucitation and Trauma Management round table sympsoium to be held in Örebro, Sweden, December 3-5, 2021.

Our goal is to offer an excellent scientific program and an outstanding exhibition of the latest treatment options and technology within Endovascular and hybrid rescusitation. With an international faculty of renowned experts and clinicians we will cover most aspects of Endovascular resuscitation, trauma and bleeding management, REBOA, Endovascular technologies and tools as well as new concepts and algorithm for bleeding management from pre-hospital to the post-surgical period.

The EVTM round table symposium is inspired by the collaboration with many centers and its extensive array of experimental research and clinical knowledge in Endovascular and hybrid resuscitation including REBOA. We aim for good cooperation, open discussions and debate as well as high scientific data exchange. The EVTM round table symposium offers a new, modern, live platform and we hope that you will be a part of it.

In the name of the symposium chairs and scientific committee and the local organizers,

Tal Hörer
Örebro University Hospital
Sweden

Regarding COVID-19:

Our number one priority is the well-being and safety of our delegates and speakers. To insure that, we follow the restrictions from the Public Health Agency of Sweden (Folkhälsomyndigheten).
Our conference venue is large and offer plenty of space for our delegates to be able to apply physical distancing.
Our partners, such as the conference venue, hotels and restaurants have rigorous procedures and routines in place regarding enhanced cleaning, physical distancing and food and beverage offering.
The spreading of of COVID-19 is currently low and the vaccine rate is high.
For more information regarding the situation in Sweden, please visit the Public Health Agency if Sweden: https://www.folkhalsomyndigheten.se/ or contanct MKON: lotta@mkon.se

We belive that real, person to person meeting is important and will do all neccessery to arrange a great and safe EVTM symspoium, in Örebro, Sweden.

PROGRAM

7th EVTM Symposium

HOT TOPICS in EndoVascular resuscitation and Trauma Management
in collaboration with the European Society of Vascular Surgery

Preliminary scientific program

FRIDAY December 3rd	
07.00	**Registration opens / Coffee**
07.30	**Opening remarks** - *Tal Hörer, US, Megan Brenner (US), Joe DuBose (US), Viktor Reva (RU), Boris Kessel (IL) and Anna Maria Ilerardi (IT) Welcome by Prof. Mats Karlsson (SE)*
Opening session, Keynote Talks - Hot topics in EVTM applications 6 min talk + 4 min discussions **Speakers and panelists (TBA):** Ken Boffard (ZA), Thomas Scalea (US), Eugene Moore (US), Frank Plani (ZA), Todd Rasmusson (US), Thomas Larzon (SE), Stephan Haulon (FR), Carl Magnus Wahlgren (SE), Megan Brenner (US), Louise Riddez (SE), Lional Lamhault (FR), Gustavo Oderich (US), Viktor Reva (RU), Martin Malina (UK)	
07.40	EndoVascular resuscitation and Trauma Management: Where do we stand -
07.50	The unstable bleeding trauma patient- Where does EVTM come in? -
08.00	Advances in endovascular surgery for bleeding control in rAAA, rTAA, acute dissections -
08.10	EVTM multidisciplinary issues- Who should do what? USA vs EU vs non-EU perspectives -
08.20	Modern technology, new tools and EVTM (endografts, embolization and balloons) - where do we go? -
08.30	Complications in vascular surgery and endo/hybrid solutions- what can we do and where do we go -
08.40	Developments in modern trauma and bleeding management - View of a senior trauma surgeon -
08.50	EndoVascular resuscitation- what is new, what is coming? -
09.00	**Round table discussion:** How to go forward with EVTM?
Session 2: Hot topics in Vascular access for the unstable patient 6 min talk + 4 min discussion **Speakers and panelists (TBA):** Zoran Rancic (CH), Martin Delle (SE), David Lindström (SE), Lionel Lamhault (FR), Chuck Fox (US), James Daley (US), Paul Rees (UK), Anna Maria Ilerardi (IT), Offer Galili (IL), Derek Roberts (CA), Maya Paran (IL), Mårten Falckenberg (SE), Federicco Coccolini (IT)	
09.10	Landmark papers on vascular access- review -
09.20	Who needs vascular arterial or venous access and when? Cases -
09.30	The difficult vascular access, tips, tricks and solutions -
09.40	Complications, how to avoid and how to solve? Cases
09.50	Surgical and non-surgical solutions for the failing access. Cases and examples -
10.00	Vascular access for ECMO and patients with ongoing CPR -
10.10	How to gain access in the unstable patient? -
10.20	Vascular access in the pre-hosiptal enviroment -
10.30	**Panelist debate:** All hemodynamically unstable patients should get a femoral vascular access. PROS-CONS.
10.40	**Coffee and industry exhibition**
Session 3: Hot topics in Endografts for the bleeding patient 6 min talk + 4 min discussion **Speakers and panelists (TBA):** Claes Forsell (SE), Ravi Rajani (US), Greg Magee (US), Josef Galante (US), Joe DuBose (US), Stephan Haulon (FR), Artai Pirouzram (SE), Stefano Ancetti (IT), Enrico Gallitto (IT), David McGreevy (SE), Lu Qingsheng (CN), Pirkka Vikatmaa (FI), Aho Pekka (FI), Maarit Vernemo (FL), Gustavo Oderich (US), Simone Fajer (IL), Martin Malina (UK)	
11.00	Landmark papers on Endografts in the endovascular era - review -
11.10	The "easy" vs. the "complexe" rupture - What can be done and how. Examples -
11.20	Thoracic rAA and endovascular solutions. Cases -
11.30	Endografts in Non-Aortic locations (iliac, subclavian and others). Cases, solutions -
11.40	The ruptured, injured or iatrogenic iliac artery- endovascular and hybrid solutions -
11.50	Advanced thoracic aortic trauma-endo and hybrid techniques. Updates and examples -

12.00	Doing EVAR in rAAA - how to achieve best results -
12.10	In-situ fenestrations and other innovative acute solutions. Case examples -
12.20	Surgeon modified endografts for the acute patient. Technique and examples -
12.30	The junior point of view: Thoracic endografts. Evidence and current data -
12.40	**Panelist debate**: All endo? Or good old open surgery should not be forgotten -
13.00	**Lunch and industry exhibition**

Session 4: Hot topics in Embolization for the bleeding patient

6 min talk + 4 min discussion

Speakers and panelists (TBA):
Anna Maria Ilerardi (IT), Mårten Falckenberg (SE), Rishi Kundi (US), Megan Brenner (US), Carl Magnus Wahlgren (SE), Gad Shaked (IL), Boris Kessel (IL), Martin Delle (SE), Göran Wallin (SE), Ken Boffard (ZA), David Lindström (SE), Igor Koncar (RS), Anahita Dua (US), Anna Romagnoli (US), Mikosh Balla (IL), Ilan Bruchin (IL), Viktor Reva (RU)

14.00	Landmark papers on bleeding embolization- review -
14.10	What to embolize, general principles and examples -
14.20	Embolization in traumatic bleeders. Indications and solutions -
14.30	Embolization in non-traumatic bleeders. Indications and solutions - *Miklosh Balla (IL)*
14.40	Embolizations agents- what to use and how. Basic and advanced. Cases -
14.50	Clinical cases (Trauma) -
15.00	Clinical cases (Radiology) -
15.10	Gynecological bleeding and intervention- what and when? - *Ilan Bruchim (IL)*
15.20	The junior point of view: embolization in trauma. Who should do it and how to gain experience?
15.30	**Panelists debate**: Embolize this patient! (Proactive) vs. Don't touch! (conservative) -

Session 5: Hot Topics in imaging developments. CT, Ultrasound, Angiography and hybrid suites.

6 min talk + 4 min discussion

Speakers and panelists (TBA):
Takahiro Kinoshita (JP), Yosuke Matsamura (JP), Stephan Haulon (FR), Offer Galili (IL), Ravi Rajani (US), Rishi Kundi (US), Per Skoog (SE), Anna Maria Ilerari (IT), Thomas Vogl (GR), Gustavo Oderich (US), Pirkka Vikatmma (FI), Simone Fajer (IL), Martin Malina (UK), Zoran Rancic (CH)

15.50	Landmark papers on imaging in the bleeding patient - review -
16.00	Use of hybrid suites and hybrid-ER; benefits, evidence? -
16.10	New upcoming imaging modalities and their applications. What is available and what is coming? -
16.20	Practical use of hybrid or/ER cases -
16.30	Advanced ultrasound imaging in unstable patients -
16.40	More on advanced ultrasound imaging in unstable patients -
16.50	The junior point of view: Using new technology for hemodynamically unstable patients and learning it's use -
17.00	Angiography suites on the market- overview and advantages of the systems available -
17.10	Panelist debate: Hybrid suite is the place to be vs. Surgical suit with C arm is good enough -
17.20	**Coffee / Industry Exhibitors**

Session 6: Hot topics in Endovascular resuscitation: The non-trauma patient

6 min talk + 4 min discussion

Speakers and panelists (TBA): Zaff Quasim (US), James Daley (US), Kristofer Nilsson (SE), Jim Manning (US), Paul Rees (UK), Jon Barratt (UK), Lional Lamhault (FR), Stein Brede (NO), Hans Hjelmqvist (SE), Sam Sadek (UK), Pat Thompson (UK), Tony Hudson (UK), Geir Strandenes (NR), Tom Woolley (UK), Alexis Smith (US), Maya Paran (IL)

17.20	Vascular access for patient in arrest or pre-arrest, how to do, tips and tricks -
17.30	eCPR and where does EVTM come in, or at all? -
17.40	Indications for REBOA in non-trauma; is there any? Data! - *Dr. Maya Paran (IL)*
17.50	REBOA as bridge to ECMO- is it feasible? Data? -
18.00	Medical arrest and eCPR- physiology and rationale -
18.10	ECMO for the unstable patient- current data and where do we go? -
18.20	Indications for ECMO (all) and what does the future hold? Who? When? By who? -
18.30	The junior point of view: Endovascular solutions in cardiac arrest -

18.40	Transport REBOA - can be done but should it? practical aspects -
18.50	**Panelist debate**: REBOA or SAAP has no place in cardiac arrest, ECMO yes Pro: Con: -
19.30	**Get together and dinner**

SATURDAY December 4th

07.30	**Coffee / Industry Exhibitors**

Session 7: #EVTM meets #DCR (Damage control resuscitation)

6 min talk + 4 min discussion

Speakers and panelists (TBA):
Louise Riddez (SE), Juan Duchesne (US), Mansoor Khan (UK), Frank Plani (ZA), Ken Boffard (ZA), Victor Reva (RU), Mikosh Balla (IL), Federicco Coccolini (IT), Carl Magnus Wahlgren (SE), Artai Pirouzram (SE)

07.40	Prehospital resuscitation: Blood/TXA and Calcium (indications and benefits) -
07.50	Prehospital "RAPTOR" (REBOA vs ResQ foam) -
08.00	Death of permissive hypotension? -
08.10	Circulation first, airway second: Time to identify meningful interventions -
08.20	Hybrid-ER vs conventional system (ED to OR system) -
08.30	Whole blood vs balanced resuscitation: outcomes of RCT -
08.40	The junior point of view/oral presentation -
08.50	**Panelist debate**: scoop and control vs scoop and run -
09.10	**Break**

Session 8: Hot Topics in trauma applications of EVTM and REBOA. Session by Shock & Trauma, Baltimore

6 min talk + 4 min discussion

Chair: Thomas Scalea

Speakers and panelists (TBA): Yaakov Daskal (IL), Daniel Sheffer (IL), Max Marsden (UK)

09.20	Landmark papers on REBOA- a review - *Dr. Yaakov Daskal (IL)*
09.30	TBA -
09.40	REBOA in hemodynamically unstable patients - here is the data! -
09.50	REBOA in hemodynamically unstable patients - This is how we do it -
10.00	More endo-tools in the trauma patient- what can be done and how? -
10.10	The subclavian artery injury- endo and hybrid treatment -
10.20	Endo in acute pediatric cases- what do we know? -
10.30	New data on use of partial REBOA (ER REBOA PRO)- TBA
10.40	The junior point of view - *Dr. Daniel Sheffer (IL)*
10.50	Panel debate

Session 9: Hot Topics in military and austere environments EVTM

6 min talk + 4 min discussion

Speakers and panelists (TBA):
Todd Rasmussen (US), Joe DuBose (US), Viktor Reva (RU), Paul Rees (UK), Rigo Hoencamp (NL), Jon Barratt (UK), Sam Sadek (UK), Chuck Fox (US), Josef Galante (US), Tom Woolley (UK), Gad Shaked (IL), Anahita Dua (US), Brian Knipp (US), Offer Galili (IL), Boris Kessel (IL)

11.00	What EVTM methods can be used in the military or austere setting? -
11.10	REBOA update military cases USA -
11.20	Update UK Military -
11.30	Should military forces adopt REBOA in their arsenal? -
11.40	Practical issues with EVTM, issues in military scenarios - embolization? Endografts? Is is feasable? -
11.50	Our experience with austere EVTM/REBOA -
12.00	Prehospital REBOA update. Data -
12.10	The junior point of view -
12.20	**Panelist debate**
12.30	**Lunch in the exhibition**

PROGRAM

Session 10: Registry data, Experimental studies and developments within EVTM 6 min talk + 4 min discussion **Speakers and panelists (TBA):** Kristofer Nilsson (SE), David McGreevy (SE), Joe DuBose (US), Megan Brenner (US), Federico Coccolini (IT), Derek Roberts (CA), Jim Manning (US), Greg Magee (US), Maya Paran (IL), Per Skoog (SE), Igor Koncar (RS), Anna Romagnoli (US), Rebecka Hultgren (SE), Lu Qingsheng (CN), Sivan Barkai (IL), Daniel Sheffer (IL)	
13.20	REBOA in animal studies- Current data - *Dr. Sivan Barkai (IL)*
13.30	REBOA in registry data- Current data -
13.40	Thoracic blunt trauma registry- data and conclusions by now -
13.50	The junior point of view; Experimental data - *Dr. Daniel Sheffer (IL)*
14.00	Registry data update , the UK-REBOA trial -
14.10	Post partum bleeding- strategies and data -
14.20	**Panelist discussion:** upcoming experimental models-what is missing?
Session 11: Hot topics in anesthesia and critical care. Joined session with #THOR. 6 min talk + 4 min discussion **Speakers and panelists (TBA):** Pat Thompson (UK), Tony Hudson (UK), Tom Woolley (UK), Geir Strandenes (NO), Kristofer Nilsson (SE), Zaff Quasim US), Eugene Moore (US, Yosuke Matsamura (JP), Geir Strandenes (NO)	
14.30	The pathophysiology of blood failure - *Pat Thompson (UK)*
14.50	Prehospital airway management for patients with traumatic blood failure - *Tony Hudson (UK)*
15.10	Permissive hypotension in massive hemorrhage - *Tom Woolley (UK)*
15.30	Whole blood and cold platelets for hemostatic resuscitation - *Geir Strandenes (NO)*
15.40	**Discussion:** Implemenation of critical care issues in EVTM- future aspects.
15.50	**Coffee / Industry Exhibitors**
Session 12: New and rising EVTM technologies, access devices, imaging and endografts. 6 min talk + 4 min discussion **Chairs:** **Speakers and Panelists (TBA):** Zoran Rancic (CH), Claes Forsell (SE), Artai Pirouzram (SE), Stephan Haulon (FR), David Lindström (SE), Ravi Rajani (US), Greg Magee (US), Carl Magnus Wahlgren (SE), Gustavo Oderich (US), Rebecka Hultgren (SE), Thomas Larzon (SE), Per Skoog (SE), Ofer Galili (IL), Simone Fajer (IL), Martin Malina (UK)	
16.10	How to close a vascular access- my tools -
16.20	How to close a vascular access- pros and cons -
16.30	Advances in hybrid room and endovascular suites -
16.40	The junior point of view: Low profile endografts -
16.50	New tools and developments in endovascular surgery -
17.00	More on viceral endografts in rAAA and rTAA -
17.10	Practical use of endografts in rAAA- tips and tricks -
17.20	Iliac and viceral endografts- what is out there and what to choose -
17.30	First Aid Platform – How novel sensor and digital technologies integrates vital parameters from the scene of the accident to support decision making for the trauma team - *Thomas Larzon (SE)*
17.40	Free abstract talk -
17.50	Free abstract talk -
Session 13: EVTM Society meeting	
18.00 - 19.00	**EVTM Society meeting**

PROGRAM

SUNDAY December 5th

Session 14: Joined session with the European Society for Trauma & Emergency Surgery (ESTES). Education of the future trauma surgeon and vascular trauma

6 min talk + 4 min discussion

Chairs:

Speakers and Panelists (TBA): Shahin Mohseni (SE), Carlos Yanez (SP), Mansoor Khan (UK), Louise Riddez (SE), Ken Boffard (ZA), Frank Plani (ZA), David McGreevy (SE), Mikosh Balla (IL), Piotr Koleda (PL), Gary Bass (UK), Federico Coccolini (IT),

08.30	Vascular trauma in Europe, current status, Who is doing what? -
08.40	Management of vascular trauma in Europe vs. USA, South Africa -
08.50	The European trauma surgeon should be able to repair these injuries. Clinical cases for discussion -
09.00	Training trauma team dynamics in a dedicated simulation center -
09.10	Non-technical skills, an essential aspect of trauma team training. Cases/expamples -
09.20	Endovascular training in surgical residency - should it be done? How? -
09.30	The junior point of view -
09.40	**Discussion**
10.00	**Coffee / Industry Exhibitors**

Session 15: Hot topics in mass casualties and EVTM aspects. Surgeons from Israel and Iraq exchange clinical experience

6 min talk + 4 min discussion

Chairs (TBA): Todd Rasmussen (US), Ken Boffard (ZA), Lousie Riddez (SE)

Speakers and Panelists (TBA): Nori Sabach (IQ), Muhammed Al Musawi (IQ), Boris Kessel (IL), Maya Paran (IL), Abdualmaar (IQ)

10.30	Clinical experience from Iraq -
10.40	Clinical experience from Israel -
10.50	Lessons learned Iraq -
11.00	Lessons learned Israel -
11.10	**Panelist debate**: Does EVTM have a role in mass causalties? How, what, when?
11.20	TBA
11.30	TBA
11.40	TBA
11.50	TBA
12.00	TBA
	Conference closing

The program is preliminary and may be subject to changes.

WORKSHOP

Information about the EVTM-workshop
December 2nd, 2021
Örebro, Sweden

Registration is made on the website:
www.evtm2021.com
Limited seats!

WORKSHOP

Region Örebro County
Örebro University Hospital

HANDLED BY
Dept. of Cardiothoracic and Vascular Surgery, Dr. Tal Hörer

DATE
2021-06-12

EndoVascular resuscitation, bleeding and Trauma Management (EVTM)

Hands-on Workshop

Örebro, Sweden 2nd December 2021

Endovascular and hybrid solutions for the bleeding patient;
Aortic balloon occlusion (*REBOA*) usage, Vascular Access, Embolization, Imaging, Endografts, ECMO, SAAP and modern techniques in Resuscitation

EVTM instructors
TBA

Dept. of Cardiothoracic and Vascular Surgery, Dept. of General Surgery,
Dept. of Anesthesia and Intensive Care, Örebro University Hospital, Sweden

International EVTM instructors:
TBA

Local team: Maria Wikström, Emanuel Dogan, Anna Stene,
Monica Clomén, Nina Adolfsson, Jonas Berlin, Johan Josefsson, Mitra Sadeghi

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

Date: 2nd December 2021 at Örebro University Hospital Animal Lab

Workshop Director: Dr. Tal Hörer MD, PhD, Associate Professor of Surgery

Workshop Secretary / Registration: Åsa Strandberg (asa.strandberg@regionorebrolan.se)

Tal Hörer, Örebro University Hospital, tal.horer@regionorebrolan.se
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More info at www.jevtm.com/workshop and social media #EVTM

WORKSHOP

Region Örebro County
Örebro University Hospital

HANDLED BY
Dept. of Cardiothoracic and Vascular Surgery, Dr. Tal Hörer

DATE
2021-06-12

Cost (cover expenses only): 300€, 200€ for EVTM Society members

Partners: Örebro University Hospital and TBA

The aim of this one day workshop is to stimulate discussion, mutual learning and sharing of experiences while practicing EndoVascular resuscitation and Trauma Management (EVTM) using a multidisciplinary team approach. "No ego, just good science and cooperation" is the main motion of the event. It is built on an individual, professional level and we will together explore different methods for resuscitation, bleeding control and trauma management. Some methods used clinically world-wide while some are under developments and have been used in selected patients.

- Vascular access:
  - Different methods (blind, doppler, ultrasound, fluoroscopy and cut down)
  - Its use in hemodynamic unstable patients
- Aortic Balloon Occlusion (REBOA) basic and advanced methods and SAAP
- Basic and advanced endograft and embolization methods
- Damage Control EVTM and Bailout methods
- Basic and advanced postoperative considerations
- Up-to-date research and clinical experience
- ABOTrauma Registry cases; Local and international cases
- Knowledge of basic material and new technologies on the market
- Intensive training on live tissue
- ICU and ECMO aspects
- Basics for building an "EVTM service"
- Advanced experimental methods in resuscitation

The workshop is designed for experienced physicians but is individually tailored during the practical parts. Participants will get basic training and knowledge of REBOA placement as part of the EVTM concept. The workshop has been certificated by the EACCME and acknowledged by collaboration with societies like the European Society for Trauma and Acute Care Surgery, the European vascular society and others.

Program at the animal lab training & research center, USÖ

07:00 Gathering/changing at the Training Center (2nd floor)

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

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

WORKSHOP

Region Örebro County
Örebro University Hospital

HANDLED BY
Dept. of Cardiothoracic and Vascular Surgery, Dr. Tal Hörer

DATE
2021-06-12

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

09:30-15:00 Hands-on animal lab including:

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

Practical training points in the animal lab:

1. Material usage in bleeding patients, general considerations and management scenarios
2. Vascular Access
    - Basic principles/advanced methods
    - Cut down techniques
    - Endoshunts (and shunts)
    - Hybrid procedures
    - Puncture methods
    - Seldinger technique
    - The failing access - alternatives
    - Venous access and Ultrasound
3. Upgrading/introducers/guide wires
4. REBOA
    - Material and REBOA kit
    - Deflation and re-positioning
    - Intermittent/Partial inflation (MAP as target - iREBOA/pREBOA)
    - Ongoing bleeding practice
    - CPR procedures and pending arrest
5. ECMO practical use with tips and tricks
6. Embolization – from coils to fluid embolization, with hands on practice
7. Endografts for bleeders with practical use

As times allows and based on individual level:

8. Balloon in alternate locations (Iliac, Subclavian, Brachiocephalic trunk/Zone 1 neck)
9. Aortography and Angiography considerations (type, volume etc.)
10. Bailouts in endovascular and hybrid surgery

15:00 End of workshop and evaluation

"No ego, just good science and cooperation"

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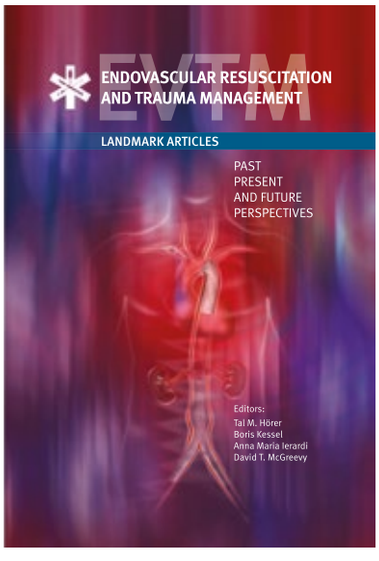

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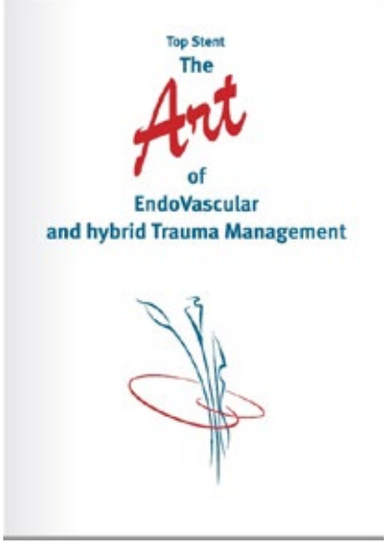

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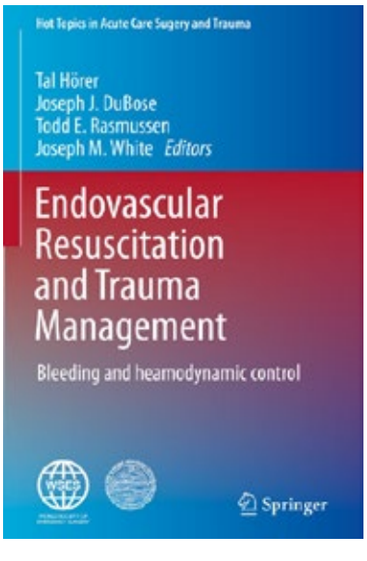

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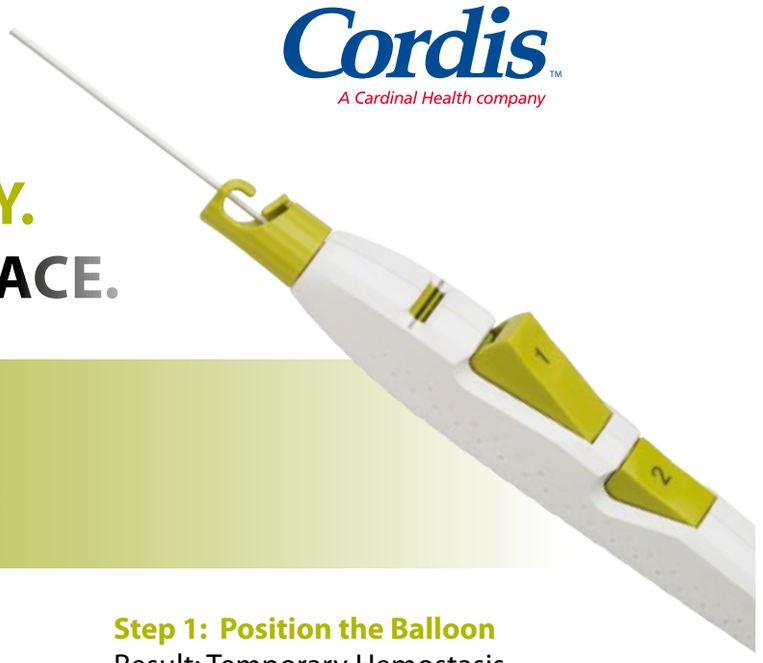

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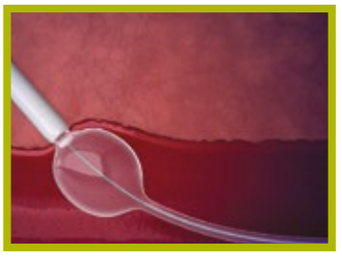
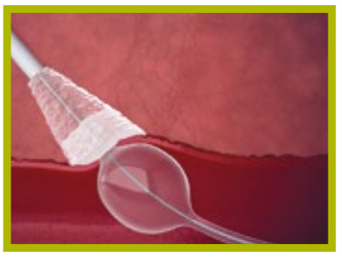


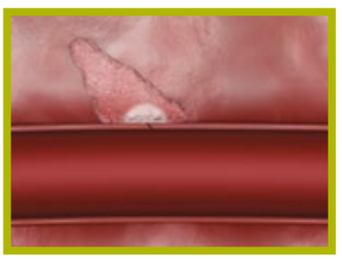
Step 2: Deploy the Sealant

Result: Delivery



Step 3: Remove the Device

Result: Secure Extravascular Closure



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*Note: MYNX CONTROL™ VCD is incompatible with Medtronic Input® Introducer (11cm) sheaths, Cook Check-Flo®Performer® Introducer sheaths, and procedural sheaths longer than 12cm in effective length.

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RBK20305007	20/30 (mm)	15,0 mL	7F

*both kits are delivered with a 23 cm long introducer

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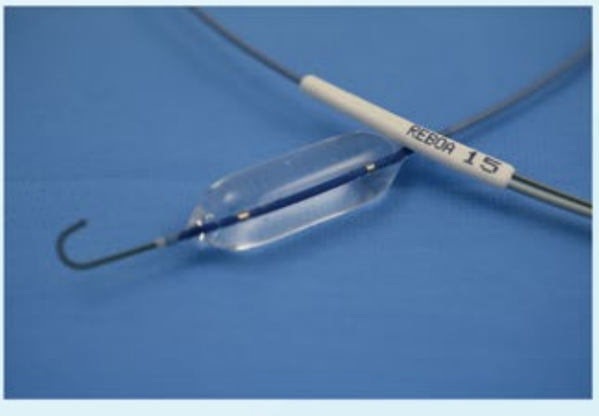
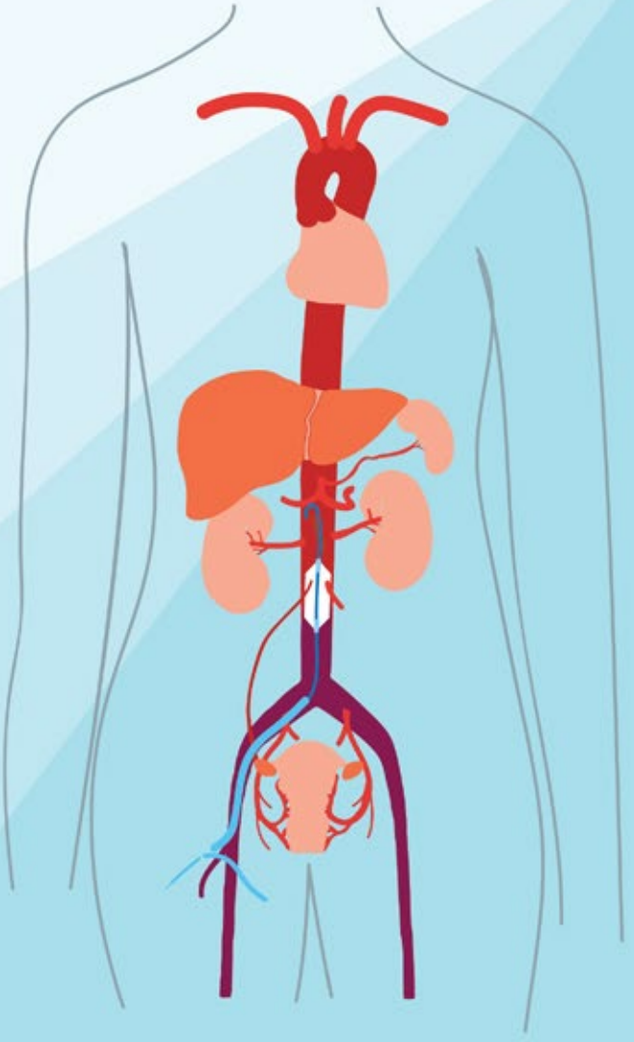


Approved by CE, FDA, and Health Canada.



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