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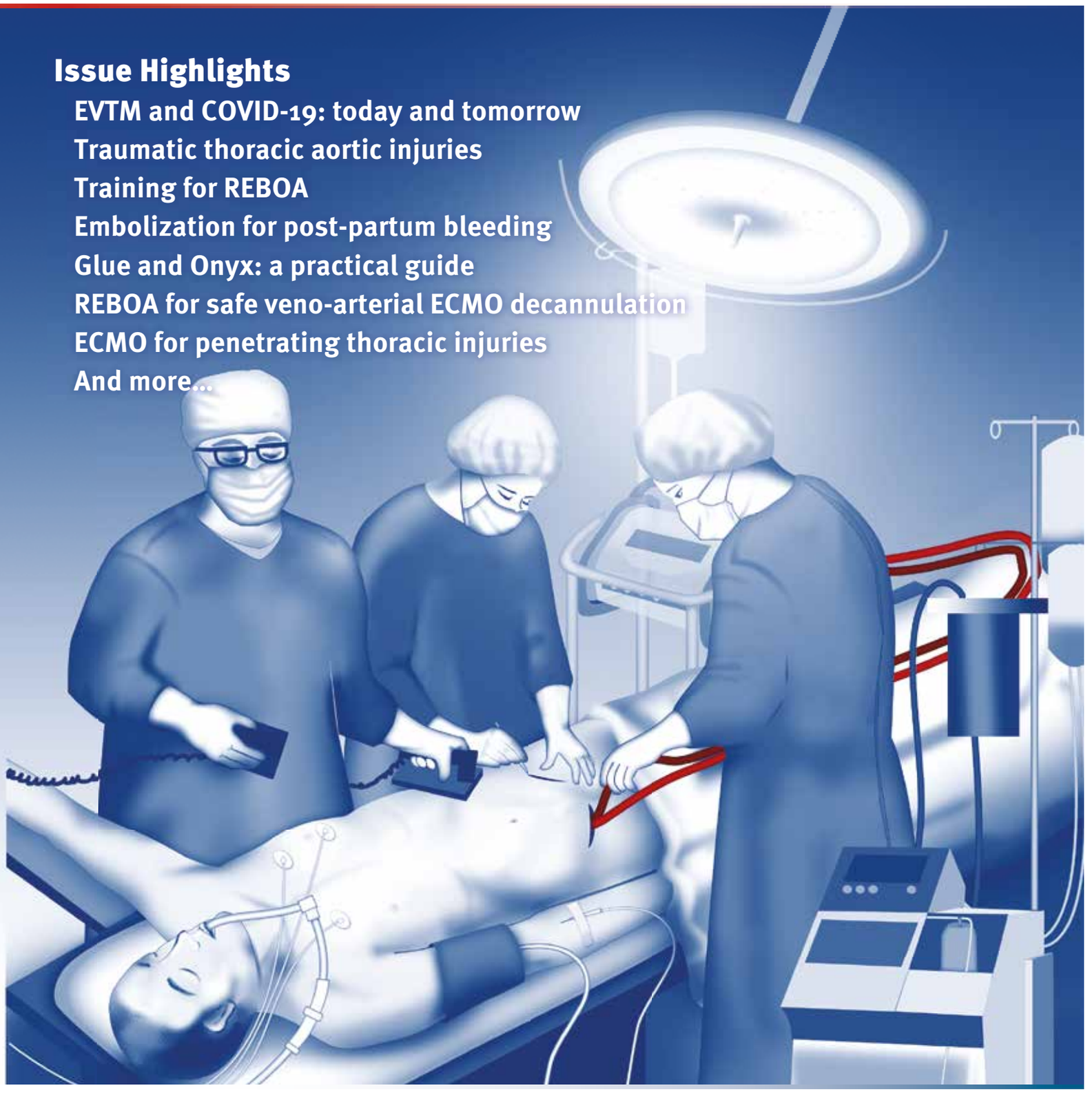
Issue Highlights



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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.

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

Region Örebro County
Örebro University Hospital

Address:
EVTM Program
Tal Hörer
Dept of Cardiothoracic and Vascular Surgery
Örebro University Hospital and Örebro University
Södra Grev Rosengatan
703 62 Örebro
Sweden

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 and click on "Join EVTM Society" in the menu.

Membership is free at this stage.

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/join-the-evtm-society

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.
- Affiliations: The institution(s) that the authors are affiliated with should be listed. A full address is not required, but enough to ensure identification.
- Corresponding Author: This individual should be clearly identified, along with full institutional address and e-mail address.
- Author Contributions: All authors are expected to have substantially contributed to the study and manuscript writing.
- Funding Declaration: Any grant funding should be listed.
- Presentation: The meeting where any of the submitted data was presented should be listed.

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.

Ethical & Legal Considerations

The journal is committed to maintaining the highest level of integrity in the content published. This journal has a Conflict of Interest policy in place and complies with international, national and/or institutional standards on research involving Human Participants and/or Animals and Informed Consent. The journal 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.

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

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

Protection of Human Subjects & Animals in Research
For original articles in the Journal that report research involving animals, the corresponding author must confirm that all experiments were performed in accordance with relevant guidelines and regulations (i.e. IACUC guidelines and federal regulations, or EU guidelines for animal research). One recommended 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).

Contents

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Invited Educational Commentary

The Role of EVTM in the Austere Environment

Mohammed Al-Musawi MBChB, MSc, FIBMS-CTV, FRCS "Glasg"

Research Faculty, Department of surgery/Division of Cardiothoracic Surgery, School of Medicine, University of Colorado, USA

In November 2019 we, as a group of Iraqi cardiovascular surgeons, were invited to give a lecture in the Pan-American Endovascular Resuscitation and Trauma Management (EVTM) [1] symposium in Denver, Colorado to share our experience in management of mass causalities in the austere environment. The main topic we tried to highlight was how we approached bleeding control and resuscitation with scarcity of resources while dealing with large volumes of trauma cases. Before attending this symposium we did not know what EVTM was or what it stood for. That EVTM was a two-day symposium and our lecture was last; therefore, we had the ability to learn more about its principles and goals. We were surprised to find that we use the same principles in our daily practices in Iraq without calling it EVTM. The main difference is our scarcity of resources and how we modify less sophisticated catheters or balloons to help control bleeding or to resuscitate patients during their transfer. Of course, the main principles are the same regarding early prehospital trauma care, which is one of the most important measures to improve outcome in trauma surgery [2]. This includes securing airways, packing wounds, using tourniquets for bleeding limbs, getting intravenous access with fluid replacement, stabilizing fractures and a quick transfer to the nearest medical facility [3]. Unfortunately, in our daily practice in Iraq we don't get all of these steps done – sometimes some of them are done but most of the time none of them. One example of improvisation is the use of simple occlusion catheters or the Fogarty catheter either during patient transfer or peroperatively to stop exsanguination and help resuscitation. We notice in our practice that the impact of poor prehospital care significantly increases prehospital and in-hospital mortality. In a normal emergency department, with a few cases a day, this is not a problem. However, when you see 80–100 unstable patients from a massive explosion in a crowded city or neighborhood in a few hours, this can be overwhelming. And in these severely traumatized patients, traumatic bleeding remains a leading cause of potentially preventable death among severely traumatized patients [4]. Our problem in these patients is how to control anatomically and surgically the inaccessible bleeder, and usually these are intrathoracic, intra-abdominal, pelvic and zone I cervical bleeds. It is a surgical fact that in these situations control can be achieved effectively through an intraluminal approach using balloon catheters and catheter-guide wire techniques [5]. We use variable occlusion catheters to control intra-abdominal aortic, inferior vena cava injuries and subclavian artery injuries. Because of a lack of a proper angiography suite we carry out all these in the emergency department blindly. The aim is to have an endoluminal occlusion proximal to the suspected level of injury. Not having imaging guidance forces us to push the catheter to occlude the abdominal aorta as high as possible by mapping the catheter topographically to the abdominal surface before insertion, so that we know how far we need to push the catheter in different patients with different body sizes. This is not a perfect solution but it helps to buy time to resuscitate and transfer the patient to operative theatre.

With advances in imaging and in catheter-based endoluminal techniques such as Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) [6], catheter-based embolization and hybrid operative theatres, it is now possible to provide better use of endovascular techniques in controlling and resuscitating inaccessible bleeders [6, 7]. This can have a great impact, especially in managing mass causalities, by providing quick and precise control of bleeders and resuscitation. This helps the trauma team to have more time to operate on a large number of cases, so that patients are then better controlled and resuscitated. We believe that EVTM has an excellent place to operate in these mass causality situations. It is in these situations that the trauma team faces a large number of cases

Corresponding author:

Mohammed Al-Musawi MBChB, MSc, FIBMS-CTV, FRCS "Glasg", Research Faculty, Department of surgery/Division of Cardiothoracic Surgery, School of Medicine, University of Colorado, USA.

Email: mohammed.al-musawi@cuanschutz.edu

Figure 1 The medical city emergency department during receipt of mass casualties.

Figure 2 From a tent used as an emergency room in the battle field.

admitted over a short time, where most of them require bleeding control and resuscitation, and then need to be triaged to the surgery waiting queues. EVTM is useful in almost all situations as the techniques can be tailored to the available resources, similar to what we do in Iraq. They can be applied using a simple occlusion catheter, and they can be applied having all the modern resources of imaging endoluminal catheter-based intervention. This broad spectrum and the flexibility of the principles and tools of EVTM can help with the dissemination of practice guidelines in different places and scenarios.

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.

Funding

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Editorial

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Introducing EVTM In Turkey

Yunus Emre Özlüer MD[1] and Mücahit Avcil MD[1]

[1]*Department of Emergency Medicine, Adnan Menderes University Hospital , Aydin, Turkey*

Trauma is one of the leading causes of death affecting mostly young populations worldwide [1]. Trauma is not only the "sickness of the healthy", but also causes workforce loss in addition to the cost of the healing the trauma victims [2]. Considering the trimodal distribution of the mortality in trauma patients, one can say that trauma is a "syndrome" with a significant rate of mortality and morbidity.

Endovascular trauma management (EVTM) options such as resuscitative endovascular balloon occlusion of the aorta (REBOA), stenting, and embolization are the state-of-the-art tools in the resuscitation of the critically ill trauma patients. However, stenting and embolization require an angiography suite or ideally hybrid suites where REBOA can be placed under the guidance of the ultrasonography making it more accessible even in the austere environments [3].

In Turkey, the health system is mostly carried out through emergency departments (ED) causing an annual ED admittance over 137 million. On the other hand, most of the EDs are not equipped with modern infrastructure (hybrid suites to be specific) to provide up-to-date trauma care. Also, there are not any EDs that are specifically designed for the management of trauma patients.

Trauma surgery is not recognized as a subspecialty/specialty in Turkey and teamwork is mostly hard to establish by emergency physicians because of the "over-conservative approach" of the surgeons. Although the emergency medical services (EMS) are doing an exceptional job, mobile units tailored for the management of the trauma patients on the scene are not available yet. Considering these, one can say that the system has a major part in the high rates of mortality and many unnecessary deaths from trauma.

Corresponding author:

Yunus Emre Özlüer, Department of Emergency Medicine, Adnan Menderes University Hospital, Aytepe Mevkii, 09100, Efeler, Aydın, Turkey.

Email: yeozluer@adu.edu.tr

The EVTM Symposium in 2018 in Örebro clearly showed us that we needed a paradigm shift in the trauma concept of our country by introducing endovascular resuscitation solutions and ultimately the "endo mind". After experiencing REBOA, stenting, and embolization in the two consecutive EVTM workshops in Örebro, we have analyzed the perspectives of the adaptability of EVTM into our trauma care system. Considering the feasibility and the needs of the system, we thought that REBOA would make a significant difference in the management of trauma patients in Turkey. Thus, we have established the Turkish Endovascular Resuscitation and Trauma Management (TR-EVTM) Platform which stems from our clinic, Adnan Menderes University Hospital Department of Emergency Medicine, designed as a working group to establish a network between EDs and spread the knowledge about REBOA and other endo tools. On the other hand, we have set up a REBOA kit which includes various sizes of introducer sheaths, an 8-Fr Fogarty occlusion catheter, and have started to perform REBOA for the first time in Turkey. To date, we have had 26 REBOA cases. Although REBOA is designed for trauma in the first place, a significant portion of our patients have needed an aortic occlusion on a medical basis. Paying attention to the protection of privacy, in a few of our cases we tried to use social media platforms to draw attention and to prove that REBOA is practically feasible.

By internalizing the motto of the EVTM society, we have started organizing REBOA workshops on live animal models in collaboration with the Emergency Physicians Association of Turkey (EPAT). Members of our platform pledged themselves to promote EVTM at every academic meeting, symposium, and congress they attended. We also had the honor of hosting one of the precious members of the EVTM society, Mr. Yosuke Matsumura, at an emergency medicine congress last year and with a group of committed emergency physicians we have completed the translation of the book "Top Stent" into Turkish by the end of January 2020. Another example of collaboration with colleagues from cardiology at our hospital provided a fantastic opportunity to perform the first pelvic embolization by emergency physicians in a patient with an open book pelvic

trauma in Turkey. After introducing REBOA in our country, embolizing a bleeding artery was another revolutionary step for EVTM in Turkey.

The industry is a vital part of EVTM. Stent-grafts and embolization materials such as coils and plugs are currently used by interventional radiologists, even in elective cases. However, in Turkey none of the low-profile catheters, which are specifically designed for REBOA, are available on the market. This does not leave any other option other than using large bore, generic catheters. Thanks to the EVTM society, we are increasing our relations with catheter companies and, hopefully, we will be able to have them on the market soon.

TR-EVTM is planning to increase the number and enrich the content of the REBOA workshops where the industry and health professionals come together and share their experiences and knowledge, similar to EVTM workshops. Our main goal is to encourage the use of REBOA in trauma all over the country as a first step. The attendees of our workshops are subscribed to a mailing list (TR-REBOA Registry) designed as a platform for sharing their future REBOA cases. With the collection of data from REBOA cases in Turkey, we will be able to publish our country-wide experience on REBOA. Apart from the workshops, we are planning to hold REBOA courses to a lesser extent than workshops where we will make demonstrations on mannequins rather than live animal models. We think this will provide us with the mobility we need and allow the introduction of REBOA to more people dealing with trauma every day.

Ethics Statement

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

Conflicts of Interest

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Funding

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Author Contributions

YEO and MA both did the literature review and the manuscript writing.

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Editorial

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Trauma Management During and After COVID-19

Federico Coccolini MD[1], Fausto Catena MD, PhD[2], Emiliano Gamberini MD[3], Anna Maria Ierardi MD[4], Massimo Sartelli MD[5], Mirco Nacoti MD[6] and Massimo Chiarugi MD[1]

[1]General, Emergency and Trauma Surgery Department, Pisa University Hospital, Pisa, Italy
[2]Emergency Surgery Department, Parma University Hospital, Parma, Italy
[3]ICU Department, Bufalini Hospital, Cesena, Italy
[4]Interventional Radiology Department, Niguarda Hospital, Milano, Italy
[5]General Surgery Department, Macerata Hospital, Macerata, Italy
[6]Pediatric ICU Department, Papa Giovanni XXIII Hospital, Bergamo, Italy

The current COVID-19 pandemic can most certainly be described as a mass casualty incident (MCI). An MCI occurs "when the destructive effects of natural or man-made forces overwhelm the ability of a given area or community to meet the demand for health care" [1]. The greatest difference in comparison with a "typical" MCI is that its presentation is subtle, and it does not require all the emergency services that are usually involved with most MCIs [2]. Furthermore, this outbreak is more than an intensive care phenomenon; it is instead, in some parts of the world, a public health and humanitarian crisis. It requires the skills of social scientists, epidemiologists, experts in logistics, psychologists, and social workers [3]. Hospital resources are fully utilized but trauma surgeons are not involved.

The disease presentation and the preventive measures progressively adopted by many countries, first in Europe and then around the world, have in fact dramatically reduced the number of trauma events. People are confined to their houses with restricted possibilities for socializing.

Even though they are reduced in number, trauma events continue to occur and must be managed to the best of the system's possibilities with the additional necessity of protecting personnel and patients from possible contagion. Maintaining the capacity to treat trauma patients represents one of the cornerstones of health care. Many papers have been published in order to share knowledge and experience, although few of them are about surgery. The main Italian surgical societies have published a set of operative guidelines to help in the reorganization of systems in order to manage this unusual situation, based on the experience derived from the (unfortunate) Italian situation [4].

In order to efficiently face the situation, the mitigation phase should be carefully planned and put into action, especially in those countries where COVID-19 has not yet demonstrated its full deadly power. However, an epidemic requires a change of perspective and a move from patient-centered care toward a concept of community-centered care, with the need for decision making to take into consideration the epidemiological and clinical issues of the virus.

Each level of the trauma system must be considered in the reorganization and redistribution of resources and demands.

Regional systems must prepare defined protocols to facilitate the distribution or re-distribution of patients within different hospitals according to the surge in requests for assistance that necessarily involves and overlaps with resources commonly utilized for trauma care.

In each individual hospital, pathways must be reorganized in order to separate patients who are infected or possibly infected, from all others who are definitely not infected. This means preparing separate routes, separate rooms, separate facilities, and even separate buildings to host the two groups of patients. Moreover, a sort of "grey-zone" is required to manage those patients waiting for definitive workup to detect infection or those who have arrived at the emergency department requiring emergency surgical treatments but who are also infected. Dedicated operating rooms and operating areas should be organized in order to maintain the separation of infected from non-infected patients.

Corresponding author:
Federico Coccolini, General Emergency and Trauma Surgery, Pisa University Hospital, Via Paradisia, 1, 56124 Pisa, Italy.
Email: federico.coccolini@gmail.com

Even though the recognized principles of damage control surgery should be applied, trauma surgeons have to nonetheless keep in mind that the rising tide of COVID-19 takes its toll by restricting access to intensive care unit (ICU) facilities. Trauma surgical procedures need, therefore, to be carried out with the aim of both achieving the best outcome for the patient and reducing the burden of a prolonged stay in ICU.

Trauma teams and shifts of dedicated personnel must be organized in order to respond to all requests in a period of shortage of both material and human resources. All necessary personal protection equipment must be used, and shifts should be reorganized such that there is as much continuity as possible in the persons involved in the management of each infected patient. Moreover, dedicated staff should be prevented from proceeding with ordinary emergency surgery on non-infected patients in parallel with performing the same activity on infected patients. Separate pathways are necessary in order to reduce the risk of contagion of non-infected patients.

The fact that trauma surgeons and ultra-specialized personnel are at present underutilized may lead to health care providers relocating them to COVID-19 ICU or medical wards in order to support colleagues in the management of sick patients.

During an MCI, especially one deriving from infective or easily inter-individual transmissible causes, the careful use of human resources is crucial [3,5]. Trauma and emergency general surgeons and super-specialized doctors should be preserved during an MCI because their contagion or death will lead to the remaining emergencies and necessities becoming impossible to manage. In fact, the consequent lack of experienced teams cannot be solved simply by reintegrating retirees or replenishing the ranks with the newly qualified [2]. The contagion or death of trauma team members would result in a lowering of skills and, consequently, a decrease in the quality of care.

A shortage of blood is something that the countries that are already involved in the pandemic are experiencing. People are not giving blood because of lock-down restrictions combined with the fear of being infected when entering the hospital. This may result in the reorganization of necessary and undemanding surgical interventions, but also in the preparation of campaigns to encourage the population to continue to give blood. As a consequence, this requires the preparation of dedicated environments or facilities to allow blood donors to avoid the risks of coming to the hospital.

Historically, we are living in a period rarely seen before. Our systems are not ready to face this emergency, from an organizational point of view rather than from a technical or medical one. An actual pandemic is something that has rarely been faced before. We are dealing with something that we usually read about in newspaper reports from far off countries and that we have scarcely thought about in terms of such proximity to our own lives. In fact, an outbreak of such a deadly infectious disease has not been experienced in our latitude since the early 20th century.

Paradoxically, less structured trauma systems are more able to face this pandemic because of their intrinsic flexibility. More organized and efficient systems will face more problems because they will have to force their organization to rapidly restructure in order to maintain the standard of care. Lessons learned from the dramatic situation we are all living in must be recorded in order to be ready for the next one [6,7]. As Nacoti et al. have recently written: "Western healthcare systems have been built around the concept of patient-centered care, but an epidemic requires a change of perspective toward a concept of community-centered care (…). We lack expertise in epidemic conditions, guiding us to adopt special measures to reduce epidemiologically negative behaviors" [3].

Trauma surgery must begin the extensive task of reorganization so that systems are structured to be able to rapidly change setting in order to face such infectious outbreaks without contributing to the general chaos, but instead responding rapidly to the needs.

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.
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Commentary

Trauma Management During and After COVID-19

B Kessel Prof, D Sheffer MD and V Zilbermints MD

Surgical Division, Hillel Yaffe Medical Center, Hadera, Israel, affiliated with Rappoport Medical School, Technion, Haifa, Israel

We have read with great interest the editorial written by our colleagues from Italy. Their work covers many strategical, tactical, and even, from our point of view, philosophical aspects of trauma care during the COVID-19 pandemic. The recent situation is proving time after time, country after country, that any unexpected pandemic event deals a major "blow" to even the best national health care systems in the world.

It cannot be argued against that we have much to learn, both from each other and certainly from previous experiences. We watch and learn about what can be done now, taking into consideration that the situation is changing daily. We look optimistically forward, watching the effects of government measures, and we are still amazed by the situation.

We completely agree with Dr Coccolini that COVID-19 is, per definition, a mass causality incident. In Israel, we have probably one of the most developed countrywide preparedness plans for mass causality events. This national program was developed on the basis of extensive experience in trauma mass casualty incidents. The strategy is based on very strict rules of central control, early army and Home Front Command involvement, regulations for all essential and pre-hospital services as well as multiple logistics [1]. One of the most important cornerstones of this policy is that of being prepared in advance, creating a "war tactical plan" for the skilled primary and early secondary triage manpower among the hospitals [2]. This plan has always succeeded in preventing such situations when hospital capabilities could not deliver optimal individual care. Every Israeli public medical center has its own plan based on hospital capacities, their geographic in-hospital locations, the presence of professional staff, and much more [3]. Annual training at each hospital is mandatory by governmental law.

Unfortunately, such a plan does not routinely exist during times of pandemic. As with many things, our medicine should learn from trauma surgery and several recommendations may be obtained from the literature and the experience from recent mass casualty incidents [4]. We would be happy if Dr Frederico could let us know whether such a strategy exists in Italy and whether he knows of any inter-hospital regulations. It is clear to us that even multiple-bed hospitals do not have enough experienced staff to ventilate many patients simultaneously. We would also like to take this opportunity to ask Dr Coccolini's opinion concerning which medical personnel he thinks are most appropriate to do this job when there is a shortage of intensivists and internal medicine experts? Is there a plan for the relocation of staff, moving them in from another hospital? In Israel, there is a dissonance between the expertise and skills of the seniors in tertiary hospitals in comparison with smaller medical centers, but there is a plan to fill the void in the case of an emergency. We would like to know whether in Dr Coccolini's hospital, and maybe throughout the country, such plans were developed as the epidemic worsened.

In our opinion, our civilization has never met and has never planned for such a scenario, and we must draw some conclusions for the future. Specifically, concerning trauma care, the best situation for trauma patients today is where we can separate clean and infected patients. However, nowadays, a hemodynamically unstable victim of a stabbing does not provide us this "luxury" situation. In such a situation, do you regard these trauma victims as corona virus infected patients until proven otherwise? Furthermore, it will be very interesting to learn from your experience about whether you are practicing endovascular and hybrid trauma techniques these days. Such procedures are certainly considered time-consuming, especially while working in a busy trauma center, performing a whole body computed tomography for trauma several times daily. We would therefore like to know whether your hospital has changed the routine indications for imaging.

In your very interesting editorial you have raised a philosophic question to which we have no answer, whether the most experienced trauma surgeons should be "treated with silk gloves." It would probably be interesting for our readers to know how you have defined the necessity of their involvement.

Corresponding author:
Boris Kessel, Hillel Yaffe Medical Center, Ha-shalom Street 2, Hadera 3846203, Israel.
Email: bkkessel01@gmail.com

Finally, we would really like to praise the authors of this manuscript who found it possible to share with us their "hopefully unique" experience in these very difficult times.

Ethics Statement

(1) All the authors mentioned in the manuscript have agreed to the authorship, read and approved the manuscript, and given consent for the submission and subsequent publication of the manuscript.
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Conflicts of Interest

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Editorial

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Extracorporeal Membrane Oxygenation in Coronavirus Disease 2019: Experience from a Single Italian Center

Emiliano Gamberini MD[1], Federico Coccolini PhD[2], Alessandro Circelli MD[1], Emanuele Russo MD[1], Marco Benni MD[1], Gustavo Iacono MD[3], Emanuela Giampalma MD[4] and Vanni Agnoletti PhD[1]

[1]Anesthesia and Intensive Care Department, "M. Bufalini" Hospital, Cesena, Italy
[2]General, Emergency and Trauma Surgery Department, Pisa University Hospital, Pisa, Italy
[3]Vascular Surgery Department, "M. Bufalini" Hospital, Cesena, Italy
[4]Radiology and Interventional Radiology Department, "M. Bufalini" Hospital, Cesena, Italy

The novel coronavirus infection, declared by the World Health Organization (WHO) as coronavirus disease 2019 (COVID-19), has spread rapidly around the world from China. About 15–30% of COVID-19 affected patients will develop acute respiratory distress syndrome (ARDS) and, in centers where it is routinely used, extracorporeal membrane oxygenation (ECMO) may be necessary to sustain respiratory and circulatory function, as postulated by WHO [1,2]. ARDS can lead to refractory hypoxemic respiratory failure, while the relatively high incidence of shock in most severe COVID-19 patients requiring intensive care unit (ICU) admission is probably associated with bacterial superinfection, multiple organ failure and myocarditis [3,4]. Veno-venous ECMO (VV-ECMO) is the first choice ECMO configuration for isolated severe respiratory failure. Venous blood is withdrawn from the vena cava and pumped through an artificial membrane lung where oxygen (O_2) is added and carbon dioxide (CO_2) removed. Blood with more O_2 and less CO_2 than normal venous blood is then returned to the patient in another site of the vena cava, helping the impaired native lung to perform gas exchanges. Veno-arterial ECMO (VA-ECMO) is a different configuration where venous blood is withdrawn and pumped through the artificial membrane lung as in VV-ECMO, but it is returned to the patient through a major artery, thus providing even circulatory support but less effective respiratory support.

ECMO is a highly specialized and expensive form of life support with the potential for significant complications, in particular hemorrhage, thrombosis and embolization, and its role in the management of pandemic COVID-19 infection remains unclear. Together with the lack of skills, a huge outbreak such as that of the COVID-19 exacerbates the limitations of providing ECMO due to the unavailability of devices and skilled healthcare professionals. ECMO cannot be considered for use in the frontline in a pandemic when all resources are stretched, even in adequately equipped centers, and its application should be reserved for patients with a substantial chance of survival [5].

"M. Bufalini" Hospital is a major trauma center and stroke center in the eastern part of the Emilia-Romagna region in Italy, with the Adriatic Sea forming its oriental border. The outbreak in this area has been linear rather than exponential and, so far, the availability of resources has not been a critical issue. The first ICU cases were admitted on March 6th and, up until March 27th, we have treated 30 severely ill COVID-19 positive patients. COVID ICU patients usually require long periods of mechanical ventilation and ICU stay. In order to face this situation, the existing 17-bed ICU was converted to a COVID-ICU and nine additional beds were set up in the adjacent five rooms in the surgical ward and equipped with vacuum, oxygen and compressed air connections,

Corresponding author:
Emiliano Gamberini, Anesthesia and Intensive Care Department, "M. Bufalini" Hospital, Viale Ghirotti 286, 47251 Cesena, Italy.
Email: egamberini74@gmail.com

ICU monitors, and mechanical ventilators. A new five-bed ICU dedicated to non-COVID patients was created by reopening the old post-operative ICU in order to allow for the unavoidable ICU needs of the residual elective surgical activity, trauma, and neuro-intensive patients. The number of ICU staff was increased by transferring anesthesiologists and anesthesia nurses from the operating theatre where elective surgical activity had been reduced by up to 80%.

These organizational changes put us in a position, both structurally and professionally, to be able to treat two patients with ECMO during this period. VV-ECMO was performed in a patient with severe refractory hypoxemia after four cycles of prolonged prone position ventilation, while extracorporeal cardiopulmonary resuscitation with VA-ECMO was necessary to rescue a patient suffering cardiac arrest as a consequence of septic shock; this was then switched to VV-ECMO 3 h later because of hemodynamic improvement with persistent severe hypoxemia.

In conclusion, ECMO can be a rescue option in the COVID-19 pandemic only in settings where the outbreak does not overwhelm the available resources. ARDS induced refractory hypoxemia is the most common indication for VV-ECMO, while myocarditis leading to cardiogenic shock, together with bacterial superinfection with septic shock, can be treated with VA-ECMO.

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.
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Resident Corner

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Extra Corporeal Membrane Oxygenation (ECMO) for Patients with COVID-19

David T McGreevy MD and Jenny Seilitz MD

Department of Cardiothoracic and Vascular Surgery, Faculty of Medicine and Health, Örebro University Hospital and Örebro University, Örebro, Sweden

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2), also known as Coronavirus disease 2019 (COVID-19), has spread worldwide since December 2019 and has presented serious challenges to healthcare systems. As of 15 April 2020, over 2 million people have been diagnosed with COVID-19 worldwide, with over 130,000 having died. A total of 11,927 patients have been diagnosed in Sweden, 954 have required intensive care and 1,203 have deceased. Admission to intensive care is after an average of 10.5 days, 75% are men with a mean age of 59 years [1]. To date, there is no effective therapy for the treatment of this disease and its management mainly focuses on preventing its spread. Severe symptoms with respiratory failure or acute respiratory distress syndrome (ARDS) develop in about 20% of cases with the principal therapy being lung protective ventilation, prone position, restrictive fluid management and adequate management of organ failure [2,3]. The mortality rate in those requiring mechanical ventilation is high. Extracorporeal membrane oxygenation (ECMO) can provide artificial respiratory or cardiac support to patients without effective gas exchange and systemic perfusion and has in some studies shown improved survival rates in patients with ARDS. However, it is recommended as a rescue strategy as part of the Endovascular Resuscitation and Trauma Management (EVTM) concept when other treatment options have failed [4–6]. ECMO was used during the Influenza A (H1N1) pandemic in 2009 for the treatment of ARDS and was associated with a lower in-hospital mortality of 21–24% [7,8]. Similar findings were reported with the use of ECMO in 5.8% of patients treated for refractory respiratory failure caused by Middle East Respiratory Syndrome [9]. Initial data show the World Health Organization guidelines on the management of patients with ARDS from COVID-19 suggest that veno-venous (VV) ECMO should be considered for patients with fulminant lung failure and refractory hypoxemia despite lung protective ventilation. The number of patients who require this level of support is currently unknown [10]. Henry et al. recently published an article with a pooled analysis of available data reporting a 7.2% use of ECMO due to ARDS from COVID-19 and a mortality rate of 94.1% with no significant difference compared with conventional therapy [11]. This early report would suggest that ECMO neither harms nor benefits critical patients with COVID-19. However, the small sample size (n = 17) as well as the limited data on disease severity should be taken into consideration, remembering that this is an ongoing pandemic with many patients still being treated with ECMO. An early report by Ruan et al. showed increased levels of interleukin-6 and decreased levels of lymphocytes in patients dying from COVID-19 [12]. These are changes that are regularly observed during ECMO which is why the immunological status of patients with COVID-19 should be considered before starting ECMO treatment [13,14]. It is important to remember that patients with COVID-19 may also become critically ill through septic shock, multiorgan failure or the exacerbation of comorbid diseases, and ECMO may be of limited use in such cases. However, little is still known about these different subsets of patients; experience of using ECMO is limited and should therefore only be performed by expert centres with a sufficient case volume to ensure clinical expertise [15,16]. It has also been reported that severe COVID-19 patients are hypercoagulable, that disseminated intravascular

Corresponding author:

David T McGreevy, Department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, SE-701 85 Örebro, Sweden.

Email: david.mcgreevy@regionorebrolan.se

Figure 1 Patient on VV-ECMO at Örebro University Hospital because of fulminant lung failure and refractory hypoxemia caused by COVID-19.

coagulation may exist in the majority of deaths and that early anticoagulation therapy may be associated with increased survival [17,18]. This is an important consideration since ECMO can be associated with both haemorrhage and thrombosis [19]. As a response to this lack of evidence, the Extracorporeal Life Support Organization (ELSO) Registry is now in the process of adapting to include information regarding the use of ECMO in the treatment of COVID-19 patients and prospective observational studies will follow. ELSO has also released guidelines on the use of ECMO in the treatment of COVID-19 patients that are frequently updated. They highlight specific consideration for patient selection, deeming ECMO solely suitable in young, previously healthy COVID-19 patients with single organ failure only after maximizing traditional therapies at available ECMO centres with appropriate organization of trained personnel, equipment, facilities and routines [20].

Ethics Statement

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Author Contributions

DM drafted the manuscript. JS contributed to the manuscript.

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Original Article

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Traumatic Thoracic Aorta Injuries: Outcomes up to 15 years Post Thoracic Endovascular Aortic Repair

Varun J Sharma MBBS[1], Martin J Jarmin MD[2], John A Crozier FRACS[1], Saksham Gupta MBBS[1] and Jim N Iliopoulos PhD FRACS[1,3]

[1]*Department of Vascular Surgery, Liverpool Hospital, Liverpool, New South Wales, Australia*
[2]*Department of Trauma Surgery, Liverpool Hospital, Liverpool, New South Wales, Australia*
[3]*Department of Surgery, University of New South Wales, Liverpool, New South Wales, Australia*

Background: Aortic injuries are a leading cause of death following trauma, with 75% pre- and 50% in-hospital mortality. Endovascular repair is technically easier with fewer complications but long-term results are unproven.
Methods: A retrospective analysis of patients with endovascular repair of thoracic aortic injuries from 2001 to 2018 at Liverpool Hospital, Sydney, Australia was undertaken. Primary endpoint was death and secondary endpoints were re-interventions, hand ischemia, access vessel repair and ischemic complications.
Results: 24 patients (10 female) were reviewed, the most common mechanism of injury being motor-vehicle related (75%) in Zone 3 (71%). Deployment was proximal (n = 11), on (n = 2) or distal (n = 11) to the left subclavian artery (LSCA). Average follow-up was 5.4 ± 5.1 years (range 0.1–15.2 years), with two deaths. At <90 days, complications were hand ischemia (n = 4, n = 1 needing intervention), access vessel endarterectomy (n = 1) and conversion to open bypass (n = 1). At >90 days, complications were hand ischemia (n = 1), graft migration (n = 2) and minor graft thrombosis (n = 1). Coverage of LSCA was not a predictor of re-intervention (P = 0.43) or supra-aortic bypass (P = 0.13). Survival free from reintervention in the non-covered LSCA group was 100% at the 30-day and 6-month timepoints, and 80% at the 1-year and 5-year timepoints. Survival free from reintervention in the covered LSCA group was 84%, 75.6%, 67.2% and 67.2% at the 30-day, 6-month, 1-year and 5-year timepoints, respectively.
Conclusions: Endovascular repair for aortic injuries has low levels of morbidity. The LSCA can be covered without arm ischemia and is not predictive of re-intervention or a supra-aortic bypass. At up to 15 years follow-up, graft complications remain low.

Keywords: *Trauma; Aorta; Endovascular; Stent*

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INTRODUCTION

Aortic injuries are one of the leading causes of death following trauma, with a 75% pre-hospital and 50% in-hospital mortality [1,2]. The aortic isthmus is the location for 90% of injuries, attributed to the osseous pinch theory, caused by a sudden deceleration and traction of the immobile isthmus at the junction of the mobile ascending arch and the fixed descending aorta combined with the shear stress between anterior and posterior bony structures [3].

The most common mechanism is motor-vehicle injuries or rarely blunt trauma from falls. The high degree of force needed generally results in a large number of concomitant injuries, in particular cardiac and pulmonary contusions, thoracic cage fractures and significant hemodynamic instability, all of which confer a high operative risk when open surgery is performed. Such intervention has historically required thoracotomy with single lung ventilation, cardiopulmonary bypass, systemic anticoagulation and aortic cross clamping, and is fraught by paraplegia from spinal cord ischemia, delayed rupture and mortality.

Corresponding author:
Department of Vascular Surgery, Liverpool Hospital, Liverpool, Sydney, Australia.
Email: varun_sharma@hsph.harvard.edu

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The advent of endovascular techniques for thoracic aortic repair (TEVAR) in 1991 and their first use in trauma in 1997 have been met with optimism, with improved perioperative morbidity and mortality [2,4–8]. However, there remains uncertainty regarding the timing of TEVAR in stable patients, management of minimal aortic injuries (periadventitial defects or hematomas), the role for prophylactic spinal drainage, choice of anesthesia and optimal follow-up imaging modality, with the level of evidence to substantiate the last series of recommendations from the Society of Vascular Surgery (SVS) remaining poor (Level IIC) [1,9,10].

In particular, as most interventions are undertaken on young patients (median age 39), there are concerns regarding the long-term stent conformation to the inferior part of the aortic arch, sequalae of left subclavian artery (LSCA) coverage, effects of age-related morphological changes, cumulative radiation exposure in follow-up, material failures, fractures and fabric fatigue [11–15].

Table 1 Patient demographics.

Patients [*n* (%)]	
Male	14 (58%)
Female	10 (42%)
Age (range)	47.9 ± 16.1 years (26–84 years)
Co-morbidities [*n* (%)]	
Hypertension	7 (29%)
Type 2 diabetes	5 (21%)
Ischemic heart disease	5 (21%)
Smoking	6 (25%)
Intravenous drug use	3 (12%)
Injury Severity Score (ISS)	35.3 ± 13.6 (16–59)
Average length of intensive care unit stay	11.2 ± 10.8 days (5–468 days)
Average length of hospital stay	59.7 ± 93.9 days (2–40 days)
Mechanism of injury [*n* (%)]	
Motor-vehicle/cycle injury	21 (87.5%)
Fall	3 (12.5%)

METHODS

Patients with TEVARs undertaken for trauma were identified using the Australian Vascular Audit, the Liverpool Hospital electronic and paper medical records and the Liverpool Hospital Trauma Database.

Retrospective analysis was undertaken to determine demographic, operative and follow-up data. The primary endpoint measured was death. Secondary endpoints were conversion to open and take back operations, hand ischemia, acute surgical complications to access vessels, cardiopulmonary complications, stroke, spinal cord ischemia and end organ dysfunction. Stents were analyzed for endoleak, graft migration, collapse and thrombosis. Statistical analyses were performed with Microsoft Excel (2016) and Stata (v15.1).

Ethical Approval and Informed Consent

As a retrospective study, ethics was approved by the Research and Ethics Department of Liverpool Hospital, Liverpool, Australia (LNR/18/LPOOL/530) in lieu of individual informed consent.

RESULTS

Since 2001, there were 24 patients who underwent thoracic stenting for traumatic aortic injuries. The average age at operation was 47.9 years (Table 1), and the most common mechanism of injury was motor-vehicle related (75%) (Figure 1). The presence of previous co-morbidities was low and the average Injury Severity Score (ISS, 2015) [4, 16] on arrival was 35 (Table 1).

The median time to intervention was 1.0 days (range 0–100 days). Common concurrent injuries were thoracic contusions, pneumo-hemothoraces and rib, pelvic, scapular, clavicular and vertebral fractures (Figure 1). Median intensive care unit and hospital stay was 4.5 (interquartile range (IQR) 3.0–19.0) and 27.5 (IQR 14.8–82.3) days, respectively.

Using the SVS guidelines [1,9,10], all patients with a Grade III (pseudoaneurysm, $n = 13$) and Grade IV (disruption with rupture, $n = 11$) injuries underwent TEVAR, which were located in Zone 2 ($n = 3$), Zone 3 ($n = 17$) and Zone 4 ($n = 4$) (Figure 2).

All grafts were Zenith Thoracic grafts (Cook Medical), with graft diameter ranging from 24–38 mm. Access was either percutaneously with a closure device ($n = 11$) or via femoral cutdown ($n = 13$). Proximal landing zone was proximal to the LSCA in 11 patients, partially covering the LSCA in 2 patients and distal to LSCA in 11 patients. In patients with LSCA covering, two patients had LSCA coiling of which one also had a prophylactic left common carotid artery (LCCA) to LSCA bypass. The classification of endoleak was defined similarly to contemporary definitions for aneurysmal pathology; Type I endoleak was defined as a lack of a proximal or distal stent graft seal, including retrograde flow from the LSCA; Type II endoleak was classified as any other retrograde filling from arteries of the descending thoracic aorta. Significant Type I endoleak was noted intraoperatively in three patients, and Type II in one patient. The distal landing zone in all patients was the distal thoracic aorta, just above the coeliac axis.

In the immediate postoperative period (up to 90 days, Table 2), there were no deaths. Indications for reintervention were hand ischemia ($n = 3$, $n = 1$ requiring urgent intervention within 24 hours), access vessel occlusion needing endarterectomy ($n = 1$) and pseudoaneurysm formation with Type Ia endoleak ($n = 1$, requiring conversion to open bypass). There was high concurrence of cardiac ($n = 2$), thoracic ($n = 12$) and acute renal failure ($n = 7$) complications, but these were not iatrogenic.

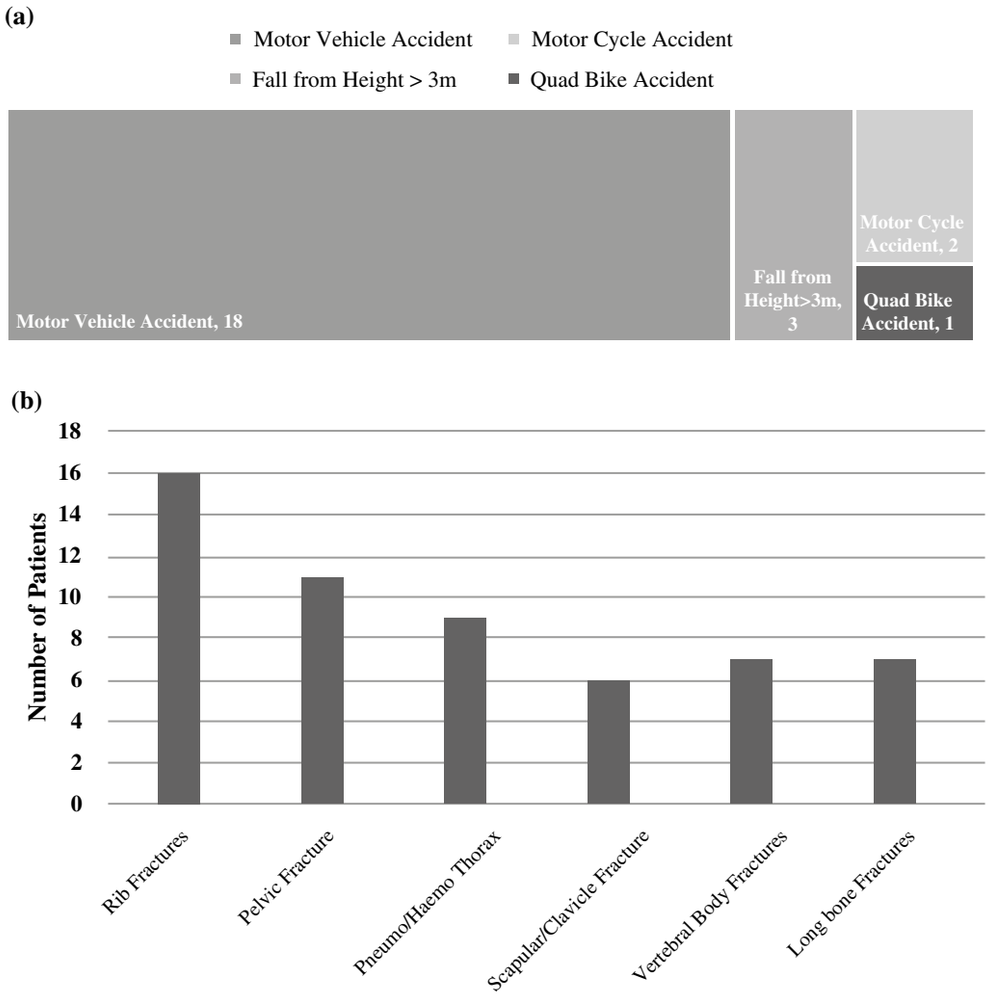

Figure 1 Mechanisms of injury and common concurrent injuries. (**a**) Mechanism of injury. Motor-vehicle injury formed the majority of cases (n = 18) followed by fall from height (n = 3), motorcycle injuries (n = 2) and four-wheel quad bike injuries (n = 1). (**b**) Common concurrent injuries in patients who underwent endovascular repair for traumatic aortic injuries.

There were no episodes of spinal cord ischemia, stroke or paraplegia secondary to endovascular intervention.

Post discharge (greater than 90 days, Table 2), average follow-up time was 5.4 years with maximal follow-up 15.2 years (Figure 3). There were two deaths; one from graft sepsis and one from intracerebral hemorrhage post fall for an unrelated admission (the patient was not anticoagulated). Of the patients with persistent hand ischemia (claudication) post 90 days (n = 3), one needed LCCA to LSCA bypass at 9 months, and the remaining two patients' symptoms resolved with physiotherapy. There was no graft thrombosis, but one patient required iliac intervention ipsilateral to the site of femoral access, and another one showed evidence of non-flow limiting stenosis at 10 years follow-up. Graft migration was noted in two patients, and there was no evidence of aortic dilation.

Coverage of the LSCA did confer any statistically significant risk on re-intervention or the need for a LCCA to LSCA bypass (Table 3 and Figure 3). Although a greater number of patients with stent placement proximal to the LSCA required LCCA to LSCA bypass (n = 3/11 vs. n = 0/11), this difference was not statistically significant (P = 0.13, Figure 3). The survival free from reintervention in the non-covered LSCA group was 100% at the 30-day and 6-month timepoints, and 80% at the 1-year and 5-year timepoints. The survival free from reintervention in the Covered LSCA group at was 84%, 75.6%, 67.2% and 67.2% at the 30-day, 6-month, 1-year and 5-year timepoints, respectively. The survival free from LCCA–LSCA bypass in the non-covered LSCA group was 100% at all timepoints; in the covered LSCA group it was 92.0%, 83.7%, 83.7% and 57.4% at the 30-day, 6-month, 1-year and 5-year timepoints, respectively. Concurrent injuries and the zone of injury did not confer any statistically significant risk of re-intervention or bypass.

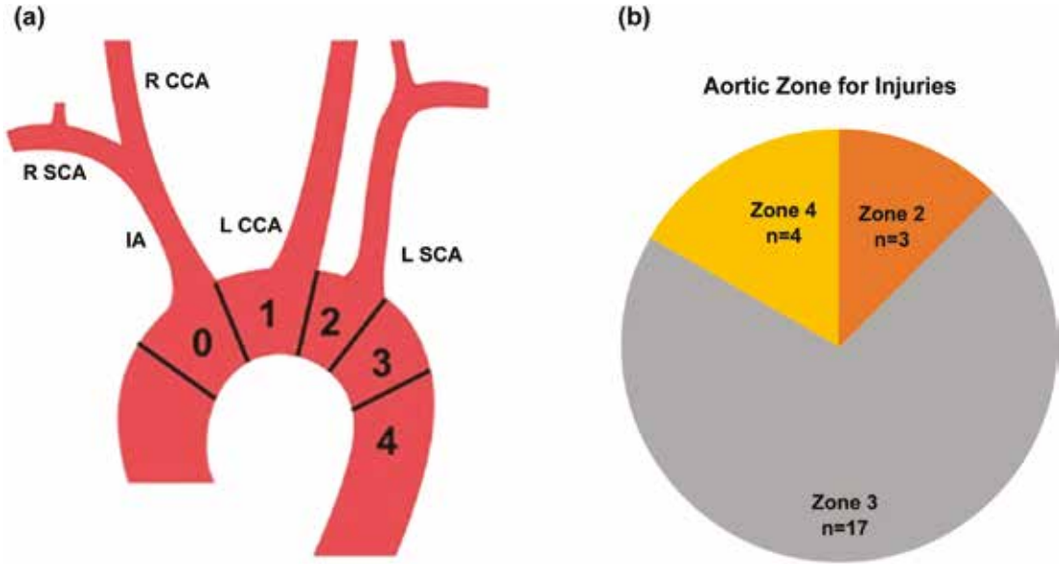

Figure 2 Zones of aortic injuries. (**a**) Schematic to classify zones of aortic Injury. RSCA, right subclavian artery; RCCA, right common carotid artery; LCCA, left common carotid artery; LSCA, left subclavian artery; IA, innominate artery. (**b**) Representation of zones of aortic injuries in this case series.

Table 2 List of complications post operatively, stratified into the post-operative period (<90 days) and post-discharge period (>90 days).

Complication	*Number of Patients*		*Number of Patients Needing Intervention*	
	<90 days	*>90 days*	*<90 days*	*>90 days*
Type I endoleak	3	0	1	2
Type II endoleak	1	0	0	0
Pseudoaneurysm formation	1	0	1	0
Access vessel damage	2	0	1	0
Graft infection	0	1	0	1
Hand ischemia	4	0	1	1
Graft migration	0	2	0	0

In the first 2 years of this therapy being undertaken at our institute, there were three patients with untreated Type I endoleak which were not initially treated, all of whom needed reintervention (Tables 2 and 3). Strategies employed thereafter to negate intra-operative endoleak included coiling of the LSCA (n = 2) or covering the endoleak with a second stent (n = 1), both of which were undertaken with no complications or hand ischemia. We did not observe any strokes, vertebral artery compromise or posterior circulation symptoms after covering the LSCA with a stent graft.

CONCLUSIONS

Thoracic aortic injuries most commonly occur at the aortic isthmus (n = 17, 70.8%) in motor-vehicle injuries (n = 18, 75%). The rates of concurrent injuries are high (Figure 1), with high trauma scores (average ISS = 35.3 ± 13.6) and lengthy inpatient admissions (average inpatient stay 59.7 ± 93.9 days). Anecdotally, we found endovascular repair of traumatic thoracic aortic injuries is technically easier, less invasive and negates the need for invasive and lengthy operations such as cardiopulmonary bypass, systemic anticoagulation and aortic cross clamping.

As a primary endpoint, we report a much lower rate of death at 8% (n = 2) versus the literature rate of 28% for open repair. There were other significant risk factors for both deaths in our series; the first death was due to graft infection in a patient with ongoing intravenous drug use, and the second was for intracerebral hemorrhage post fall in an unrelated admission (the patient

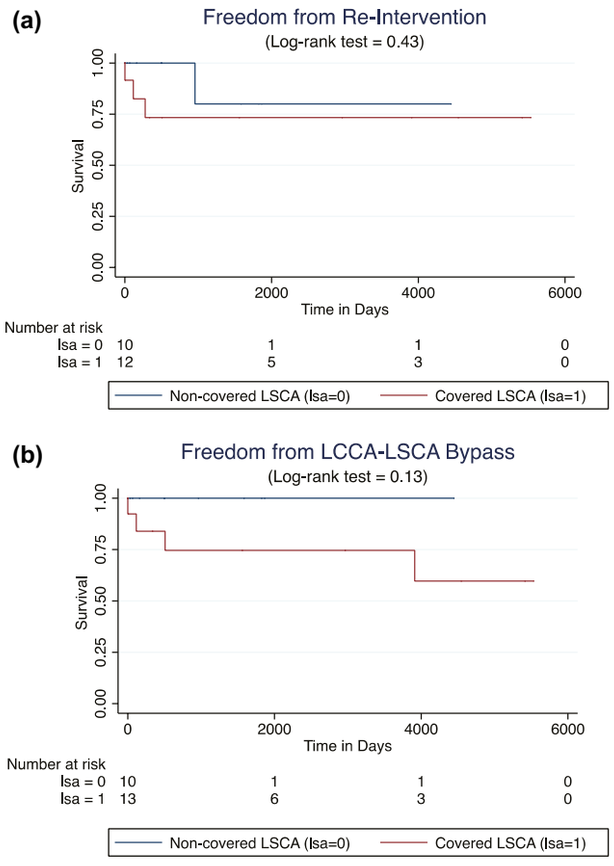

Figure 3 Time to event analysis following intervention. (**a**) Kaplan–Meier curve demonstrating freedom from RE-intervention with follow-up to 15.2 years. (**b**) Kaplan–Meier curve demonstrating freedom from left common carotid artery to left subclavian artery (LCCA–LSCA) bypass with follow-up to 15.2 years. The difference was not statistically significant (*P*-value of log-rank test = 0.43 and 0.13, respectively) between those with and without LSCA coverage.

Table 3 Predictors of re-intervention and LCCA–LSCA bypass.

Factor	*Relative Risk (95% Confidence Interval)*	*P-Value*
Re-intervention		
Any coverage of LSCA	2.54 (0.31, 21.06)	0.3882
Complete coverage of SCA	3.27 (0.40, 27.00)	0.2708
ICU LOS>5 days	1.18 (0.20, 7.06)	0.8547
Any endoleak	15.00 (2.05, 110.00)	0.0077
Type 1 endoleak	21.00 (3.10, 142.21)	0.0018
Type 2 endoleak	1.71 (0.13, 22.82)	0.6832
LCCA-LSCA bypass		
Any coverage of LSCA	3.38 (0.44, 26.00)	0.2412
Complete coverage of SCA	4.73 (0.62, 36.32)	0.1354
Any endoleak	3.33 (0.80, 13.95)	0.0992
Type I endoleak	4.67 (1.25, 17.43)	0.0220
Type II endoleak	1.09 (0.09, 13.43)	0.9458

ICU, intensive care unit; LCCA, left common carotid artery; LSCA, left subclavian artery; LOS, length of stay; SCA, subclavian artery.

was not anti-coagulated). The secondary endpoint of re-intervention is low in both the post-operative period (<90 days) (*n* = 4, 16.7%) and long-term follow-up (<90 days) (*n* = 4, 16.7%). Only two of these patients required a conversion to open repair. The first was a patient with ongoing intravenous drug use who developed graft sepsis requiring graft explant. The second patient had a pseudoaneurysm formation at the site of Type I endoleak, needing an open explant and repair with interposition graft. Rates of other endpoints were also low; in open repair, the literature reports paraplegia from spinal cord ischemia in 16% and delayed rupture in 5% of patients, whilst we had no such complications at our center [5–8].

The safety of covering the LSCA in the thoracic aorta remains controversial in the literature. In our series, all patients who developed hand ischemia (*n* = 4) had either complete or partial coverage of the LSCA, but this difference was not statistically significant and is in keeping with findings from the literature to date (*P* = 0.13). Two patients (15.4%) needed reintervention with a left common carotid to subclavian bypass (at day 1, and 9 months post operatively). The majority of patients (69.2%, *n* = 9/13) who had some or complete coverage of the LSCA did not develop symptoms and did not need re-intervention or a bypass. We therefore believe that covering the subclavian artery remains safe, albeit with risk of hand ischemia which will likely remain amenable to non-surgical interventions such as physiotherapy.

The long-term durability of the graft, irrespective of zone, remains good at an average of 5.4 years and up to 15 years follow-up. Patients with no arch involvement (Zone 4) remained complication free, and only minor evidence of graft migration (*n* = 2) and non-flow limiting graft thrombosis (*n* = 1) was seen in patients with some arch involvement (Zones 2 and 3), all of which did not necessitate reintervention. Many of these complications have been addressed with newer generation of stents which have demonstrated improved hemodynamics and conformation to the aortic arch when deployed for aneurysmal disease [8, 14, 15]. The early complications with Type I endoleak highlight the learning curve in employing this treatment strategy. At our center, we have used coiling of the LSCA or covering the endoleak with a second stent as methods to prevent endoleak and did not observe any such complications after the first 2 years of our experience.

There are several limitations to this study. First, at an average age of 47 years, but with a standard deviation of 16 years, and a range from 26–84 years, it is difficult to assess the initial goal of assessing age-related differences between open repair and true TEVAR. Second, given that the average age of intervention is generally under 50 years in patients with otherwise unremarkable

co-morbidities in both our study and the literature (Table 1), the long-term durability of this graft at greater than 20 years still necessitates further investigation. Finally, there also remains no consensus on how long-term follow-up should be undertaken. The majority of our patients underwent yearly or second yearly computed tomography scans, but with an average age of 47 years and low rates of graft complications (n = 3), this may not only be unnecessary, but also place patients at high risk of radiation and contrast exposure. Other methods of follow-up include ultrasound or echocardiogram, but the anatomical position of stents renders appropriate ultrasonographic imaging difficult, and most interpretations need to be obtained indirectly through vertebral artery or upper limb flow analyses. Routine X-rays, whilst having less exposure, do not give any functional flow information. It is hoped that, with further studies with long-term follow-up data, such guidelines can be constructed.

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

VJS carried out the writing and data collection, MJJ the data collection and writing, SG the data collection, JAC the data collection and design, and JNI the data collection, design, and writing.

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Original Article

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Hate to Burst Your Balloon: Successful REBOA Use Takes More Than a Course

Christina M Theodorou MD[1], Edgardo S Salcedo MD[1], Joseph J DuBose MD[2] and Joseph M Galante MD[1]

[1]Department of Surgery, University of California Davis Medical Center, Sacramento, California, USA
[2]Department of Surgery, University of Maryland School of Medicine, Baltimore, Maryland, USA

Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is emerging as a viable intervention for hemorrhagic shock. Training surgeons to place the device is only part of the process. We hypothesize that implementation challenges extend beyond surgical skills training and initial REBOA use should not be expected to mirror published success.
Methods: All REBOA placements from January 2016 to February 2017 at a level 1 trauma center were reviewed for opportunities for improvement. From September 2016 to February 2017, all patients meeting highest trauma activation criteria were reviewed against our REBOA algorithm to identify patients meeting criteria for REBOA placement but not undergoing the procedure.
Results: REBOA was introduced at our institution in September 2015, with the first placement in January 2016. Trauma surgery, emergency department, and operating room staff underwent training. Nine patients had REBOA placed with six survivors. One patient underwent an unsuccessful REBOA attempt and died. Four patients had complications from REBOA. Eight additional patients met indications but did not undergo REBOA.
Conclusions: Successful REBOA use requires more than teaching surgeons indications and techniques. For a successful REBOA program, system factors must be addressed. System processes must ensure equipment and procedures are standardized and familiar to all involved. Complications should be expected.

Keywords *REBOA; Implementation; Algorithm; Trauma*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a minimally invasive intervention for patients in hemorrhagic shock. Trauma centers are increasingly adopting REBOA use in initial resuscitation and during operative interventions for critically injured patients. It is currently being used at more than 300 centers across the United States. There have been multiple published reports of successful REBOA use and it is rapidly gaining popularity as an intervention in the unstable patient [1–9].

As with any new technique, there will be a learning curve. Although placement of the device is relatively straightforward and there are training courses, such as the American College of Surgeons Basic Endovascular Skills for Trauma (BEST) course, the Endovascular Skills for Trauma and Resuscitative Surgery course, or the Endovascular Resuscitation and Trauma Management (EVTM) workshops available for surgeons to learn the technique [10–12], implementation of a REBOA program requires the coordination and training of surgical faculty, resident trainees, emergency department (ED) staff, ancillary staff including nurses, ED department and operating room (OR) technicians, and hospital administration to be successful. Given the complexity of instituting a successful program, we posit that there will be a learning curve that is not simply explained by attending surgeons gaining experience in REBOA placement [13–15]. Despite the growing popularity of REBOA,

Corresponding author:
Christina M Theodorou, MD, 2335 Stockton Blvd Room 5107, Sacramento, CA 95817, USA.
Email: ctheodorou@ucdavis.edu

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initial REBOA implementation should not be expected to mirror published success.

We hypothesize that successful REBOA use requires more than technical skills courses, and that in the early phases of a REBOA program, patients will have REBOA placed outside of the institutional algorithms and patients who may benefit from the procedure will be missed. The challenges of implementation extend beyond the clinical skillset of trauma surgeons and will require the preparedness of other healthcare providers involved in the care of injured patients, requiring a systems-level approach.

METHODS

After approval by our Institutional Review Board (IRB# 1102164-1), all REBOA placements from January 2016 to February 2017 at a level 1 trauma center were reviewed against our institution's REBOA algorithm (Figure 1) to analyze protocol adherence. We then queried all patients who met the highest trauma activation criteria based on our institution's triage protocol from September 2016 to February 2017. From these patients, we identified all patients who met criteria for REBOA placement by the algorithm shown in Figure 1 to identify potential REBOA-eligible patients who did not undergo the procedure. We chose to perform this analysis of all trauma activations nine months after REBOA had been implemented at our institution to allow for a grace period for training surgeons and ED physicians and institutional preparation. Adult patients aged 18–90 years of age were included.

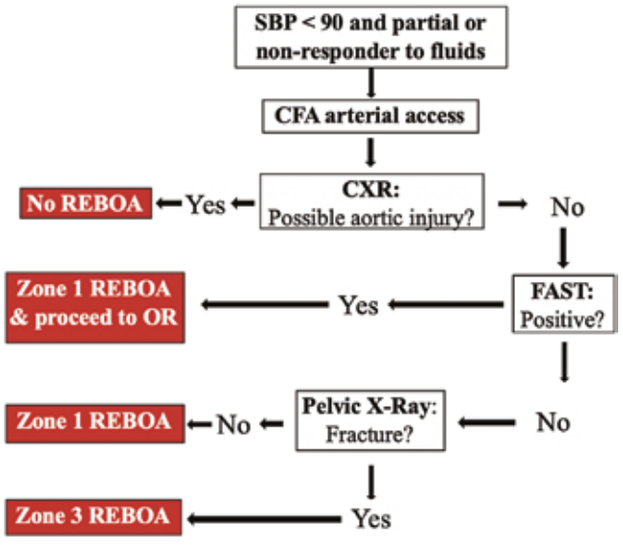

Figure 1 REBOA algorithm. Resuscitative endovascular balloon occlusion of the aorta (REBOA) algorithm – SBP: systolic blood pressure; CFA: common femoral artery; CXR: chest X-ray; FAST: Focused Assessment with Sonography in Trauma; OR: operating room. Zone 1 refers to the aorta between the left subclavian artery and the celiac axis. Zone 3 refers to the infrarenal aorta to the aortic bifurcation.

In determining which patients met REBOA indications but did not undergo REBOA, several exclusion criteria were used (Table 1). Patients with penetrating thoracic trauma were excluded because REBOA is potentially contraindicated in patients with suspected or known thoracic great vessel injury. Patients with isolated penetrating head trauma were excluded as the effect of aortic occlusion on traumatic brain injuries is unknown at this time [16]. Patients whose major trauma was burn or blast injury were excluded. Patients who did not have a chest radiograph (CXR), focused assessment with sonography for trauma (FAST) scan, and pelvis radiograph were excluded as these are part of the institutional algorithm for REBOA placement.

All quality improvement (QI) discussions were reviewed for opportunities for improvement. The QI discussions informed the development of a framework of focus areas to guide the successful implementation of a REBOA program at an institution. Via chart review we obtained demographic data, vital signs, mechanism of injury, injury list, Injury Severity Score, Abbreviated Injury Scale, outcomes, and mortality information. For patients who underwent REBOA, we recorded the type of REBOA catheter used, method of vascular access (percutaneous or via cut-down), zone of REBOA deployment, whether an angiogram was performed, and any complications related to REBOA.

Ethical Approval and Informed Consent

Ethical approval was given by our Institutional Review Board (IRB# 1102164-1). A waiver of written informed consent was obtained for this study.

RESULTS

REBOA was introduced at our institution in September 2015, with the first device placed in January 2016.

Table 1 Exclusion criteria.

Exclusion Criteria
• Age < 18 or > 90 years old
• Prisoners
• Burn or blast injury
• Isolated head or neck injury
• Penetrating thoracic trauma
• Deceased on arrival
• Normotension (Systolic blood pressure (SBP) > 90)
• Transient hypotension responsive to fluids
• Alternative diagnosis other than trauma
• Missing imaging (CXR, PXR, FAST)

CXR: chest X-ray; PXR: pelvis X-ray; FAST: Focused Assessment with Sonography for Trauma

Table 2 Patient characteristics.

Patient Characteristics	*REBOA (n = 9)*	*REBOA-Eligible (n = 8)*
Age, years: median (IQR)	41 (27–48)	46 (25–54)
Male: *n* (%)	9 (100)	7 (88)
Mechanism of injury: *n* (%)		
• Blunt	5 (55.6)	7 (88)
• Penetrating	4 (44.4)	1 (12)
CPR: *n* (%)		
• Initiated prior to arrival		
• Ongoing at arrival	1 (11.1)	0 (0)
• Initiated in ED	0 (0)	0 (0)
	2 (22.2)	1 (12)
Injury Severity Score: median (IQR)	50 (25–57)	39.5 (28–59.3)

IQR: Interquartile range; CPR: cardiopulmonary resuscitation; ED: emergency department

All 12 trauma faculty were trained via an institutional REBOA course. ED and OR nursing staff underwent in-service training. The REBOA kit was located in the ED trauma rooms as well as in the OR supply area.

REBOA Placements

A total of nine patients underwent REBOA placement in the first year at our institution. Baseline characteristics are shown in Table 2 compared with REBOA-eligible patients. Detailed information on each REBOA case is shown in Table 3. The majority (66.7%) underwent Zone 1 deployment, with two undergoing Zone 2 placement and one having Zone 3 placement. Most REBOA catheters were placed in the OR (66.7%), either at the start of the case in a hypotensive patient or intraoperatively due to ongoing bleeding to obtain temporary hemostasis. Four patients (44.4%) sustained REBOA-related complications (Table 4). Six patients (66.7%) who had REBOA placed survived to hospital discharge (Table 5); the remaining three died in the ICU (Table 6). One additional patient sustained multiple gunshot wounds to the chest and arrived under cardiopulmonary resuscitation (CPR). The patient underwent thoracotomy and attempted REBOA placement; however, femoral access could not be obtained despite the use of ultrasound bilaterally. The patient died in the ED. Consideration should be given to performing femoral artery cutdown in patients in whom percutaneous access is difficult.

When analyzed per our REBOA algorithm (Figure 1), only one placement, a Zone 3 placement for pelvic fractures with hemodynamic instability, was placed in accordance with the algorithm. The remaining eight REBOAs were placed outside of our algorithm. Of these, four were determined to be appropriate REBOA placements: two of the patients met criteria for Zone 1 placement in the ED but did not undergo REBOA placement until they were transported to the OR, and an additional two patients had REBOA placed intraoperatively for bleeding, and had not been hypotensive in the ED. Two patients had REBOA placed despite widened mediastinum on CXR, a sign of possible aortic or great vessel injury, which is a contraindication in our algorithm. Two patients had REBOA placed while undergoing CPR without prior imaging and thus could not be evaluated against our algorithm.

REBOA Complications

In total, four of the nine REBOA patients experienced REBOA-related complications (Table 4). In one patient, the REBOA catheter was inserted via the left common femoral artery and the balloon was inflated below the aortic bifurcation. The patient had a rupture of the common iliac artery on the ipsilateral side. This patient had severe pelvic fractures, and additionally had an injury to the contralateral internal iliac artery. On multidisciplinary review, it was not clear if the left common iliac artery injury was due to the patient's extensive pelvic fractures or due to the inflation of the REBOA balloon, but iatrogenic injury must be considered a possible complication in this patient. This patient succumbed to multisystem organ failure 19 days after admission.

In two patients, femoral artery thrombosis occurred. One patient had a 14 French sheath in the common femoral artery for over 60 minutes without anticoagulation due to uncontrollable hemorrhage. Vascular surgery was consulted intraoperatively to perform an aortic angiogram to evaluate for a potential aortic source of the hemorrhage and chose to perform a thrombectomy at the time of closure of the access site at the conclusion of the case. In the second patient, access was obtained via the right femoral artery. Aortic occlusion occurred for 19 min, and the sheath was removed at the end of the case. The distal femoral artery had some vasospasm but maintained biphasic flow. A completion angiogram was unable to be performed due to patient instability. However, that evening, he had diminished pulses to the right lower extremity and imaging demonstrated superficial femoral artery occlusion and he underwent thrombectomy with no further vascular complications.

The fourth patient was transferred to our institution with known celiac axis aortic injury due to a gunshot wound. Given his presentation, he proceeded immediately to the angiography-equipped OR and underwent trauma surgery and vascular surgery. There were absent bilateral femoral pulses noted at the start of the case. As the trauma surgery team performed a laparotomy, the vascular surgery team obtained percutaneous access of the right common femoral artery and placed a 7 French sheath through which the REBOA catheter was introduced. As the surgical teams worked to expose and mobilize the aortic injury, the patient became hypotensive and

Table 3 Detailed information on REBOA patients.

Patient	*Mechanism*	*Initial Vitals*	*Imaging*	*REBOA Data*	*Injuries*	*Notes*	*Died*
1*	Ped. vs. auto	HR: 75 BP: 83/69	CXR: Neg FAST: Neg PXR: Pos	Placed: ED Zone: 3 Access: percutaneous Sheath: unknown AO time: unknown	Pelvic fractures, R IIA injury, L CIA injury		Yes
2*	Crush injury to chest	CPR	CXR: N/A FAST: Neg PXR: N/A	Placed: ED Zone: 1 Access: percutaneous Sheath: 14 Fr AO time: 60 min	Sternal disruption		Yes
3	Ped. vs. auto	HR: 78 BP: 75/59	CXR: Pos FAST: Pos PXR: Pos	Placed: ED Zone: 1 Access: percutaneous Sheath: 7 Fr AO time: not inflated	Grade 3 hepatic laceration, grade 3 splenic laceration, grade 4 renal laceration, pelvic fractures	CXR with widened mediastinum but chest CT without vascular injury	Yes
4	MCC	HR: 131 BP: 112/57	CXR: Neg FAST: Pos PXR: N/A	Placed: OR Zone: 2 Access: percutaneous Sheath: 7 Fr AO time: not inflated	Grade 5 splenic laceration, grade 5 renal laceration	Met REBOA indications in ED Placed intra-operatively for expanding Zone 2 RPH	No
5	Torso stab wound	HR: 103 BP: 111/62	CXR: Neg FAST: N/A PXR: N/A	Placed: OR Zone: 2 Access: percutaneous Sheath: 8 Fr AO time: 12 min	Grade 3 kidney laceration, Grade 1 splenic laceration	Placed intra-operatively for bleeding from renal hilum	No
6	GSW chest	HR: 107 BP: 138/84	CXR: Neg FAST: Pos PXR: N/A	Placed: OR Zone: 1 Access: percutaneous Sheath: unknown AO time: unknown	Gastric injury, Grade 5 kidney laceration, splenic laceration	Placed intra-operatively for bleeding	No
7*	GSW chest	HR: 140 BP: 123/72	CXR: Neg FAST: Pos PXR: Neg	Placed: OR Zone: 1 Access: cut down Sheath: unknown AO time: 19 min	Gastric injury, splenic laceration, diaphragm injury, lung laceration	Placed intra-operatively for bleeding	No
8	Ped. vs auto	CPR	CXR: N/A FAST: N/A PXR: N/A	Placed: OR Zone: 1 Access: cut down Sheath: 12 Fr AO time: unknown	Cardiac injury, stellate liver laceration	ED thoracotomy	Yes
9*	GSW chest	HR: 130 BP: 109/97	CXR: Pos FAST: N/A PXR: Neg	Placed: OR Zone: 1 Access: percutaneous Sheath: 7 Fr AO time: 60 min	Supraceliac aortic transection	CXR: widened mediastinum REBOA placed intra-operatively proximal to known aortic injury	No

Ped. vs auto: pedestrian vs. automobile; MCC: motorcycle crash; GSW: gunshot wound; HR: heart rate; BP: blood pressure; CXR: chest X-ray; FAST: Focused Assessment with Sonography in Trauma; PXR: pelvic X-ray; ED: emergency department; OR: operating room; AO: aortic occlusion; CT: computed tomography; RPH: retroperitoneal hematoma; R IIA: right internal iliac artery; L CIA: left common iliac artery; Fr: French.
**Sustained complication, see Table 4 for detailed information.*

Table 4 REBOA-related complications.

Patient	*Complications*	*Management*
1	Left common iliac artery rupture	Stent placement
2	Right common femoral artery thrombus	Thrombectomy
7	Right superficial femoral artery thrombus	Thrombectomy
9	Right external iliac artery, popliteal, tibial thrombosis	Right iliofemoral, popliteal, tibial thrombectomy; right above knee amputation
	Left popliteal, tibial thrombosis	Left popliteal, tibial thrombectomy

Table 5 Comparison of survivors.

	REBOA Survivors n = 6 of 9	*REBOA-eligible Survivors n = 6 of 8*
Survivors: % (*n*)	66.7 (6)	75 (6)
Age: median (IQR)	35.3 (24.7–45.2)	33 (23–49)
Blunt: % (*n*)	33 (2)	83 (5)
ISS: median (IQR)	30.5 (25–46.5)	39.3 (30.3–54)

IQR: Interquartile range; ISS: Injury Severity Score

Table 6 Comparison of non-survivors.

	REBOA Deaths n = 3 of 9	*REBOA-eligible Deaths n = 2 of 8*
All deaths: % (*n*)	33.3 (3)	25 (2)
Died in ED: % (*n*)	0 (0)	0 (0)
Died in OR: % (*n*)	33.3 (1)	0 (0)
Died in ICU: % (*n*)	66.7 (2)	100 (2)
Age: median (IQR)	53 (47.5–56)	64 (59.5–68.5)
Blunt trauma: % (*n*)	100 (3)	100 (2)
ISS: median (IQR)	75 (62.5–75)	42.5 (26.3–58.8)

ED: emergency department; OR: operating room; ICU: intensive care unit; IQR: interquartile range; ISS: Injury Severity Score

the REBOA balloon was inflated in Zone 1, proximal to the known aortic injury. At this point repair of the complex aortic injury proceeded and the REBOA was exchanged for an aortic cross-clamp. The combined aortic occlusion time for both was 60 min. Lower extremity pulses were not detectable at the conclusion of the case, and duplex ultrasound revealed no flow beyond the popliteal artery. Angiography was not done at this time due to concern for contrast load from pre-operative imaging, prolonged warm ischemia time to the kidneys, and overall coagulopathy. The sheath was left in place. On evaluation on post-operative day 1, bilateral feet were cool, pulseless, and mottled and duplex ultrasound showed right iliac, superficial femoral, popliteal, and tibial artery thrombosis, as well as left popliteal and tibial thrombosis. He underwent bilateral angiogram, thrombectomy, and right leg fasciotomies. However, due to ongoing ischemia, a right above knee amputation was performed on post-operative day 12.

REBOA-Eligible Patients

A total of eight patients were found to have met indications for REBOA placement but did not undergo the procedure (Figure 2). All of these patients underwent exploratory laparotomy following initial resuscitation in the ED. Two of these patients (25%) died. The demographic breakdown of these patients is shown in Table 2. In total, six of these patients met indications for Zone 1 REBOA placement and the remaining two met criteria for Zone 3 placement. Of the patients who met the criteria for Zone 1 placement, injuries included retroperitoneal hematoma, multiple high-grade solid organ injuries, and external iliac artery and vein injury. The two patients who died did not have injuries for which REBOA would provide hemorrhage control. In one patient, a para-duodenal retroperitoneal hematoma was noted intra-operatively but did not appear to be the cause of his hemodynamic instability. The second patient had an avulsion of the left ventricle which was the likely cause of death. Half of the hypotensive patients identified did not have other contraindications to REBOA but were missing one or more of the imaging modalities in our REBOA algorithm (n = 12). These included patients under CPR on arrival who underwent thoracotomy, and some with traumatic brain injury as the identified cause of their hypotension. The most common missing imaging was the FAST (n = 7).

DISCUSSION

Our institutional review revealed nine REBOA placements over the first year of use in our program, of which only one was placed as indicated based on our algorithm, and two additional placements indicated per the algorithm but with delayed placement in the OR. Thus, only 33.33% of REBOA placements were performed according to our institutional algorithm. In addition, multiple patients were identified who did not undergo REBOA placement despite meeting criteria for placement. A relatively high complication rate was noted, with four of the nine REBOA patients sustaining related complications.

The low compliance with our institutional algorithm has several potential explanations. First, individual trauma surgeons have varied practices with regards to the management of the hypotensive trauma patient, and surgeons with prior REBOA experience may be more likely to choose this intervention. Two patients had REBOA placed despite not meeting algorithm indications as they were never hypotensive; however, these

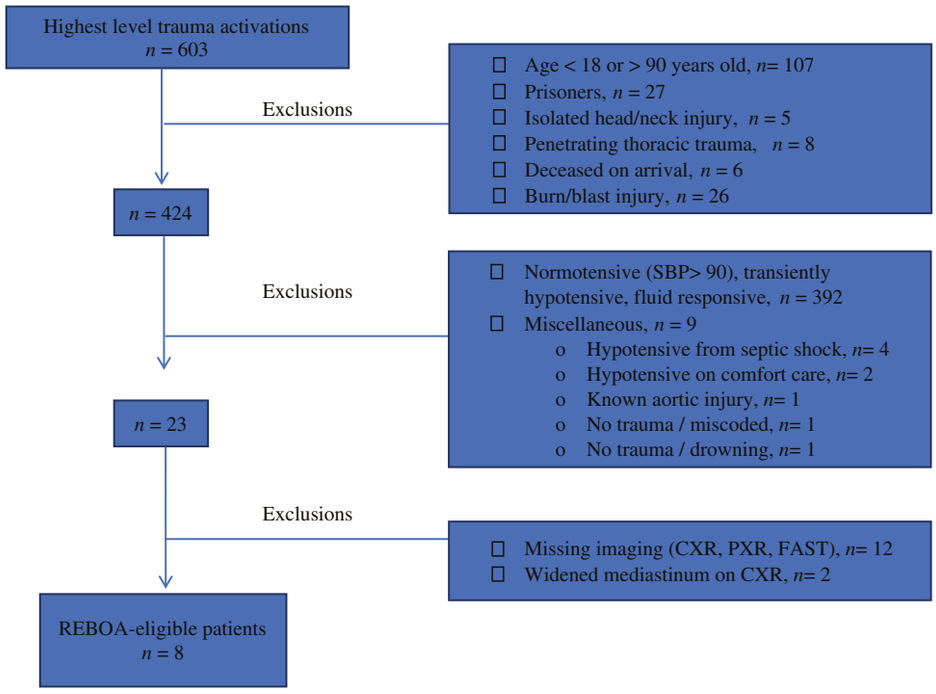

Figure 2 Breakdown of determination of REBOA-eligible patients.

were placed due to intraoperative hemorrhage and previous research has found that intraoperative REBOA placements are more likely to occur in patients with stable initial hemodynamics [17]. Two patients had REBOA placed despite widened mediastinum on CXR. In one patient, there was a known aortic injury and the REBOA was intentionally placed and inflated proximal to the injury. In the second patient, despite abnormal CXR, subsequent computed tomography of the chest did not reveal any signs of thoracic great vessel injury. Widened mediastinum has been found to have a poor predictive value for aortic injury [18] and our institutional algorithm is being redesigned to reflect this. Lastly, two patients had REBOA placed while under CPR, and could not be evaluated by our algorithm. These patients represent a unique subset of patients, and the optimal approach to hemorrhage control is not yet known; however, several studies have supported the use of REBOA in traumatic arrest [19,20]. When considering the REBOA-eligible patients who did not undergo REBOA placement in our cohort, 100% of these patients were taken straight to the OR from the ED for exploratory laparotomy. Thus, it is likely that the trauma surgeon in these cases thought the most expeditious method of hemorrhage control was via urgent surgical exploration. Ultimately, an algorithm can be used to guide decision making, but cannot replace clinical judgment.

Our complication rate was significantly higher than that reported in other studies, with one systematic review of 414 patients reporting a 5% rate of access-related complications [21]. As we are reporting a very small case series of nine patients at the start of implementation of a REBOA program, it is not surprising that our complication rate is higher than that reported in large series in the literature. As a result of the complications noted in this series, we have formalized our REBOA protocol to include mandatory vascular surgery consultation for the detection and management of potential REBOA-related injuries and the consideration of an on-table angiogram prior to sheath removal. We have additionally instituted mandatory tracking of REBOA cases and complications, with discussion at multidisciplinary QI sessions. These sessions have identified difficulties we have encountered in the implementation of a REBOA program including determining kit contents, kit location, and restocking to ensure multiple kits are routinely available. The kit has been standardized to include a 7 French introducer sheath, which is associated with lower rates of access-site complications [22]. In reviewing the complications, we have noted areas for education for staff involved, including reviewing our institutional algorithm, the steps of REBOA placement, and post-placement management. Training sessions are held as needed for nursing staff, OR staff, ED staff, and resident physicians.

REBOA is an emerging intervention for the patient in hemorrhagic shock and indications are evolving. Trauma and vascular surgeons [1–10], emergency physicians [23,24] and pre-hospital providers [25,26] are using REBOA with increasing frequency. It is being deployed

in both trauma patients as well as those with intra-abdominal hemorrhage of non-traumatic etiology [27–32]. Although the technical process of placing a REBOA catheter in a patient is straightforward, multiple factors must be in place to ensure a given institution is well-equipped to best utilize the technology. Several key focus areas that must be addressed to ensure successful REBOA implementation were identified as a result of a rigorous QI process.

Training of all members of the surgical and ED teams is paramount to instituting a successful REBOA program. There are a number of formal courses available for training, but our data suggest that simply participating in a REBOA training course is not sufficient, as we found a number of missed opportunities for REBOA in our study. There must be ongoing training opportunities, refresher courses, and in-depth quality improvement processes to ensure continual improvement. In addition, complications occur as a result of REBOA use, and coordination with vascular surgery is necessary for aid in diagnosis and treatment of these. Our recommendations for successful REBOA program implementation are as follows (Table 7):

Surgical Staff

Technical training courses for trauma staff are the first step. Multiple options are available, including the BEST course, ASSET, and EVTM workshops. Residents and fellows should be included in these sessions. Multiple modes of access should be emphasized, including percutaneous by landmarks, ultrasound, and via cut-down. Success depends on procedural competency and on operator facility with the items in the REBOA kit and their limitations. REBOA placement difficulties should be reviewed on a frequent basis at departmental QI meetings.

Table 7 Recommendations for REBOA program implementation.

Surgeons and emergency physicians	Training of physicians in the placement of the device
	Familiarity with equipment, technique, algorithm, and indications
	Percutaneous access vs. femoral cut down training
Nursing staff	Training to assist in procedure
	Kit retrieval
	Content identification
	Location of replacement items
Systems	Kit contents, location, availability, and restocking
Follow-up	Early vascular surgery involvement
	Post-operative imaging
	Multidisciplinary complication management

Emergency Department Staff

ED physicians, depending on the hospital, are present and assist in a variety of ways in the initial care of traumatically injured patients. ED physicians should be invited to in-house training sessions organized by the surgery department and QI sessions related to REBOA outcomes. Members of the ED staff must be familiar with the process for REBOA placement and are key partners in the successful rescue of these patients.

Nursing Staff

Individual training sessions should be held with ED and OR nursing and ancillary staff. The devices and the steps for placement should be reviewed. The OR nursing leadership for trauma may aid in educating staff on the equipment location and backup supplies if an item breaks or is missing.

Systems

REBOA kits have gone through various iterations since the device was created. We worked with the hospital purchasing and supplies department to arrange for kit procurement. Necessary equipment that was not part of the kits were identified to create more robust REBOA kits. Processes must be in place to re-stock kits. They must be easily accessible in both the OR and the ED, and potentially the intensive care unit.

Follow-up

The care of REBOA patients does not stop with balloon deflation. The trauma teams caring for the patients must be aware of post-REBOA complications such as thrombosis, arteriovenous fistula formation, limb ischemia, vascular injury, and spinal cord injury from ischemic time. The authors' practice pattern is to involve vascular surgery early in the care of these patients, for both management of complications and post-procedural angiograms before sheath removal. Protocols should be created to ensure patients receive appropriate imaging post-REBOA. All REBOA cases should be reviewed as part of departmental and hospital QI sessions. In particular in the beginning of implementing a REBOA program, trauma cases should be reviewed to identify patients who may have benefitted from the use of REBOA and algorithms should be modified as necessary to ensure the best care is provided to future patients.

Limitations

Our study is a single-center retrospective study of a level one trauma center and our findings may not apply to other health care systems. However, given the rising number of both trauma centers and non-trauma centers

using REBOA for various indications, we hope our experience and hard-learned lessons will pave a smoother road for new adopters.

CONCLUSION

Successful REBOA use requires more than simply teaching surgeons the indications and techniques. To successfully adopt a REBOA program, there are many system-wide factors that must be addressed. System processes must be in place to ensure the equipment and procedures are standardized and familiar to all involved. Complications should be expected [33].

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

CMT, JJD, and JMG were responsible for study conception and design. CMT performed data acquisition. CMT, ESS, and JMG performed data analysis and interpretation. CMT, ESS, and JJD, JMG drafted the manuscript and were involved in critical revision of the manuscript.

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Original Article

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A Novel Technique for the Damage Control of Huge Diaphragmatic Injuries

Boris Kessel MD[1], Victor Reva MD PhD[2], Daniel Sheffer MD[1] and Tal Hörer MD PhD[3]

[1]*Surgical Division, Hillel Yaffe Medical Center, Hadera, Israel*
[2]*Kirov Military Academy, Sanct Petersburg, Russian Federation*
[3]*Division of General and Vascular Surgery, Faculty of life science, Orebro University, Sweden*

Background: Diaphragmatic injuries are rare in trauma victims, and mostly located on the left side. The standard approach is primary closure, using non-absorbable heavy interrupted sutures. Right-sided injuries are protected by the liver and such repair is not mandatory. However, closure of large defects, not suitable for primary suture, remains a challenging problem, especially in a military setting or in severely multiple-organ injured patients. Up until now, the single surgical solution in such situations is usage of absorbable mesh.
Methods: The feasibility of a damage control closure technique for huge traumatic diaphragmatic injury was evaluated.
Results: After creation of large diaphragmatic defects in an animal model, the defects were closed with an appropriately sized plastic (Bogota) bag and using a large abdominal pad, accordingly. The total procedure time was about 3 min and no chest re-protrusion was observed until completion of the experiment.
Conclusions: This novel method is likely to be safe and simple to use as a damage control method and should be further investigated in proper models and clinically.

Keywords: *Damage Control; Diaphragmatic Injury; Temporary Closure*

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INTRODUCTION

Traumatic diaphragmatic injuries occur in 0.5% of trauma patients. They mostly result from penetrating injuries and are predominantly located on the left side [1]. The standard approach to diaphragmatic injuries in a damage-control setting is primary closure, using non-absorbable heavily interrupted absorbable sutures. Right-sided injuries are protected by the liver, and such repair is not mandatory [2]. Closure of large defects not suitable for primary suturing remains a challenge, especially in military settings or for critically ill or hemodynamically unstable trauma patients. Currently, the sole surgical solution in such cases lies in the use of absorbable mesh [3]. However, the insertion of mesh often requires complex anatomical dissections, including mobilization of the entire diaphragm, and identification of esophageal and aortic pleura. It is time consuming and demands the presence of a high level of expertise. In the context of damage-control surgery, the prevention of abdominal-organ re-protrusion to the chest should be achieved as quickly as possible.

The aim of this report is to explore the utility of Bogota bags or, alternatively, abdominal pads, for temporary diaphragmatic closure in an animal model as part of the damage-control concept.

METHODS

Two anesthetized, ventilated, instrumented, and normovolemic pigs were used to evaluate the feasibility of the technique. After creation of large diaphragmatic defects, using a scalpel and scissors in an identical fashion, a same-sized left diaphragmatic defect was created in both pigs (Figure 1). In the first pig, the defect was

Corresponding author:
Boris Kessel MD, Surgical Division, Hillel Yaffe Medical Center, Sea Road 2, Hadera, Israel.
Email: bkkessel01@gmail.com

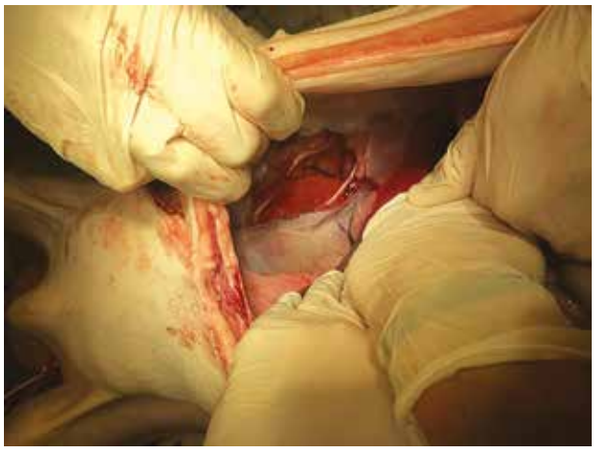

Figure 1 Creation of the diaphragmatic defect.

Figure 2 Closure of the defect using a Bogota bag.

closed with an appropriately sized plastic (Bogota) bag, fixed to the diaphragm with skin staples (Figure 2). The total time for the procedure was set at about 3 min. In the second pig, the diaphragm edges were clamped with long Allis forceps, and the defect was covered using a large abdominal pad and sewn in with a few interrupted nylon zero sutures (Figure 3).

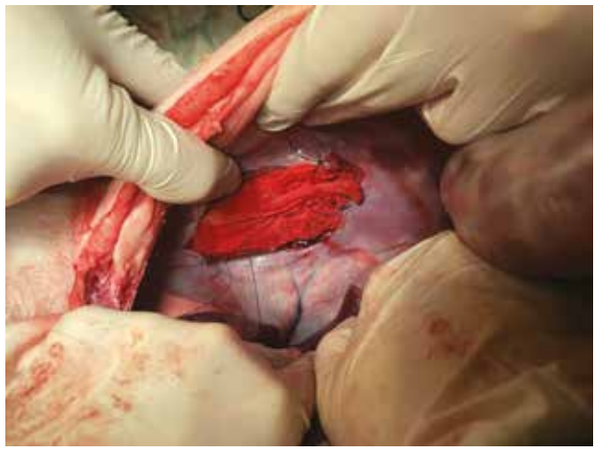

Figure 3 Closure of the defect using an abdominal pad.

Ethical Approval

The study was conducted in the frame of DSTC exercises, as approved by the regional ethical committee; the animals were euthanized immediately after completion of the experiment. The use of animals was according to the ethical rules and regulations of the Swedish government and to EU animal laws.

RESULTS

The total procedure time turned out to be about 3 min. In both cases, the closure was not hermetic, but no chest re-protrusion was observed for a period of 2 h after completion of the experiment.

DISCUSSION

Diaphragmatic injuries are rare, and compounded only in about 0.5% of all abdominal injuries [4]. The most common mechanism involved in diaphragmatic tear is thoraco-abdominal penetrating injury [5]. The conventionally accepted surgical solution for such perforation is simple closure using heavily interrupted sutures. This technique is very simple and fast, and does not require special surgical skills. Moreover, right-sided diaphragmatic injuries do not entail mandatory closure since the liver usually safely prevents the protrusion of abdominal organs into the chest cavity. In rare cases, the defect in a diaphragm is very large, usually due to high-velocity missile injuries in war or significant blunt-trauma mechanisms, such as a fall from height or a road-traffic accident [6]. During a high-impact event, the tear usually occurs in the embryologically weakest posterior-lateral part of the diaphragm [7]. In the case of a large diaphragmatic defect that is not suitable for primary suturing, the only acceptable surgical repair consists of the use of prosthetic mesh [8]. In some cases of delayed diagnosis, repair may be achieved laparoscopically or thoracoscopically [9,10]. In most patients, the open

abdominal approach is mandatory due to the high incidence of associated intra-abdominal injuries. However, such repairs are time consuming and require a high level of expertise [9]. Moreover, all the techniques described previously are inappropriate in the setup of damage-control laparotomy, especially taking into account that a significant portion of diaphragmatic injuries are associated with multiple concomitant injuries [11].

The main purpose of the method is to show the feasibility of prevention of the re-protrusion of abdominal organs after the completion of a damage-control laparotomy, which includes achieving adequate hemostasis, reducing herniated content to the abdominal cavity, and preventing contamination. Rapid evaluation of the diaphragmatic injury and inspection of the surrounding area permit selection of the best way of achieving temporary diaphragm closure. If there is no significant hematoma or persistent oozing in the left sub-diaphragmatic space, the edges of the diaphragm are clamped with long Allis or Babcock forceps, and an appropriate piece of plastic Bogota bag is secured to the diaphragm using skin staples or a few interrupted sutures.

The advantages of this approach are that it enables observation of the presence of accumulated blood in the chest, and the option of leaving the Bogota bag in place for 2–3 days if the re-laparotomy is delayed for other reasons. Another possibility for temporary closure lies in the use of a large abdominal pad, fixed to the diaphragm in the same fashion. The technique also allows proper counter compression in case the left sub-diaphragmatic space needs to be packed. Moreover, although this option was not evaluated in the experiment, the sutured diaphragm abdominal pads may be covered by an "internal" Bogota bag in order to prevent potential adherence of the small bowel loops to the pads.

CONCLUSIONS

This is a novel technique for temporary diaphragmatic closure. The method is likely to be safe and simple to use. Further investigation may enable it to be included in the routine surgical damage-control arsenal.

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 study and manuscript writing.

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Original Article

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Glue or Onyx: A Guide to Choice – Tips and Techniques

Enrico Maria Fumarola MD[1], Anna Maria Ierardi MD[2], Filippo Piacentino MD[3] and Gianpaolo Carrafiello MD PhD[2]

[1]Diagnostic and Interventional Radiology Department, ASST Santi Paolo e Carlo, San Paolo Hospital, Milan, Italy
[2]Unità Operativa di Radiologia, Fondazione I.R.C.C.S. Cà Granda Ospedale Maggiore Policlinico, Milan, Italy
[3]Unit of Radiology, Ospedale di Circolo e Fondazione Macchi, University of Insubria, Varese, Italy

Glue and Onyx are two liquid embolic agents. They have different characteristics and applications, so it is essential to know how to choose between them. The main aims of this article are to describe the principles and features of these embolic agents, to highlight the advantages and limitations of both the materials, and to provide optimal indications of each agent during endovascular arterial embolization procedures.

Keywords: *Glue; NBCA; Onyx; Ethylene-vinyl Alcohol Copolymer; EVOH; Techniques; Embolization*

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INTRODUCTION

Onyx (Onyx Liquid Embolic System; ev3 Neurovascular, Irvine, CA, USA) and cyanoacrylate glue are two distinct embolic agents extensively used in peripheral vessel embolization.

The first report on the use of cyanoacrylate glue dates back to 1972 when it was successfully tested in an animal experiment on adult mongrel dogs to evaluate the possibility of its use as an embolic agent [1]. The first clinical series dates back to 1975 [2].

Onyx consists of an elastic polymer with an ethylene-vinyl alcohol copolymer (EVOH) dissolved in an organic solvent, dimethyl sulfoxide (DMSO), with micronized tantalum powders to provide radiopacity.

The first animal experiment confirming the efficacy and safety of Onyx as an embolic agent was published in 1998 [3], and since then Onyx has been recognized as a valid tool for several embolization procedures. It was used initially in interventional neuroradiological procedures, particularly for the treatment of artero-venous malformations [4,5], but it subsequently became evident that Onyx could be used for the effective endovascular management of peripheral bleeding and for the treatment of type-II endoleaks [6,7].

The main aims of this article are to describe the principles and features of these embolic agents, to highlight the advantages and limitations of both materials, and to provide optimal indications of each agent during endovascular arterial embolization procedures.

Corresponding author:
Anna Maria Ierardi, Diagnostic and Interventional Radiology Department, University of Milan, Via di Rudinì 8, 20142 Milan, Italy.
Email: amierardi@yahoo.it

MATERIALS DESCRIPTIONS

Onyx

Onyx is a non-adhesive and non-absorbable permanent embolic agent that is injectable through DMSO-compatible catheters. It exists in liquid form and remains stable for as long as the liquid is saturated with a solvent.

Tantalum powder (28%) is added to the EVOH polymer to make it radiopaque. When it comes into contact with water or blood, the material precipitates due to rapid diffusion of the DMSO solvent, with the formation of an elastic, soft, spongy and radiopaque cohesive cast inside the vessel lumen, which solidifies completely after about 10 minutes from solvent diffusion [8].

Onyx is available in two different viscosities: Onyx 18 (with 6% EVOH) and Onyx 34 (with 8% EVOH), and in two different formulas (1.5 and 6 ml). The lower the concentration of the copolymer, the less viscous the agent becomes, achieving more distal penetration when it is used for endovascular embolization. Its non-adhesivity allows for reliable delivery. Although there have been reports of Onyx's adhesion to the microcatheter tip, this risk is substantially lower than that posed by standard

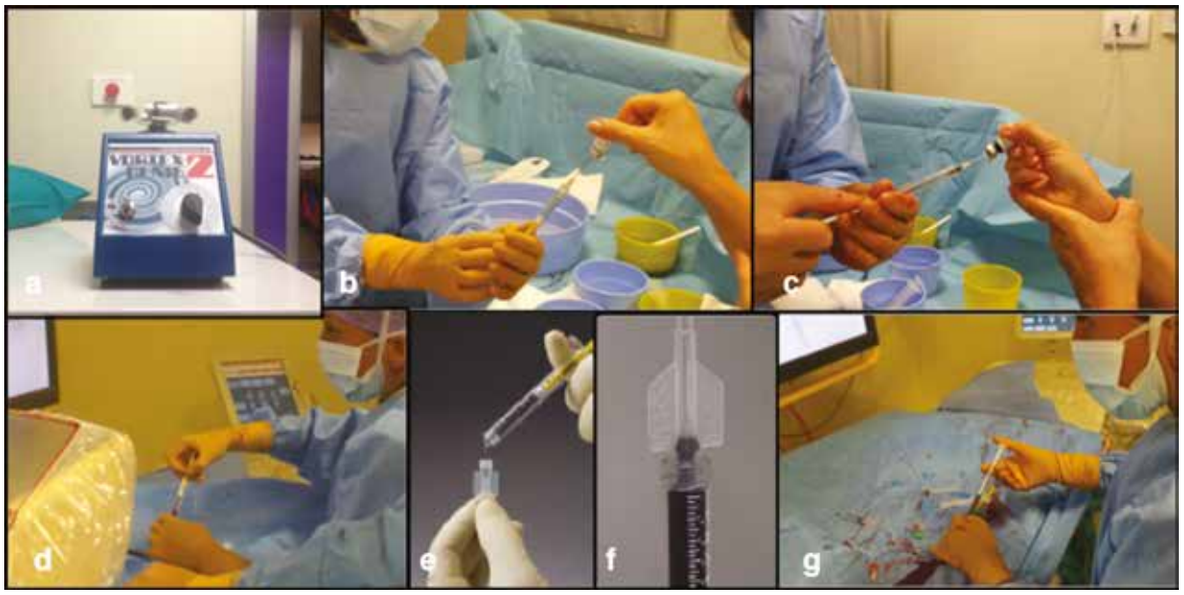

Figure 1 How to use Onyx. (**a**) Onyx Vial on a mixer for at least 20 minutes. (**b**, **c**) Fill the dedicated syringes with DMSO and Onyx respectively. (**d**) Flush a DMSO-compatible microcatheter with saline solution. (**e**) Then keep the microcatheter in a vertical position with the DMSO liquid surface at the hub of the microcatheter. (**f**, **g**) Connect the syringe containing Onyx to the microcatheter hub and start the injection.

glue; moreover, its viscosity helps to achieve optimal penetration of the embolic agent with slow injection [6].

A series of precise steps are necessary to assure expected delivery, avoiding complications such as excessive DMSO displacement into the blood stream, which can lead to severe, non-retractable pain related to endothelial necrosis.

How to use Onyx (Figure 1):

1. Place the Onyx vials on a mixer; the manufacturer suggests at least 20 minutes mixing time to obtain homogeneous distribution of the tantalum powders.
2. Flush a DMSO-compatible microcatheter with a saline solution.
3. Fill a 1-ml white syringe in the product package with Onyx through an 18 or 20 G needle.
4. Aspirate the DMSO into a 1-ml yellow syringe in the product package and slowly fill the dead space of the microcatheter; then, keep the microcatheter in a vertical position with the DMSO liquid surface at the hub of the microcatheter to facilitate a "wet-to-wet" connection with the Onyx syringe, thereby avoiding contamination from air bubbles during the following step.
5. Connect the syringe containing Onyx to the microcatheter hub and start the injection (consider the dead space) under fluoroscopic guidance (the blank road map technique is preferred). It is important to inject the Onyx slowly, such as at a 0.16 ml/min (0.25 ml/90 s) injection rate, and not to exceed a rate of 0.3 ml/min to avoid vasospasm due to DMSO.

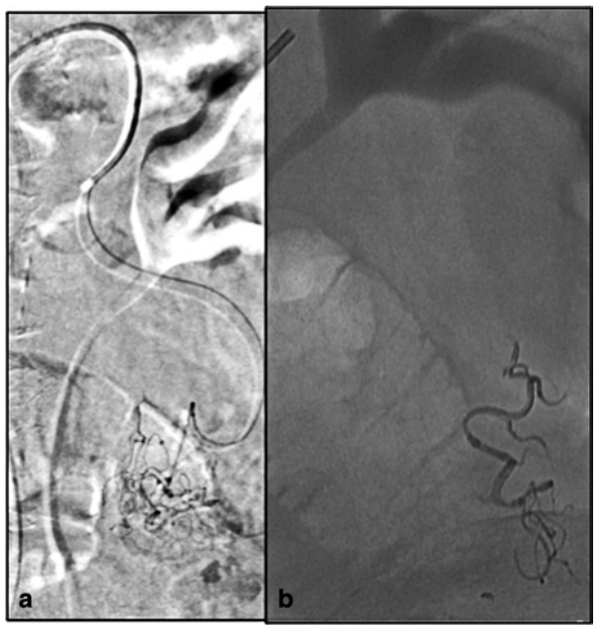

Figure 2 Ileal bleeding. (**a**) Selective arteriography shows bleeding. (**b**) Successfully embolized with Onyx 18.

Cerebral arteriovenous malformations and distal fistulae have been the leading recognized indications of Onyx. Peripheral arteriovenous malformations meet the same criteria; accordingly, it was entirely reasonable to use Onyx to occlude nidus and afferent and efferent branches [6,9].

In peripheral applications, one of the first uses of Onyx was for the embolization of endoleaks, the rationale for

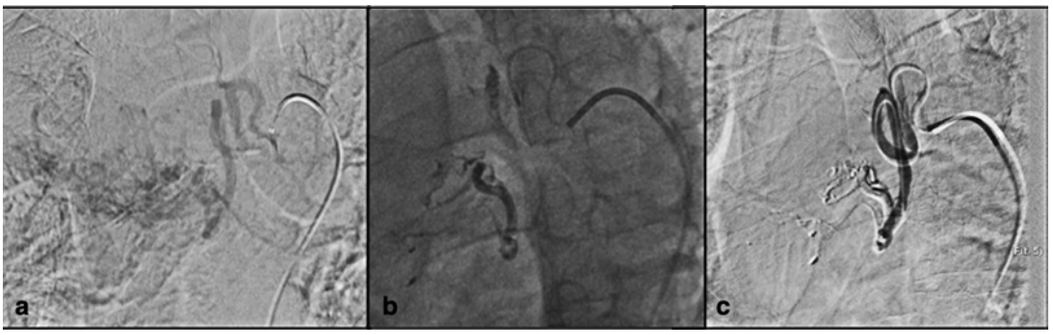

Figure 3 Bronchial artery embolization. (**a**) Massive hemoptysis in patient with hypertrophic right bronchial artery. (**b**, **c**) Embolized with Onyx 18 e 34.

which derived from the observation that recurrence is often caused by the incomplete filling of the sac. Onyx immediately came across as suitable for overcoming this limit, which is related to the use of other embolic agents [6,9].

Post-traumatic and iatrogenic bleeding, especially pseudoaneurysms, may also be successfully embolized with Onyx [6]. Onyx can now be used in a wide range of procedures, including interventions in the venous district (esophageal varices, portal vein embolization), gastrointestinal bleeding embolization (Figure 2) and bronchial artery embolization (Figure 3*a*,*b*) [5,6,9–15].

Compared with cyanoacrylate glue, Onyx has some advantages: its viscous and non-adhesive properties, with slow and steady injection, make controlled delivery during embolization feasible; the controllability and standardized viscosities of the product, as well as its non-adhesive profile, subsequently allow for optimal penetration of the agent into the target vessels; and its cohesivity, allowing an efficient continuous casting inside the target vessels, which may require a smaller amount of embolic agent to achieve complete embolization. The use of a "plug and push" technique or balloon occlusion may offer a more controlled delivery method. Although the requirement of DMSO for Onyx may cause more chemical stimulation at the time of delivery, the non-adhesive and non-absorbable features of the Onyx polymer have a weaker inflammatory effect on the endothelium than cyanoacrylate glue once embolization is completed [6]. Although both Onyx and cyanoacrylate glue theoretically polymerize independently of the coagulation status of the patients, the superior casting profile of Onyx, in addition to its non-absorbability (as opposed to the absorbability of Lipiodol mixed with cyanoacrylate glue), may enable Onyx to provide more stable embolization in a setting of prolonged coagulopathy than cyanoacrylate glue. On the other hand, there are some drawbacks to Onyx: first, although it has only been described in rare cases, DMSO can cause severe vasospasm or endothelial injury [16], and the patient may experience severe pain, which can require anesthesiologic support to manage deep sedation [6,9]. The possibility of vasospasm with DMSO causing outflow stenosis or occlusion immediately before the injection of Onyx may also give rise to a concern about suboptimal proximal embolization, particularly in target vessels with progressive significant vasospasm (e.g. in a trauma patient). Second, the duration of the injection compared with glue can often be time consuming, which, according to some authors, may restrict use of the material to elective procedures only [17]. Finally, Onyx is more expensive than other commonly used embolic materials.

In conclusion, Onyx may be considered a useful, safe, and effective liquid embolic tool with a unique profile in the management of several conditions. Even though a non-negligible learning curve to handle it appropriately is required, it has become a powerful weapon for interventional radiologists.

Glue

Cyanoacrylate glue is the most commonly used liquid adhesive for endovascular procedures in interventional radiology [18]. It is composed of liquid alkyl-2-cyanoacrylate monomers that polymerize on contact with ionic materials such as blood, water, or endothelium [19]. Dextrose 5% in water (D5W), which is non-ionic, is used to flush the catheter before and often after administration of the glue to prevent its polymerization within the catheter [20].

The injection of cyanoacrylates into the blood stream leads to an acute inflammatory reaction of the vessel wall, which subsequently evolves into a chronic granulomatous foreign-body inflammatory reaction that leads to fibrosis within about 1 month [18].

By nature, the adhesive is not radiopaque and polymerizes in 1–2 s, which is not feasible for use in clinical practice. Modifications to address these issues include the addition of powdered metals, typically tantalum or tungsten, and iodized oils.

Iodized oils do not only make the glue radiopaque but also prolong the polymerization time.

Currently, in our clinical practice, we use Glubran2 (GEM Srl, Viareggio, Italy), which consists of a mix of

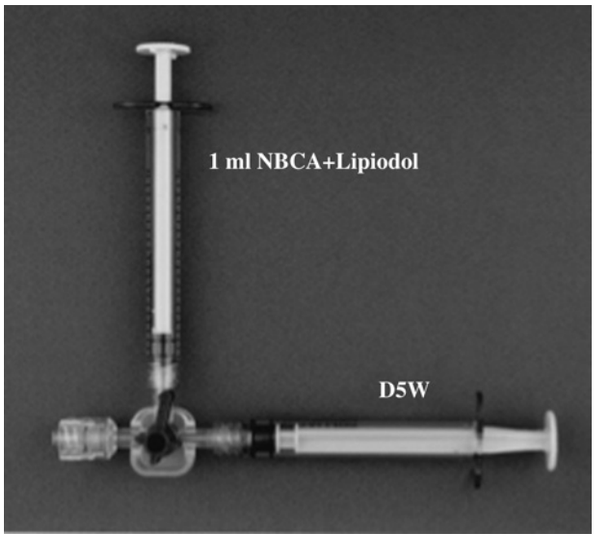

Figure 4 Two syringes (one with NBCA + Lipiodol, the other with dextrose 5% in water (D5W)), connected, ready to start embolization.

two monomers, *N*-butyl-2-cyanoacrylate (NBCA) and metacryloxysulfolane (MS), which are added to a Lipiodol solution (Guerbet, Roissy, France) to produce iodized oil emulsion in ratios ranging from 1:1 to 1:4.

A high NBCA-MS/Lipiodol ratio (1:1, 1:2), produced by adding a smaller amount of Lipiodol, offers quicker polymerization that restricts the time to inject the glue mixture through the catheter before it has to be removed due to possible adhesion of the injected glue to the catheter tip after polymerization. On the other hand, a low NBCA-MS/Lipiodol ratio (1:3, 1:4) allows more time for injection while increasing the risk of distal embolization [21].

Blood-flow control should be considered when NBCA migration is expected in high-flow lesions. Flow stagnation via the use of balloon catheters or wedge catheters, or the combined use of vascular embolization and metallic coils or other materials, and temporary vasoconstriction via the local injection of diluted epinephrine, have been reported in such situations [22].

How to use cyanoacrylate glue:

1. Use a microcatheter using a coaxial technique – advancing the catheter into a safe position to avoid reflux.
2. Perform a diagnostic angiography beforehand to confirm the exact position of your target and to assess flow dynamics.
3. Flush the microcatheter with D5W.
4. Inject the cyanoacrylate + Lipiodol; operators should closely monitor the progression of the glue during injection with the use of fluoroscopy, digital subtraction angiography, and road-mapping (Figure 4) [22].
5. Flush the microcatheter immediately with D5W, or remove the microcatheter with negative pressure on the syringe, to avoid inadvertent adherence to the surrounding vascular tissue, according to the specific glue-embolization technique used.

   The continuous column technique: The glue mixture is injected slowly but continuously to allow it to form a cast inside the lumen, which allows controlled NBCA delivery, avoiding dangerous refluxes [22]. As soon as the injection is complete, the microcatheter must be pulled out swiftly in one rapid motion and taken out of the guiding catheter. Upon withdrawal, the microcatheter must be immediately flushed with D5W, for re-use in order to reduce costs [23].

   The "drop-by-drop" technique [22]: The tip of the microcatheter has to be positioned as near as possible to the target lesion in order to prevent the administration of an excess amount of glue. NBCA is then injected "drop-by-drop" in order to maximize the dose. The injection should be stopped when the blood flow stops, or if NBCA lies alongside the catheter tip, in order to avoid severe symptoms or non-target embolization.

   The "sandwich" technique: This is a method for alternate injections of glue and D5W [24]. The use of a three-way stopcock to allow faster flushing of the microcatheter with D5W between pulses of glue injection is highly recommended. Small aliquots of glue not exceeding the dead volume of the microcatheter (0.5–0.7 ml in most cases) should be injected followed by D5W to clear the catheter and drive the glue into the target arteries. Additional aliquots of glue followed by D5W are then injected to achieve optimal embolization.

In 2014, the Japanese Society of Interventional Radiology, acting in accordance with the Committee of Practice Guidelines of the Japanese Society of Interventional Radiology, developed a document to describe the current consensus regarding the use of NBCA for vascular embolization [22].

Cyanoacrylate is a highly adaptable adhesive and can be used in a wide variety of endovascular procedures: peripheral and gastrointestinal embolization (even in the presence of coagulopathies; Figure 5), arteriovenous vascular malformations (Figure 6), type-II endoleak embolization of aortic aneurysms, treatment of venous district conditions (esophageal varices, portal vein embolization), oncological treatment (both palliative and preoperative), and bronchial artery embolization for the treatment of hemoptysis [12,15,18,20,21,25–29].

There are advantages to the use of cyanoacrylate beyond its broad usability: it polymerizes in only a few seconds to achieve prompt hemostasis; and the product

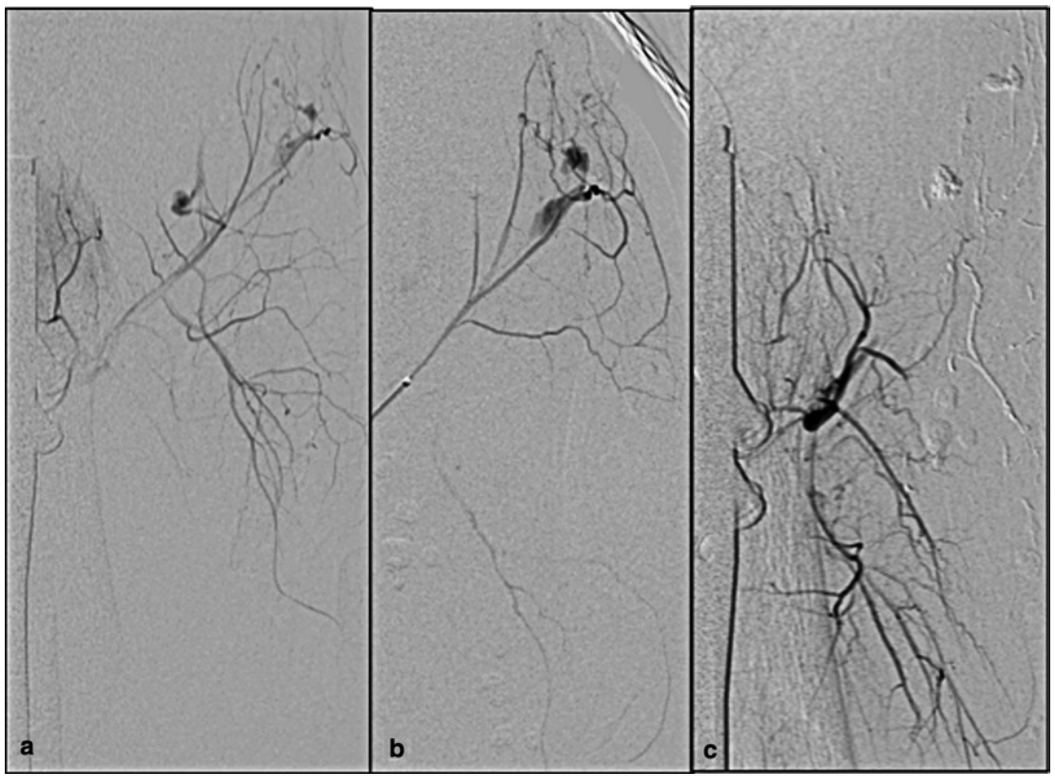

Figure 5 Peripheral embolization. (**a**, **b**) Bleeding of the lateral circumflex artery. (**c**) Embolized with glue (1:3).

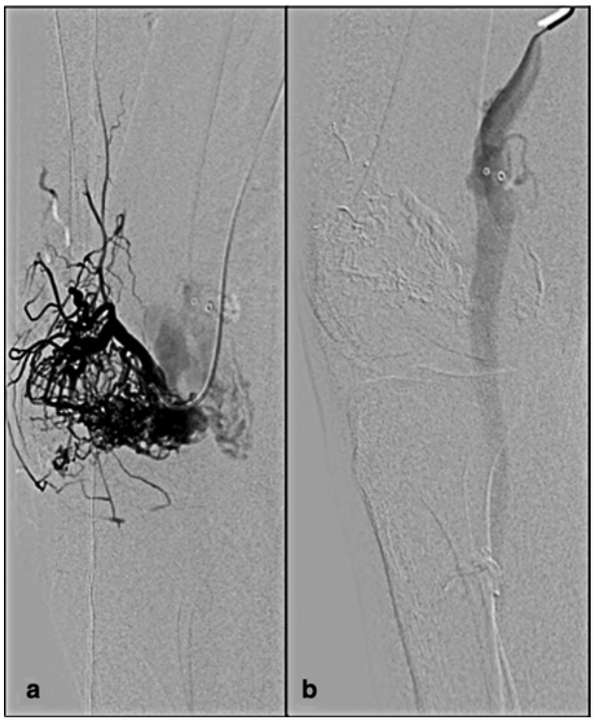

Figure 6 Arteriovenous vascular malformations. (**a**) Selective angiography of a voluminous artero-venous malformation. (**b**) Embolized with glue (1:3).

is almost ready-to-use in a few simple steps. In fact, it can be quickly administered, only requiring dilution with Lipiodol before its injection, which is a crucial feature especially when dealing with a hemodynamically unstable patient [21]. Also, cyanoacrylates are effective for hemostasis because of their independent polymerization mechanism even in the setting of a coagulation disorder, which is often present in arterial bleeding because of anticoagulant medication or is induced by the hemorrhagic shock itself. Further, it allows for the embolization of small or tortuous vessels due to its liquidity. Finally, embolization with glue is very cost-effective in most countries in the world; 1 ml is comparable in cost with a single conventional pushing coil [21].

There are also some drawbacks: cyanoacrylates are difficult to control during injection, and require high expertise due to serious potential complications, such as catheter-tip trapping or fragmentation and non-target embolization, depending on the cyanoacrylate/iodized oil ratio; the latter, in particular, needs specific attention due to its potential dramatic consequences. In this sense, information about flow dynamics and anatomical orientations provided by the test injection immediately before the embolization can be very helpful in predicting the appropriate injection rate to avoid refluxes. Lipiodol flow is slower than the flow of contrast medium in the normal setting owing to its higher viscosity. Moreover, operators have to consider that Lipiodol

viscosity varies with temperature, and is especially low at high temperatures [22,30].

In conclusion, the use of glues in interventional radiology as an embolic agent is effective, safe, and inexpensive, and may be particularly useful in settings of hemodynamic instability, coagulopathy, vessels with underlying significant vasospasm, and small or tortuous vessels. Nevertheless, the glues require careful pre-procedural assessment, attention to technical details, and a good amount of experience.

DISCUSSION

Both Onyx and cyanoacrylate glue have the great advantage of polymerizing independently of any underlying coagulopathy or low platelet count compared with mechanical devices, such as coils, which rely on patients' coagulation mechanisms for complete hemostasis [31]. Both agents can also be used for a wide range of interventions and in different areas.

To our knowledge, there are no prospective studies that compare Onyx and glues in terms of efficacy or safety in an extracranial setting.

What emerges from the literature is that Onyx's physical properties allow controlled and precise delivery of the embolic liquid so that it reaches specific distal arterial branches. Also, Onyx works equally well with or without flow, particularly with the "plug and push" technique, which might be an advantage in cases where non-occlusive vasospasm is present despite some concern about worsening underlying vasospasm with DSMO injections. By contrast, decent forward flow is necessary for cyanoacrylate glue to be appropriately delivered [31].

A great concern with cyanoacrylate glue is the difficulty in achieving controlled delivery, which is inevitably associated with the risk of distal migration or reflux to the proximal anatomy that will cause non-target embolization. Risks related to microcatheter entrapment, particularly with a high concentration of cyanoacrylate, are also a major concern [31].

Economic considerations, however, greatly favor the use of glue in the majority of countries. As already mentioned, 1 ml of glue is comparable in cost with a single conventional pushing coil and is sufficient for successful treatment in the majority of cases [21]. By contrast, Onyx is far more expensive, which can limit its availability in complex procedures in more noble districts that you have to handle with care (brain, gastrointestines), where the risks of non-target embolization outweigh the benefits of using cyanoacrylate glue.

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

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The Role of Endovascular Stents in an Experimental Model of Traumatic Arterial Occlusion – the Temporary Endo-Shunt

Viktor A Reva MD PhD[1], Marta J Madurska MD[2], Igor M Samokhvalov MD PhD[1], Alexey V Denisov MD PhD[1], Sergey Yu Telickiy MD PhD[1], Alexey B Seleznev MD PhD[1], Igor S Zheleznyak MD PhD[3], Valery N Adamenko MD[1] and Kenji Inaba MD[4]

[1]Department of War Surgery, Kirov Military Medical Academy, Saint-Petersburg, Russian Federation
[2]R. Adams Cowley Shock Trauma Center, University of Maryland Medical System, Baltimore, USA
[3]Department of Radiology, Kirov Military Medical Academy, Saint-Petersburg, Russian Federation
[4]Department of Surgery, Division of Acute Care Surgery and Surgical Critical Care, Los Angeles County and University of Southern California Medical Center, Los Angeles, USA

Background: The aim of this study was to evaluate patency following the deployment of a bare-metal stent (BMS) or covered stent (CS) across a traumatic occlusive peripheral arterial lesion and to estimate the feasibility of urgent stent placement for temporary endovascular shunting.

Methods: Fifteen sheep (25–45 kg) underwent laparoscopic creation of a left external iliac artery (EIA) thrombosis by means of repeated clamping. Sixty minutes after achievement of thrombotic occlusion, animals were randomized into one of three groups: no-treatment (control group), a BMS group, or CS group. Animals were followed up for 30 days with no anticoagulants or anti-platelet drugs administered postoperatively. Doppler ultrasound, computed tomography angiography (CTA), and digital subtraction angiography (DSA) were used to evaluate EIA patency.

Results: Stent implantation resulted in the restoration of in-line flow through the EIA in all cases. The peak systolic velocity (PSV) in the injured limb increased from 10 (0–16) to 31 (28–37) cm/s in the BMS group ($p < 0.0001$) and from 15 (7–18) to 24 (21–29) cm/s in the CS group ($p = 0.043$) immediately after stent deployment (both $p = 0.001$ compared with the control group). There was no difference in the PSV between the groups at post-injury day 3, and thereafter. Day-14 CTA and day-30 DSA demonstrated only one patent stent in each study group.

Conclusions: Urgent stent (BMS or CS) implantation can restore arterial patency of a traumatic occlusion for a short period of time and serve as a temporary endovascular shunt. Distal embolization can complicate this procedure and worsen long-term patency.

Keywords: *Vascular Trauma; Occlusion; Covered Stent; Bare Metal Stent; Recanalization; Endovascular Trauma Management*

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Corresponding author:
Viktor A. Reva MD PhD, Department of War Surgery, Kirov Military Medical Academy, 6, Lebedeva str. Saint-Petersburg, Russian Federation 194044.
Email: vreva@mail.ru

INTRODUCTION

Blunt arterial injury is often associated with significant morbidity. This is multifactorial due to the extent of vascular injury, resulting ischemia, and surrounding tissue damage [1,2]. The magnitude of the problem is compounded if the patient has sustained other life-threatening injuries, which take precedence over extremity reperfusion [2]. Peripheral occlusive vascular injury, if indicated, typically undergoes surgical exploration and control of the injured

segment. This is followed by either formal vascular reconstruction or temporary shunting depending on the patient's condition and status of the injured extremity [3]. However, both of these approaches can be time consuming, and incur blood loss and trauma [4].

Endovascular techniques are becoming increasingly important in trauma [4–7]. While stent-grafting has become common place in difficult anatomical locations such as the aorta, subclavian artery, and iliac artery, the experience in peripheral lesions is limited [5,7]. Currently, there are limited data on the immediate endovascular stenting of the occluded arterial segment [8,9].

While anticoagulation is crucial in endovascular surgery, it is often contraindicated in trauma. Most studies examining stent-grafting in trauma report the use of an anti-platelet agent postoperatively [10–13].

We hypothesized that even in a setting where systemic anticoagulation is not recommended, self-expandable stent implantation can be used for temporary endovascular shunting of an injured major extremity artery. The aim of this study was to evaluate short-term arterial patency following the deployment of a bare metal (BMS) or covered stent (CS) across a traumatic occlusive arterial lesion in the absence of postoperative anticoagulation or anti-platelet drugs.

METHODS

Overview

Female non-pregnant sheep, weighing between 25 and 45 kg, were utilized in this study, which was approved by the local institutional ethics committee. The study protocol consisted of four phases: preparation, injury, intervention (BMS ($n = 5$), CS ($n = 5$); or control ($n = 5$)), and follow-up (Figure 1).

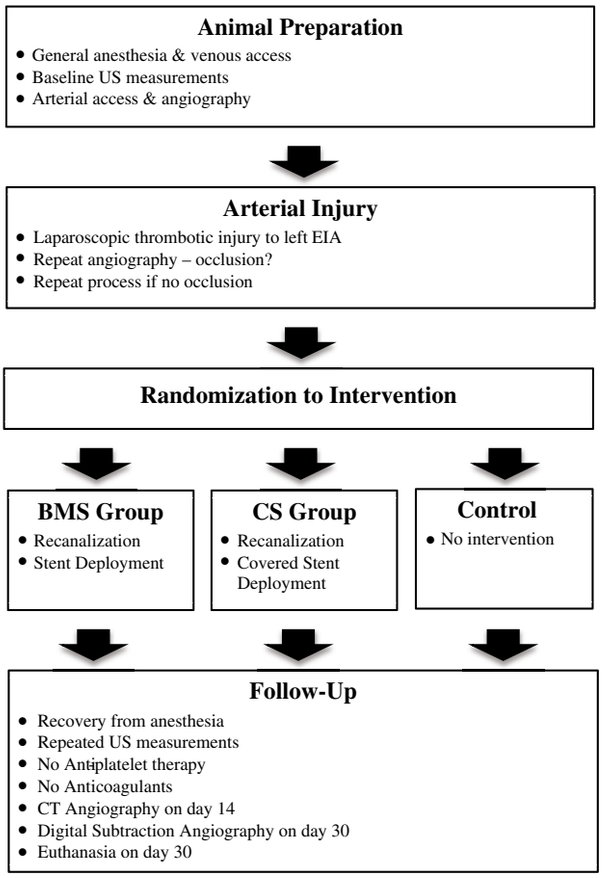

Figure 1 Experimental protocol. BMS: bare metal stent, CS: covered stent, CT: computed tomography, EIA: external iliac artery, US: ultrasound.

Animal Preparation

Intramuscular (IM) injection of 10 mg/kg tiletamine and zolazepam (Zoletil®; Virbac, Carros, France) was performed for induction of general anesthesia. Isoflurane at 1–2% concentration was used to maintain anesthesia.

A 5-Fr 11-cm sheath was percutaneously placed into the left external jugular vein for drug and fluid delivery. An 11-Fr 11-cm sheath (Cordis Endovascular, USA) was percutaneously placed in the left carotid artery, and fluoroscopy was used to confirm the tip placement in the brachiocephalic trunk. All sheaths and catheters were flushed with heparinized saline. A mobile fluoroscopy unit (C-arm SM-20HF, Listem Corporation, Republic of Korea) was used for capturing fluoroscopy images. The technique for catheterization of extremity arteries in sheep via the carotid artery, as well as the angiographic survey of the ovine pelvis and hind extremity, are described elsewhere [14]. A non-hydrophilic 0.035″ Emerald 260-cm wire (Cordis Endovascular, USA) was left in the aorta following angiography.

Laparoscopic Thrombotic Arterial Injury

A laparoscopic technique was used to develop a traumatic occlusive lesion of the left external iliac artery (EIA; Figure 2). A 10-mm laparoscopic port was placed into the peritoneal cavity, by insertion immediately caudal to the xiphoid process using a Hassan technique. The abdominal cavity was insufflated with carbon dioxide to maintain pneumoperitoneum (15 mm Hg). A 5-mm port was placed just medial to each iliac crest and one additional 10-mm port was placed between the former two parts, immediately left of the midline. The animal was placed in the Trendelenburg position on the right side.

The left EIA was then exposed laparoscopically using diathermy and a dissector. In order to isolate a 3-cm segment of the EIA, the origin of the deep circumflex iliac artery was ligated with 1 or 2 ligaclips via a separate 10-mm trocar. A standardized arterial lesion was then created: a 3-cm section of the artery was controlled, and then

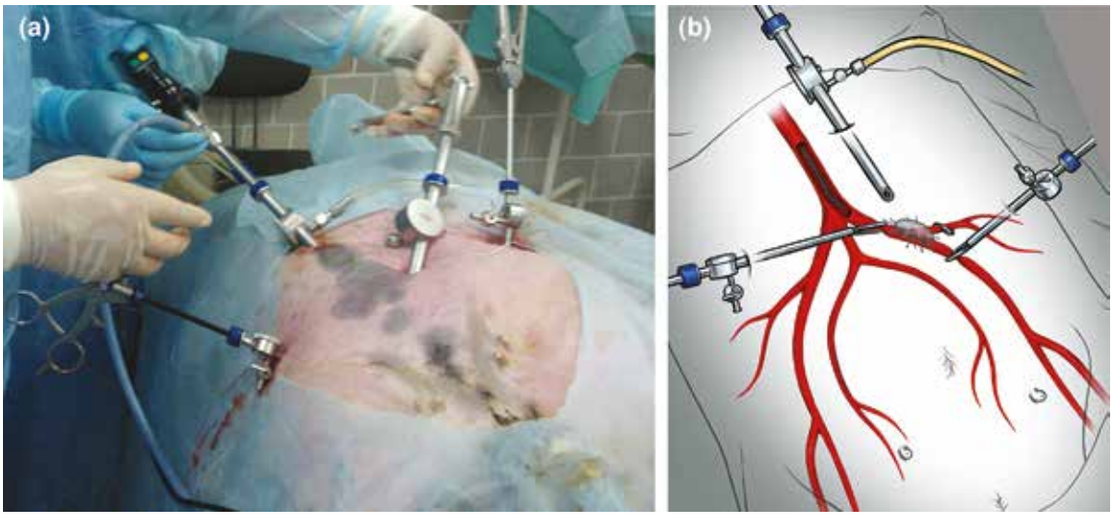

Figure 2 A view of the operative laparoscopic procedure of making occlusive external iliac artery injury. Laparoscopic view. (**a**) Optimal ports and instruments places are seen. Lower part of the sheep's body is at the bottom. Operative view. (**b**) A main stage of the laparoscopic procedure is shown. The iliofemoral lymphatic node is located exactly above a targeted zone of the external iliac artery.

clamped repeatedly (10×) using grasping forceps and a needle holder in order to induce thrombosis while the forceps were left in place for 30 min. After clamp removal the left EIA underwent repeat angiography in order to confirm thrombosis resulting in full occlusion. If any flow through the injured segment remained, the forceps were applied again for an additional 30 min followed by completion angiography until full occlusion was confirmed. After the completion of the injury, a set of ultrasound (US) measurements was taken at both femoral arteries as post-injury values using the linear transducer (10–5 MHz) of a MicroMaxx® Ultrasound System (Sonosite Inc., USA). At the end of the injury phase, the abdomen was desufflated, all laparoscopic ports were removed, and incisions were closed with interrupted sutures.

Intervention

Then, 60 min after thrombotic arterial occlusion was achieved, animals in the study groups underwent an endovascular procedure. An indwelling non-hydrophilic wire was exchanged for a 0.035" hydrophilic guidewire (MIT, Moscow, Russia) which was then used to recanalize the occlusive thrombotic lesion. Once passed through the thrombus, the tip of the wire was left in the distal superficial femoral artery (SFA).

After systemic administration of 2,500 units of Heparin, in the stent groups, a 7 × 50 mm nitinol self-expandable or CS (both MIT, Moscow, Russia) overlapping the 3-cm zone of arterial injury was implanted. Neither pre- nor post-implantation dilatation was performed to avoid distal embolization. When post-implantation distal thrombi were identified with angiography, no attempts at thrombus removal were undertaken. After completion angiography, catheters, wires, and sheath were removed and the defect in the carotid artery was sutured with 5-0 polypropylene (Prolene®).

In the control group, no stenting was performed following injury and the access sheaths were removed 60 min after the EIA thrombosis was obtained.

Follow-up

Sixty minutes after the intervention phase, post-operative US measurements were taken. The sheep were then extubated and returned into the vivarium with free access to food and water. All animals received 1.0 g of Cefazoline IM twice a day for 5 days post procedure. No anticoagulants or anti-platelet drugs were administered in the post-operative period.

Hind limb function was evaluated daily by a veterinarian and a surgeon for the first 2 weeks using the modified Tarlov scale (from 0 – unable to sit, paralyzed limb, to 4 – fully ambulatory).

US measurements were performed on post-injury day 1, 3, 7, 14, and 30. On post-injury day 14, the animals underwent computed tomography angiography (CTA). Toshiba Aquilion 16 Slice Scanner was used for CT and 3 ml/kg of iodine contrast iopromide 370 mg I/ml (Ultravist®, Bayer, Australia) was automatically injected intra-arterially.

On post-injury day 30, animals were placed under general anesthesia, underwent control angiography (Ziehm RFD C-arm, Germany) via a carotid access to estimate the patency of the iliac, femoral arteries and run-off vessels, followed by euthanasia with an intravenous injection of 100 mEq of potassium chloride.

Table 1 A comparison of baseline and operative characteristics between groups.

Parameter	*Bare Metal Stent Group*	*Covered Stent Group*	*Control Group*	*P*
n	5	5	5	
Male	5 (100%)	5 (100%)	3 (60%)	0.099
Weight, kg	41.0 (28.5–43.6)	42.5 (31.0–44.0)	25.3 (23.2–41.6)	0.156
Physiology				
Heart rate, beats/min	95 (84–120)	110 (97–119)	80 (72–92)	0.072
Systemic SBP, mm Hg	120 (103–133)	132 (113–159)	109 (98–123)	0.236
Thrombosis				
Time to creation of injury, min	60 (58–98)	60 (43–85)	55 (48–60)	0.283
Operative				
Anesthesia time (including laparoscopy), min	255 (230–352)	320 (193–345)	200 (170–250)	0.204
Time for endovascular procedure, min	25 (23–45)	40 (35–53)	–	0.168
Volume of contrast medium, ml	70 (58–70)	80 (55–90)	60 (40–65)	0.191
Arterial data				
Diameter of EIA, mm	6.0 (6.0–7.0)	7.0 (6.8–7.3)	6.0 (5.5–6.5)	0.053

Values are median (IQR). EIA: external iliac artery; SBP: systolic blood pressure.

Animals with clinical signs of severe illness (coenurosis cerebralis, diarrhea) or in distress due to extremity dysfunction, were euthanized before the end of the study (EOS), as determined by a veterinarian. A complete autopsy was performed after the completion angiography to examine for any pathology, laparoscopic, or vascular access-related complications.

Study Endpoints and Statistical Analysis

The primary endpoint of this study was stent patency. Early patency was assessed by quantitative and qualitative Doppler waveform analysis. Blood peak systolic velocity (PSV) in cm/s, and pulsatility index (PI) comparing the left (injured) and right (control) sides at the following time points: pre- and post-injury, post-operative, at day 1, 3, 7, 14, and 30, were measured. Doppler waveform type in the SFA was also utilized to assess proximal patency.

After animal recovery, CTA and digital subtraction angiography (DSA) allowed evaluation of the run-off vessels for evidence of occluding distal emboli.

Secondary endpoints consisted of laboratory indices of hypocoagulation, reperfusion injury, contrast-induced acute kidney injury (AKI), complications relating to the procedure and/or arterial access, functional gait outcomes, and early euthanasia due to limb-related or systemic complications.

Data were analyzed using IBM SPSS Statistics v21.0 (IBM, Chicago, IL). Variables were evaluated for normal distribution, and nonparametric data were reported as medians with interquartile ranges. Differences in baseline and interventional characteristics between the three groups were tested using the chi-square test for categorical data and the Kruskal–Wallis test for continuous data. Paired continuous data were assessed with the Wilcoxon matched pairs signed rank test. Baseline US parameters were tested using Mann–Whitney *U* test, while using repeated US indices – a one-way repeated measure analysis of variance with the Bonferroni correction. Results were considered significant when $p \leq 0.01$.

Ethical Approval

Ethical approval was given by the local institutional ethics committee.

RESULTS

Baseline Characteristics, Arterial Injury, and Intervention

In total, $N = 15$ animals had undergone trauma-induced EIA occlusion before being randomly allocated into either the BMS ($n = 5$), CS ($n = 5$), or control ($n = 5$) group. Baseline characteristics and laboratory values were similar amongst the study groups (Table 1 and 2).

Successful occlusion was achieved in all animals as confirmed by angiography and US (Figure 3). Both intervention groups demonstrated a significant reduction in PSV and PI in the injured limbs ($p < 0.001$). While in the uninjured limbs there was no change in the PSV, there was a significant drop in the PI in the BMS group (from 2.86 (2.62–4.35) to 2.72 (2.54–3.21; $p = 0.005$)). The median time to occlusion was 60 min in the BMS and CS groups, and 55 min in the control group ($p = 0.283$; Table 1).

Successful stent deployment across the vascular injury was achieved in all animals. No animals in either study group showed >20% luminal narrowing on completion angiography and no signs of protruding thrombi were seen during stent deployment. An immediate significant increase in PSV and PI for both study groups ($p < 0.001$) was noted following stent deployment (Figure 3).

Table 2 A comparison of baseline and end-of-study laboratory tests between groups.

	Bare Metal Stent Group			Covered Stent Group			Control Group				
			BL vs. EOS			BL vs. EOS			BL vs. EOS	CSG vs. BMSG vs. CG	
Parameter	BL	EOS	P*	BL	EOS	P*	BL	EOS	P*	P**	P**
Hb, g/dl	9.6 (8.2–10.0)	11.2 (9.5–14.4)	0.068	9.1 (8.5–10.7)	9.9 (9.6–10.9)	0.999	12.6 (11.7–13.1)	11.4 (10.4–13.6)	0.225	0.009	0.348
RBC, $\times 10^{12}$/l	7.8 (3.7–9.1)	10.9 (5.9–14.3)	0.068	8.2 (5.7–10.3)	9.7 (4.2–10.5)	0.285	5.7 (4.7–9.0)	5.5 (4.6–6.4)	0.893	0.763	0.289
APTT, s	37.7 (32.0–42.6)	34.9 (29.4–44.1)	0.593	30.3 (28.3–55.7)	37.1 (13.4–39.8)	0.285	32.0 (25.0–32.8)	30.3 (22.1–33.9)	0.465	0.213	0.407
PT, s	25.8 (21.0–28.4)	24.6 (19.8–33.0)	0.715	25.9 (19.6–29.2)	23.2 (23.2–23.2)	0.999	26.8 (20.2–29.8)	26.2 (21.1–54.7)	0.715	0.946	0.875
INR	1.56 (1.22–1.75)	1.48 (1.13–2.10)	0.715	1.56 (1.12–1.80)	1.37 (1.37–1.37)	0.999	1.53 (1.16–1.85)	1.60 (1.22–3.87)	0.715	0.991	0.875
Lactate, mmol/l	0.8 (0.6–1.4)	3.1 (1.5–4.2)	0.068	1.2 (0.6–3.8)	2.0 (2.0–5.1)	0.999	1.7 (0.9–2.2)	3.4 (2.9–5.0)	0.068	0.332	0.522
Urea, mmol/l	6.7 (5.5–7.9)	6.9 (4.1–8.3)	0.999	5.2 (4.1–6.4)	8.3 (3.0–9.6)	0.593	4.7 (4.1–5.2)	5.4 (4.9–7.3)	0.144	0.054	0.750
Crea, µmol/l	69.5 (42.8–80.1)	77.3 (63.8–104.1)	0.273	59.0 (57.7–78.0)	80.7 (46.8–106.6)	0.593	91.7 (68.8–92.8)	89.4 (72.0–125.3)	0.715	0.114	0.628

*Values are median (interquartile range). *Wilcoxon matched-pairs signed rank test, **Kruskal–Wallis test. APTT: activated partial thromboplastin time, BL: baseline, BMSG: bare-metal stent group, CG: control group, CSG: covered stent group, Crea: creatinine, EOS: end of study, Hb: hemoglobin, INR: international normalized ratio, PT: prothrombin time, RBC: red blood cells.*

Primary Outcome: Patency

In addition to stent patency, completion angiography also demonstrated a degree of distal embolization in all animals who had undergone stenting, regardless of the stent type. Occluding fresh thrombi could be found in the profunda femoris, popliteal, and tibial arteries. No fresh thrombi protruding through the cells of the BMSs were seen. In the stent group, 60 min following stenting a diminished, monophasic arterial flow was recorded in 2/5 and 1/5 animals (BMS and CS groups respectively). In the control group all EIAs were demonstrated to remain occluded 60 min following the injury ($p = 0.031$). There was no significant difference in US measurements between the stent groups in the post-operative time points. Figure 3 demonstrates gradual convergence of PSV and PI in the left (injured) leg between groups. On post-injury day 1, there was a significant difference in PSV between groups ($p < 0.001$), although the Doppler waveforms demonstrated stent patency in 2/5 and 1/5 animals in the BMS and CS groups, respectively. These results remained unchanged on day 3 post-operation.

On post-injury day 14, CTA showed only one EIA patent in both the BMS and CS groups, with persisting occlusion in the control group. Day 30 DSA confirmed the same arterial patency rate (Table 3 and Figure 4) and demonstrated no difference in collateral development between the stent and control groups. According to CTA and DSA, the blood flow and morphology of distal thrombi were identical between day 14 and day 30 in all groups. In case of stent re-thrombosis, a zone of occlusion was localized and extended only 1–2 cm in the proximal and distal direction, but not extending to the femoral artery bifurcation. Below-the-knee popliteal or proximal tibial artery occlusion by distal emboli was seen on control angiograms. Non-occluding thrombi were seen in the proximal profunda femoris artery. Run-off vessels were filled by collaterals and seen on angiography.

Secondary Outcomes: Laboratory Indices, Limb Function and Morbidity

Laboratory baseline and EOS indices presented in Table 2 demonstrate no differences between and within groups. No signs of coagulopathy or AKI were seen.

However, post-operative lactate level was significantly higher in the control group compared with the stent groups ($p = 0.002$, Figure 5). This correlated with early limb dysfunction in the control group as demonstrated by a lower Tarlov gait score ($p > 0.05$; Table 3). Ischemic time in this group was much longer than the stent groups where flow was restored 2 hours after thrombosis occurred. Gradual functional improvement was demonstrated in animals in all of the groups, where most animals achieved a Tarlov score of 4 at 7 days, and all animals scored 4 at 14 days.

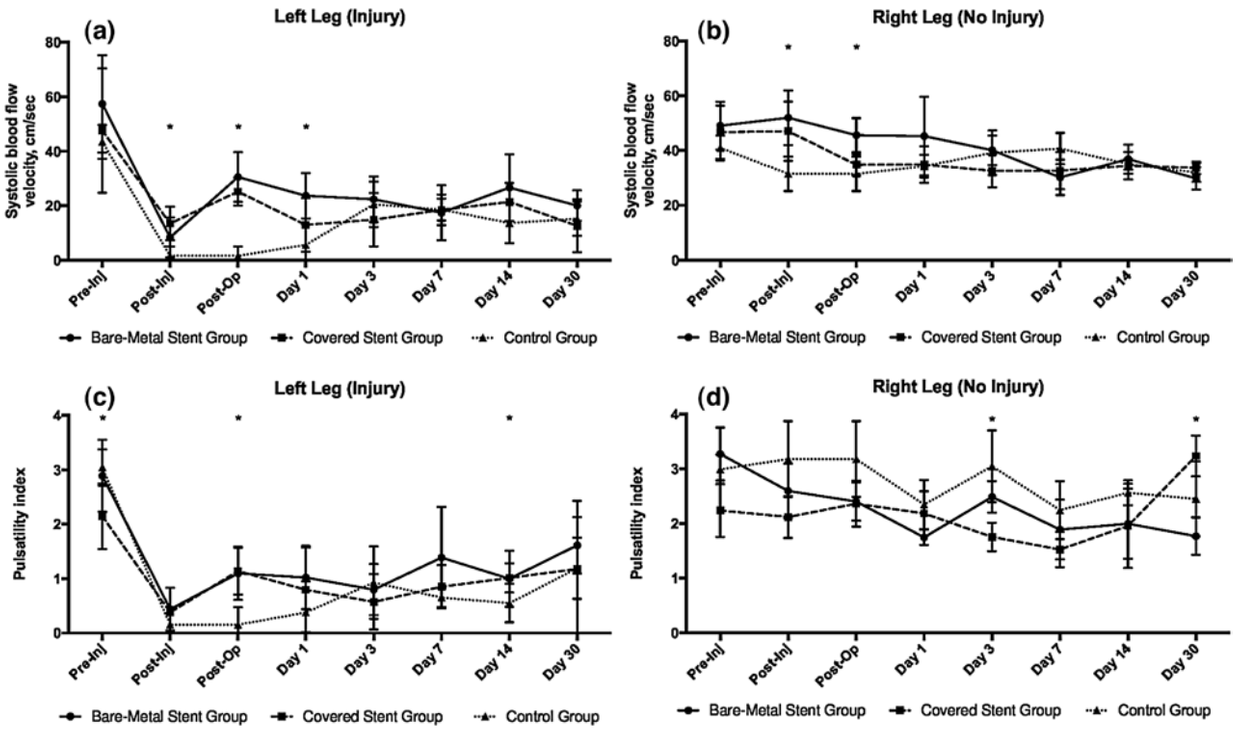

Figure 3 Ultrasonographic measurements of blood flow. (**a, b**) Systolic blood flow velocity. (**c, d**) Pulsatility index. Asterisks show significant differences between groups. Data are presented as mean with standard deviation. Pre-inj: pre-injury, Post-inj: post-injury.

Table 3 A comparison of follow-up characteristics between groups.

Parameter	*Bare Metal Stent Group*	*Covered Stent Group*	*Control Group*	*P*
n	5	5	5	
Tarlov gait score				
Day 1	3.0 (2.5–3.5)	4.0 (2.0–4.0)	2.0 (2.0–3.0)	0.121
Day 3	4.0 (3.0–4.0)	4.0 (2.5–4.0)	3.0 (2.5–3.5)	0.295
Day 7	4.0 (3.5–4.0)	4.0 (4.0–4.0)	4.0 (2.5–4.0)	0.549
Day 14	4.0 (4.0–4.0)	4.0 (4.0–4.0)	4.0 (4.0–4.0)	1.000
EOS patency (%)	1/5 (20)	1/5 (20)	0/5 (0)	0.562
Survival (%)				
14-day survival (%)	5/5 (100)	3/5 (60)	4/5 (80)	0.287
1-month survival (%)	4/5 (80)	3/5 (60)	3/5 (60)	0.741
Operative complications (%)	2/5 (40)	2/5 (40)	0 (0)	0.256

EOS: end of study.

Over the 30-day follow-up period no animals died in protocol or developed signs of tissue necrosis. No stenosis or occlusion were found at the carotid artery access site. In total, 5 of 15 animals required euthanasia before the end of the study (Table 3). In the control group, one was euthanized on day 13 due to severe diarrhea and another on day 16 due to coenurosis cerebralis. Two animals in the CS group and one animal in the BMS group developed systemic infection and were euthanized on post-injury day 3, 12, and 18, respectively. At autopsy, the source of infection was identified as the site of tissue dissection around the left EIA (a zone of manipulation with the iliofemoral lymphatic node). Another animal in the BMS group developed an asymptomatic lymphocele in the zone of operation.

DISCUSSION

The current study is the first reported evaluation of bare metal and covered endovascular stents in a traumatic ovine model of peripheral blunt arterial injury resulting in occlusion. Both types of stent were demonstrated to

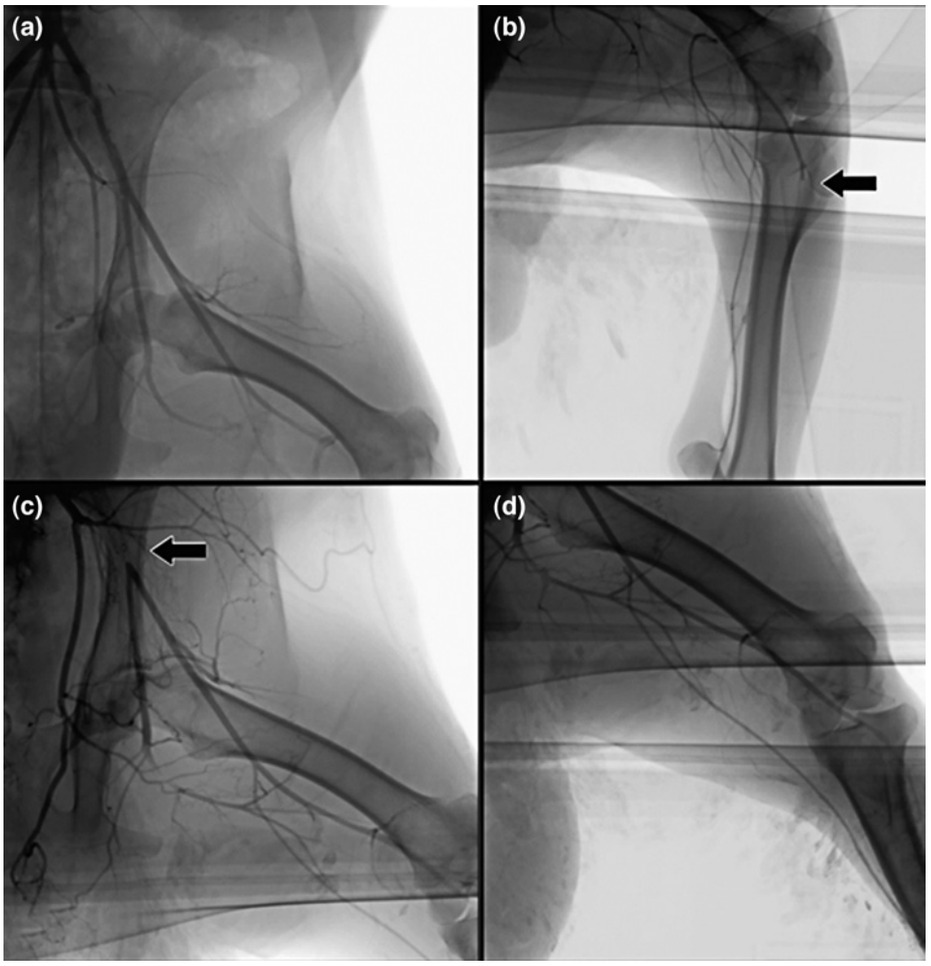

Figure 4 Representative completion angiograms of the injured hind limb 1 month after the injury and bare-metal stent implantation. (**a, b**) Angiograms demonstrate the only patent stent, with embolization of the distal part of the popliteal artery (arrow). (**c, d**) Angiograms show the occluded stent (arrow) of another animal with good collateral supply from the deep femoral artery and no distal emboli.

be effective in restoring initial arterial patency, but distal emboli and uniform in-stent thrombosis was seen beyond day 3.

This work represents an extension of our group's efforts to further develop and refine an animal model of occlusive arterial injury [15]. We have previously described a model of blunt arterial injury that demonstrates the compatibility of the ovine arterial tree with endovascular interventions. The use of laparoscopy in the current model permits access to a more proximal portion of the animals' arterial tree, allowing for the generation of occlusion in a larger caliber artery. However, dissection in lymphatic nodes and vessels led to relatively high animal long-term morbidity. EIA thrombosis resulted in significant ischemic injury manifested by early lactate elevation and limb dysfunction in the control group. Lactate level increased in all groups on day 1 followed by sequential regress. The absence of

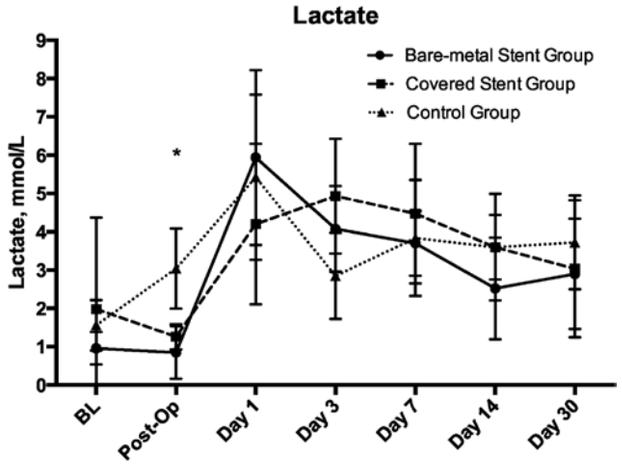

Figure 5 Time course changes in lactate level. An asterisk shows significant difference between groups. Data are presented as mean with standard deviation. BL: baseline.

amputations and timely recovery of limb function can be explained by a sufficient collateral supply.

This research also adds to the limited body of laboratory and clinical evidence examining the role endoluminal stenting in traumatic vascular injury [13,14]. Tang and co-workers evaluated 2-month patency rate after CS deployment into a 2-cm defect of the ovine SFA [13]. Nearly half of the stents were patent at the end of that study, but the animals were administered aspirin daily. Belczak and co-authors developed a porcine model of partial and complete carotid arterial transection to evaluate the feasibility of CS deployment [15]. The authors demonstrated that if a wire successfully passed through the injury zone, a CS can be easily deployed. However, arterial patency was only assessed at the time of implantation when the animal was fully heparinized. Using our previous ovine model [14], we were able to demonstrate the feasibility of BMS implantation into a zone of arterial traumatic occlusion [16]. All stented arteries remained patent during the 7-day follow-up period; however, the animals were fully heparinized during the study time frame, which is rarely feasible in a real trauma scenario.

The current study addresses the most challenging trauma scenario – limb ischemia with contraindication for post-operative systemic anticoagulation. However, it must be noted that intraoperative heparin was administered in this protocol. Modern imaging modalities (US, CTA, and DSA) allowed definitive evaluation of the injured artery for relatively long follow-up. BMS and CS deployment, the two main endovascular options for the treatment of peripheral arterial lesions, could be clearly investigated and compared in terms of arterial occlusion. The lesion was easily traversed by a wire and a delivery system, but it is likely that thrombus was not limited to the site of injury and embolized distally. This may have contributed to the reduction in distal flow and early in-stent occlusion. Although stent deployment in this model was feasible and straightforward, it cannot be viewed as a definitive revascularization, as demonstrated by a high rate of re-occlusion on day 3.

The concept of temporary reperfusion is well established in the form of open temporary vascular shunting (O-TVS). A variety of conduits have been described, with successful shunt times beyond 24 hours reported, without anti-coagulation. The findings from the current study lead to the question – can an endoluminal stent perform as a method of endovascular temporary vascular shunt (E-TVS)? This is conceptually attractive for certain anatomical regions that are difficult to reach surgically, especially if a patient is undergoing another endovascular intervention. Rapid endovascular restoration of blood flow (endo-shunting) can theoretically allow focus to remain on other more critical injuries and permit simultaneous resuscitation. In trauma surgery, there is no single solution to a particular clinical problem and the utility of O-TVS or E-TVS will depend on many factors. Open shunting allows for back bleeding, embolectomy, and wound exploration. E-TVS permits rapid restoration of perfusion, depending on the morphology of the lesion, without the violation of the overlying tissue.

The concept of E-TVS been described in limited terms within the literature. In a recent paper, Rohlffs et al. reported a case in which a through-and-through wire technique followed by three CS deployments was successfully used as a temporary bridging tool for a completely transected axillary artery resulting from blunt trauma [9]. Some other techniques have recently been proposed to maintain limb perfusion [17,18].

There are several limitations to this study. First, the distal thrombi were not quantified and no attempts were made to retrieve them. This was deliberate, as the intention was to evaluate a pragmatic endovascular procedure, accepting that small emboli were unlikely to significantly compromise limb function. In a clinical scenario, such a procedure will often result in peripheral smaller caliber artery occlusion and be ultimately compensated by collateralization. Second, although there was no postoperative anticoagulation, intraoperative anticoagulation was given. Our prior work and the published literature demonstrated that sheep have a tendency toward hypercoagulability [19,20]. Catheters and sheaths are easily thrombosed if heparin is not used at all. Because of the acute coagulopathy seen in trauma patients, this initial bolus of heparin may better represent the milieu in which one of these stents may be used. Although no strong contraindications exist for post-operative (post-stenting) anti-platelet therapy (APT) in trauma, we avoided it in this pilot study. Future research is warranted to evaluate long-term patency of E-TVS of traumatic occlusion in case of APT administration and/or associated brain injury. Our model focuses predominantly on grade IV level of blunt arterial injury and cannot be translated to evaluate lower grades of blunt injury resulting in intimal disruption, pseudoaneurysm, or dissection. Whilst clinical equipoise might exist in stenting lower grade, peripheral, arterial injuries, another model should be applied to study this.

Despite these limitations, the current study demonstrates that both BMS and CS deployment can restore perfusion acutely in an ovine model of thrombotic arterial occlusion. Without anticoagulation, however, thrombosis occurs by day 3. Endovascular stenting may be an option for temporary restoration of flow as a damage control strategy.

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

VAR and MJM carried out the study design, data interpretation, and manuscript writing. AVD, SYT, ABS, ISZ and VNA performed the data analysis and interpretation. IMS and KI carried out critical revision and work supervision.

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Original Article

Scalpel or Sheath? Outcomes Comparison Between Pre-Peritoneal Pelvic Packing and Angioembolization for Definitive Hemorrhage Control After REBOA

Megan Brenner MD MS[1], Laura Moore MD[2], Bishoy Zakhary MPH[1], Alexander Schwed MD[3], Alexis Cralley MD[3], Anna Romagnoli MD[4], Charles Fox MD[5], Thomas Scalea MD[4] and Clay Cothren Burlew MD[3]

[1]Comparative Effectiveness and Clinical Outcomes Research Center, University of California Riverside/Riverside University Health Systems, Riverside, CA, USA
[2]Department of Surgery, University of Texas at Houston, Texas Trauma Institute, Houston, TX, USA
[3]Department of Surgery, Denver Health Medical Center, Denver, CO, USA
[4]Department of Surgery, University of Maryland Shock Trauma Center, Baltimore, MD, USA
[5]Department of Surgery, University of Colorado, Denver, CO, USA

Background: The role of angioembolization (AE) and pre-peritoneal pelvic packing (PPP) for pelvic hemorrhage control in the era of resuscitative endovascular balloon occlusion of the aorta (REBOA) has not been well described. Our aim was to investigate outcomes of PPP and AE after REBOA.
Methods: Patients who received aortic occlusion (AO) at Zone 3 (distal abdominal aorta) plus PPP and/or AE at three high-volume REBOA centers between February 2013 and December 2018 were identified. Outcomes were compared between three groups based on procedures performed: REBOA with PPP only (RPPP), REBOA with angioembolization only (RAE), and REBOA with PPP and AE (RPPPAE).
Results: Fifty-eight patients underwent REBOA at Zone 3; 37 RPPP, 13 RAE, 8 RPPPAE. Mean age was 45 ± 16 years, mean injury severity score (ISS) 35 ± 13, mean systolic blood pressure (SBP) pre-AO was 71 ± 19 mmHg, and post-AO SBP was 110 ± 34 mmHg. In-hospital mortality was 28%, with the majority of deaths occurring in the intensive care unit. Age, ISS, admission SBP, physiology on admission and at the time of AO, response to AO, admission hemoglobin, blood products transfused, and rate of local wound infections were not different between RPPP and RAE groups. Comparing RPPP to RAE groups, duration of AO was significantly lower in the RPPP group (45 + 34 vs 81 + 37 mins, $p = 0.012$), while rates of acute kidney injury (14% vs 46%) and distal embolism (8% vs 31%) were higher in the RAE group ($p = 0.015$, 0.04, respectively).There was no statistical difference in mortality between RPPP (22%) and RAE patients (39%), including on regression analysis controlling for duration of AO and ongoing CPR at the time of AO.
Conclusion: Despite a longer duration of AO and higher rates of ongoing CPR at the time of AO in RAE patients, mortality rates are similar whether hemostasis is achieved after REBOA with pelvic packing or angioembolization. RPPP results in significantly lower systemic and local complication rates.

Keywords: *REBOA; Pelvic Packing; Angioembolization*

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Corresponding author:
Megan Brenner MD MS, Professor of Surgery, University of California Riverside School of Medicine, Riverside University Health System, 26520 Cactus Ave CPC Suite 102-5, Moreno Valley CA 92555, USA.
Email: m.brenner@ruhealth.org

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been adopted by many trauma centers as an adjunct in temporary control of pelvic fracture-related hemorrhage. Traditional options for hemorrhage control include product resuscitation, pelvic stabilization, reversal of coagulopathy, preperitoneal pelvic packing (PPP), and angioembolization (AE). REBOA has been added into algorithms of patients with pelvic hemorrhage [1,2]; however, little data exists to guide this practice. Where REBOA is utilized may also be determined by local factors such resource allocation and availability. REBOA, PPP, and AE can all be useful adjuncts in the setting of severe pelvic fracture hemorrhage. These techniques likely complement each other; however, institutional differences in practice have permitted the comparison between PPP and AE after REBOA in this study.

Our objective was to describe the characteristics and outcomes of patients who receive REBOA and additional procedures for pelvic fracture hemorrhage control.

METHODS

Patients who received aortic occlusion (AO) at Zone 3 (distal abdominal aorta) plus PPP and/or AE for isolated blunt pelvic fracture-related hemorrhage at 3 high-volume REBOA centers between February 2013 and December 2018 were identified. The three participating centers are high-volume REBOA centers known to have differing practice patterns for definitive hemorrhage control, but who all utilize REBOA as a temporizing measure for severe pelvic fracture hemorrhage refractory to initial resuscitation and/or pelvic stabilization. Data was collected prospectively into each center's database and the de-identified data was shared for analysis. Demographics, physiologic variables, and outcomes were reviewed from prospectively collected institutional registries. Inclusion criteria were patients older than 18 years of age who received REBOA on admission for pelvic-fracture related hemorrhage, then went on to additional procedures for hemostasis: PPP, AE, or both. Patients were divided into three groups based on hemostatic procedures performed: REBOA with PPP only (RPPP), REBOA with angioembolization only (RAE), and REBOA with PPP and AE (RPPPAE). The decision to perform REBOA was at the discretion of the attending physician according to each institution's algorithm, which follows the same indications for use of REBOA: a hypotensive patient with severe sub-diaphragmatic hemorrhage who has not responded to resuscitation. In this case, the hemorrhage was from severe blunt pelvic fracture.

Captured data included patient demographics, admission laboratory values and vital signs, Injury Severity Scores (ISS), and Abbreviated Injury Scale (AIS) scores. Physiologic data from admission until after AO was collected, as well as blood product utilization and procedural details. Outcomes such as hospital and intensive care unit (ICU) stay, ventilator days, discharge location, mortality, acute kidney injury (AKI), acute lung injury/acute respiratory distress syndrome (ALI/ARDS), distal embolism, pneumonia, sepsis or septic shock, hematoma, bacteremia, multi-organ dysfunction/multi-organ dysfunction syndrome (MODS), infections, local wounds, and need for amputation were also collected.

Univariate chi-squared analysis was performed between groups. Continuous variables were reported in mean ± standard deviation while categorical variables were reported by count and their appropriate percentages. Binomial logistic regression was then performed controlling for covariates such as age, AO systolic blood pressure (SBP), and duration of AO with RPPP and RAE. Models were validated using the Hosmer–Lemeshow test.

Ethical approval and informed consent

Each institution received approval from their Institutional Review Board for this study including waiver of informed consent.

RESULTS

Demographics

During the study period, 58 patients undergoing REBOA for pelvic bleeding were identified: 37 RPPP, 13 RAE, and 8 RPPPAE (Table 1). Mean injury severity score (ISS) was 35 ± 13, and mean admission SBP was 96 mmHg, while SBP at AO initiation was 72 mmHg, none of which differed between groups. Only 7.9% of patients had ongoing cardiopulmonary resuscitation at AO initiation: 5.4% of RPPP patients and 7.7% of RAE patients ($p = 0.471$). Mean time from admission to AO was not significantly different among the treatment groups (Table 1). Duration of AO was significantly different between RPPP and RAE groups (45 ± 34.39 vs 81.01 ± 37.21 min, $p = 0.012$). In total, 52% of patients had a pelvic binder, and 59% received pelvic external fixation. A total of 21 patients had both pelvic binders then subsequent external fixation (36%). Mean blood products transfused within the first 24 hours were 17 ± 16 UPRBC, 13 ± 12 FFP, 8 ± 10 pack platelets. In total, 31 patients (53.4%) received REBOA with the ER-REBOA catheter (Prytime Medical Inc, Boerne, TX).

Outcomes and Complications

In-hospital mortality was 28% and was not significantly different between groups (RPP 8 (21.6%), RAE 5 (38.5%), and RPPPAE 3 (37.5%); Table 2). The majority of deaths occurred in the intensive care unit and significantly more deaths occurred in the intensive care unit in the RAE group (38.5%) than RPPP group (5.4%) ($p = 0.009$; Table 2). Hospital stay, ICU stay, and ventilator days were also not significantly different between

Table 1 Demographic and other baseline characteristics of REBOA and pre-peritoneal pelvic packing (RPPP), REBOA and angioembolization (RAE), and REBOA with both PPP and AE (RPPPAE).

Baseline characteristics	*Total (n = 58; 100%)*	*RPPP (n = 37; 63.8%)*	*RAE (n = 13; 22.4%)*	*RPPPAE (n = 8; 13.8%)*	*RPP vs RAE p value*
Age, mean ± SD, years	45.1 ± 16.47	43.89 ± 15.17	44.15 ± 16.52	52.25 ± 22.17	0.959
Gender					0.828
Female, *n* (%)	14 (24.1)	9 (24.3)	3 (23.1)	2 (25.0)	
Male, *n* (%)	43 (74.1)	27 (73.0)	10 (76.9)	6 (75.0)	
Missing, *n* (%)	1 (1.7)	1 (2.7)	0 (0.0)	0 (0.0)	
ISS, mean ± SD	35.78 ± 10.67	34.79 ± 9.41	39.09 ± 13.14	34.57 ± 11.9	0.259
Head AIS, mean ± SD	2.05 ± 1.68	1.92 ± 1.68	2.55 ± 1.63	1.67 ± 1.86	0.307
Chest AIS, mean ± SD	2.81 ± 1.13	3.05 ± 0.83	2.36 ± 1.21	2.83 ± 1.72	0.07
Abdomen AIS, mean ± SD	2.8 ± 1.08	2.75 ± 1.03	2.91 ± 1.3	2.83 ± 0.8	0.699
Admission vitals					
SBP, mean ± SD, mmHg	95.53 ± 33.07	94.13 ± 30.83	93.92 ± 38.28	104.71 ± 36.25	0.985
HR, mean ± SD, bpm	115.7 ± 32.1	114.88 ± 29.67	127.58 ± 30.06	98.86 ± 41.93	0.214
GCS, mean ± SD	10.65 ± 5.17	10.81 ± 4.95	9 ± 5.85	13 ± 4.43	0.297
Hgb, mean ± SD	12.08 ± 2.76	12.26 ± 2.89	10.73 ± 2.77	12.86 ± 1.76	0.186
INR, mean ± SD	1.46 ± 0.5	1.49 ± 0.49	1.65 ± 0.68	1.15 ± 0.05	0.509
pH, mean ± SD	7.23 ± 0.16	7.21 ± 0.14	7.3 ± 0.29	7.22 ± 0.05	0.246
Base deficit [–], mean ± SD	8.51 ± 8.99	8.65 ± 9.96	8.33 ± 4.55	8.07 ± 8.55	0.941
Lactate, mg/dl, mean ± SD	6.81 ± 4.59	6.99 ± 4.96	7.36 ± 4.88	5.5 ± 2.22	0.859
AO initiation vitals					
SBP, mean ± SD, mmHg	71.52 ± 18.9	68.3 ± 17.8	77 ± 18.37	76.71 ± 23.34	0.177
HR, mean ± SD, bpm	114.9 ± 31.6	113.44 ± 35.35	125.55 ± 18.59	103.57 ± 32.59	0.294
GCS, mean ± SD	6.02 ± 4.86	6.35 ± 5.2	4.54 ± 3.31	7.57 ± 5.86	0.262
Post Initial AO Vitals					
SBP, mean ± SD, mmHg	110.4 ± 34.3	104.64 ± 39.96	124.33 ± 22.83	109.57 ± 18.34	0.12
HR, mean ± SD, bpm	102.2 ± 36.9	100.8 ± 38.11	109.33 ± 40.79	94.86 ± 26.47	0.537
GCS, mean ± SD	3.95 ± 3.0	4.12 ± 3.56	3.45 ± 1.21	4.14 ± 3.02	0.552
Change after AO					
Change in SBP, mean ± SD, mmHg	38.59 ± 30.1	35.58 ± 31.25	49.36 ± 22.2	32.86 ± 36.05	0.194
Change in HR, mean ± SD	–13.4 ± 32.6	–13.5 ± 35.28	–16.09 ± 34.76	–8.71 ± 21.93	0.843
Change in GCS, mean ± SD	–1.83 ± 4.24	–2.04 ± 4.56	–0.36 ± 1.21	–3.43 ± 5.86	0.241
Lowest base deficit [–], mean ± SD	8.52 ± 8.55	9.36 ± 9.47	6.23 ± 4.08	7.54 ± 8.45	0.403
Highest INR, mean ± SD	1.63 ± 0.51	1.74 ± 0.57	1.43 ± 0.19	1.36 ± 0.26	0.172
Highest lactate, mean ± SD, mg/dl	8.27 ± 5.03	8.58 ± 5.6	7.77 ± 3.58	7.47 ± 3.97	0.72
Lowest Hgb, mean ± SD	8.73 ± 1.84	8.8 ± 2.1	8.9 ± 1.02	8.24 ± 1.24	0.903
Lowest pH, mean ± SD	7.21 ± 0.15	7.18 ± 0.12	7.31 ± 0.26	7.23 ± 0.03	0.06
CPR at AO initiation, *n* (%)	3 (5.2)	2 (5.4)	1 (7.7)	0 (0)	0.471
Time to initial AO, mean ± SD	34.67 ± 36.1	33.03 ± 36.2	48.3 ± 44.3	26.7 ± 25.1	0.519
Duration of initial AO, mean ± SD, min	60 ± 39.93	45 ± 34.39	81.01 ± 37.21	80 ± 44.53	0.012
≤ 60 min, *n* (%)	19 (32.8)	16 (43.2)	1 (7.7)	2 (25.0)	0.001
> 60 min, *n* (%)	19 (32.8)	6 (16.2)	9 (69.2)	4 (50.0)	
Missing, *n* (%)	20 (34.5)	15 (40.5)	3 (23.1)	2 (25.0)	
Final sheath diameter					0.147
7 Fr, *n* (%)	31 (53.4)	23 (62.2)	4 (30.8)	4 (50.0)	
11/12 Fr, *n* (%)	14 (24.1)	8 (21.6)	3 (23.1)	3 (37.5)	
Other, *n* (%)	2 (3.4)	1 (2.7)	1 (7.7)	0 (0.0)	
Missing, *n* (%)	11 (19.0)	5 (13.5)	5 (38.5)	1 (12.5)	
Pelvic binder, *n* (%)	27 (51.9)	18 (51.4)	5 (55.6)	4 (50.0)	0.969
Pelvic external fixation, *n* (%)	34 (58.6)	22 (59.5)	8 (61.5)	4 (50.0)	0.895
TXA given, *n* (%)	10 (17.2)	25 (67.6)	3 (23.1)	1 (12.5)	0.152
Resuscitation products					
Packed red blood cells, mean ± SD	17.4 ± 15.9	17.58 ± 16.47	14.14 ± 10.62	19.86 ± 18.84	0.141
Fresh frozen plasma, mean ± SD	12.7 ± 12.2	12.58 ± 13.04	13.29 ± 9.01	12.86 ± 12.59	0.893
Platelets, mean ± SD	7.93 ± 10.04	10.11 ± 11.62	4 ± 2.16	3.14 ± 3.24	0.18
Cryoprecipitate, mean ± SD	1.27 ± 1.96	1.43 ± 2.15	1 ± 1.53	0.83 ± 1.6	0.624
Crystalloids, mean ± SD	4.98 ± 4.21	3.3 ± 1.61	9.72 ± 7.4	7.5 ± 2.08	<0.001

SD: standard deviation; bpm: beats per minute; GCS: Glasgow Coma Scale; Hgb: hemoglobin; HR: heart rate; INR: international normalized ratio; AIS: Abbreviated Injury Score; CPR: cardiopulmonary resuscitation.

Table 2 Outcomes and complications of REBOA and pre-peritoneal pelvic packing (RPPP), REBOA and angioembolization (RAE), and REBOA with PPP and AE (RPPPAE) patients.

Outcomes	*Total (n = 58; 100%)*	*RPPP (n = 37; 63.8%)*	*RAE (n = 13; 22.4%)*	*RPPPAE (n = 8; 13.8%)*	*RPP vs RAE p value*
In hospital mortality, *n* (%)	16 (27.6)	8 (21.6)	5 (38.5)	3 (37.5)	0.285
ICU, *n* (%)	10 (17.2)	2 (5.4)	5 (38.5)	3 (37.5)	0.009
Operating room, *n* (%)	6 (10.3)	6 (16.2)	0 (0.0)	0 (0.0)	
Hospital LOS, mean ± SD, days	27.96 ± 25.2	30.76 ± 27.05	19.54 ± 18.02	30.43 ± 27.49	0.176
ICU stay, *n* (%)	47 (81.0)	28 (75.7)	12 (92.3)	7 (87.5)	0.371
ICU stay, mean ± SD, days	17.39 ± 19.9	15.371 ± 19.6	13.33 ± 14.12	18 ± 17.64	0.791
Ventilator use, *n* (%)	47 (81.0)	29 (78.4)	11 (84.6)	7 (87.5)	0.780
Ventilator days, mean ± SD, days	12.9 ± 16.59	13.59 ± 18.59	9.36 ± 11.17	15.43 ± 16.01	0.710
Discharge GCS, mean ± SD, days	11.1 ± 5.29	11.73 ± 4.85	11 ± 6	9.4 ± 6.07	0.746
Discharge disposition					0.022
Rehab/nursing facility, *n* (%)	26 (70.3)	14 (56.0)	8 (100.0)	4 (100.0)	
Home, *n* (%)	11 (29.7)	11 (44.0)	0 (0.0)	0 (0.0)	
Complications, *n* (%)	28 (48.3)	14 (37.8)	9 (69.2)	5 (62.5)	0.051
Acute kidney injury, *n* (%)	16 (27.6)	5 (13.5)	6 (46.2)	5 (62.5)	0.015
ALI or ARDS, *n* (%)	7 (12.1)	4 (10.8)	2 (15.4)	1 (12.5)	0.662
Distal embolism, *n* (%)	7 (12.1)	3 (8.1)	4 (30.8)	0 (0.0)	0.043
Pneumonia, *n* (%)	8 (13.8)	6 (16.2)	2 (15.4)	0 (0.0)	0.944
Sepsis or septic shock, *n* (%)	5 (8.6)	3 (8.1)	2 (15.4)	0 (0.0)	0.452
Hematoma, *n* (%)	3 (5.2)	1 (2.7)	2 (15.4)	0 (0.0)	0.098
Bacteremia, *n* (%)	2 (3.4)	1 (2.7)	1 (7.7)	0 (0.0)	0.43
Multi-organ dysfunction/MODS, *n* (%)	2 (3.4)	0 (0.0)	1 (7.7)	1 (12.5)	0.549
Infection requiring antibiotics, *n* (%)	1 (1.7)	1 (2.7)	0 (0.0)	0 (0.0)	0.549
Infection requiring surgery, *n* (%)	1 (1.7)	1 (2.7)	0 (0.0)	0 (0.0)	0.549
Local wound infection, *n* (%)	1 (1.7)	1 (2.7)	0 (0.0)	0 (0.0)	0.549
Need for amputation, *n* (%)	1 (1.7)	0 (0.0)	1 (7.7)	0 (0.0)	0.549

LOS: length of stay; ALI: acute lung injury; ARDS: acute respiratory distress syndrome.

groups. Of those who survived to discharge, 44.8% of patients were transferred to rehab or nursing facilities, and of these 56.0% were RPPP patients and 100% were RAE patients ($p = 0.02$).

Systemic complications were more common within RAE patients than RPPP and RPPPAE groups. Rates of AKI were higher in the RAE group compared with the RPPP group (46.2% vs 13.5%, $p = 0.015$), as was distal embolism (30.8% vs 8.1%, $p = 0.043$). ARDS/ALI, pneumonia, sepsis or septic shock, hematoma, bacteremia, multi-organ dysfunction/MODS, infections requiring antibiotics, infections requiring surgery, local wound infections, and need for amputation were not found to be significantly different among the treatment groups (Table 2).

In total, 62% of RPPP patients and 31% of RAE patients received REBOA using a 7-Fr introducer sheath ($p = 0.15$). When examining the subgroup of patients whose maximum sheath size was 7 Fr, there were no significant differences in mortality, but AKI was higher in RAE (50%) than in RPPP groups (17.4%, $p = 0.015$; Table 3). Distal embolism was higher in RPPP (4.3%) than in RAE (0%) patients.

Logistic Regression Analysis

There were no significant differences between RAE and RPPP groups when controlling for ongoing CPR during AO initiation and duration of AO (Table 4). Duration of AO was also found to be significantly associated with mortality as AO durations of AO greater than 60 min were found to correlate with higher mortality (Table 4). Duration of AO was not found to be significantly associated with either systemic or access-related complications (Tables 5 and 6).

DISCUSSION

REBOA has been advocated in severe pelvic trauma patients to temporize fracture-related hemorrhage until definitive hemostasis can be achieved. This study focuses on a severely injured cohort as demonstrated by vital signs, ISS, and laboratory values. REBOA was initiated after a mean of 33 min in the resuscitation area during which time blood product resuscitation did not result in improved hemodynamic status; the mean SBP at the time of REBOA was 72 mmHg, which was not different between groups. Despite some minor differences in these protocols, based on patient characteristics, the decision to initiate REBOA was similar in all three centers. The decision to proceed to either AE or PPP was institution and resource dependent. At one institution, the trauma hybrid operating room is down the hall from the resuscitation room, immediately available, and staffed with catheter-trained trauma surgeons [3,4]. The concurrent

Table 3 Outcomes and complications of 7-French final sheath diameter patients between pre-peritoneal pelvic packing only (RPPP) and angioembolization only (RAE) patients.

Outcomes	*Total (n = 27; 100%)*	*RPPP (n = 23; 85.2%)*	*RAE (n = 4; 14.8%)*	*RPP vs RAE p value*
Duration of initial AO, mean ± SD	59.06 ± 39.9	47.86 ± 35.1	98.28 ± 32.4	0.02
≤60 min, *n* (%)	10 (37.0)	10 (43.5)	0 (0.0)	>0.05
>60 min, *n* (%)	8 (29.6)	4 (17.4)	4 (100)	
Missing, *n* (%)	9 (33.3)	9 (39.1)	0 (0.0)	
In hospital mortality, *n* (%)	3 (11.1)	2 (8.7)	1 (25.0)	0.470
Complications ≥ 1, *n*, (%)	12 (44.4)	10 (43.5)	2 (50.0)	0.809
Acute kidney injury, *n* (%)	6 (22.2)	4 (17.4)	2 (50.0)	0.015
ALI or ARDS, *n* (%)	4 (14.8)	4 (17.4)	1 (25.0)	0.662
Distal embolism, *n* (%)	1 (3.7)	1 (4.3)	0 (0.0)	0.043
Pneumonia, *n* (%)	4 (14.8)	4 (17.4)	0 (0.0)	0.944
Sepsis or septic shock, *n* (%)	1 (3.7)	1 (4.3)	0 (0.0)	0.452
Hematoma, *n* (%)	1 (3.7)	1 (4.3)	0 (0.0)	0.098
Bacteremia, *n* (%)	1 (3.7)	1 (4.3)	0 (0.0)	0.43
Multi-organ dysfunction/MODS, *n* (%)	0 (0.0)	0 (0.0)	0 (0.0)	0.549
Infection requiring antibiotics, *n* (%)	1 (3.7)	1 (4.3)	0 (0.0)	0.549
Infection requiring surgery, *n* (%)	1 (3.7)	1 (4.3)	0 (0.0)	0.549
Local wound infection, *n* (%)	1 (3.7)	1 (4.3)	0 (0.0)	0.549
Need for amputation, *n* (%)	0 (0.0)	0 (0.0)	0 (0.0)	0.549

Table 4 Binomial logistic regression examining the outcome of mortality between pre-peritoneal pelvic packing only (RPPP) and angioembolization only (RAE) patients when controlling for CPR during AO and duration of AO.

Independent covariates	*Mortality OR (95% CI)*	*Mortality excluding patients with CPR at AO OR (95% CI)*
RAE vs RPPP	0.146 (0.004, 5.119)	2.52 (0.062, 102.06)
CPR during AO	649.5 (1.697, 24853)*	N/A
AO duration	1.073 (1.01, 1.14)*	1.062 (1.004, 1.124)*

**Denotes p <0.05. CI: confidence interval; OR: operating room.*

Table 5 Binomial logistic regression examining the outcome of mortality between pre-peritoneal pelvic packing only (RPPP) and angioembolization only (RAE) patients when controlling for SBP pre-AO and duration of AO .

Independent covariates	*Mortality OR (95% CI)*	*Complications ≥ 1 OR (95% CI)*
RAE vs RPPP	2.284 (0.138, 37.704)	12.585 (0.939, 168)
SBP pre-AO	0.909 (0.787, 1.048)	0.949 (0.889, 1.012)
AO duration	1.047 (1.003, 1.094)*	0.992 (0.965, 1.019)

**Denotes p <0.05.*

implementation of REBOA, a trauma hybrid room, and trauma surgeons with endovascular training has led to a near-abandonment of PPP. A second institution has interventional radiologists immediately available who are paged upon admission of any patient with a severe pelvic fracture who receives a REBOA. Almost all patients in the RAE group were enrolled from these two sites. The third institution has immediate access to trauma operating rooms, interventionalists who are available when consulted, and has set the gold standard for preperitoneal packing in trauma [5]. A retrospective study from this site investigating 40 patients with hemodynamic

Table 6 Binomial logistic regression examining the outcomes of mortality and complications within Zone 3 patients with 7-French final catheter diameter between pre-peritoneal pelvic packing only (RPPP) and angioembolization only (RAE) patients when controlling for SBP pre-AO and duration of AO.

Independent Covariates	*Mortality* *OR (95% CI)*	*Complications ≥ 1* *OR (95% CI)*
RAE vs RPPP	0.166 (0, 110.03)	2.514 (0.101, 62.62)
SBP pre-AO	0.974 (0.844, 1.125)	0.929 (0.840, 1.027)
AO duration	1.06 (0.978, 1.149)	1.000 (0.970, 1.031)

instability from pelvic hemorrhage demonstrated that PPP decreases need for pelvic AE and post-procedure blood transfusions [6], although this was performed prior to the advent of REBOA. Almost all patients in the RPPP group were enrolled from the third site.

There is little data available to recommend safe duration of AO in Zone 3. In this study, AO for longer than 60 min resulted in higher mortality. These findings are consistent with guidelines for clinical use of REBOA lead by the Committee on Trauma, which recommend a target duration of AO for 30 min at Zone 3, with a maximum of 60 min [7]. While it was not captured, the use of partial or intermittent AO was not routinely used at any of the institutions during this time period.

If the duration of AO is used as a surrogate for time to hemostasis, it appears that hemostasis can occur fastest with PPP, most likely due to the immediate availability of an operating room and surgeon to perform it. The longer duration of AO in the RAE group may be related to one institution's initial learning curve with AE and hybrid room workflow, or due to the availability of consultants, physical space, and location at others. Recent evidence demonstrates that a surgical endovascular service can result in faster times to hemostasis compared with IR-based teams [2], but no comparisons have been made between PPP and AE.

Mortality was unaffected by method of hemostasis after REBOA, including in those patients who required both PPP and AE for definitive hemostasis. Location of death was significant, however, with all deaths in the RAE and RPPPAE group occurring in the ICU whereas 75% of the deaths in the RPPP group occurred in the OR. This finding is not consistent with the duration of AO, as the RPPP patients had shorter durations of AO, thus location of death must be due to other factors not captured in this study. More RPPP survivors were discharged home compared with those who survived to discharge after RAE; the reason for this difference in hospital disposition is also unclear.

AKI rates were high in both RAE and RPPPAE groups, and significantly higher in the RAE group than the RPPP group, despite the RAE group receiving significantly more crystalloid. Rates of AKI in a multi-institutional trial of REBOA patients have been reported up to 18% [8] and are likely due to the systemic inflammatory response to AO as well as the initial injury and resultant hypoperfusion to the kidneys prior to AO. Despite the fact that AO occurred below the levels of the renal arteries allowing "normal" antegrade renal blood flow, patients still had significant AKI. The renin–angiotensin–aldosterone system responds to hypoperfusion at any level by increasing angiotensin II, which increases renal vascular resistance and results in decreased renal function. This mechanism may explain why AKI is high in REBOA patients as they are in profound hemorrhagic shock. Rates of AKI in patients in hemorrhagic shock who did not receive REBOA have been reported to be higher than the patients in the RPPP group, particularly those with a longer time to hemostasis [9]. The AKI is more likely to due to initial hypoperfusion than AO. The higher rate of AKI in the RAE group could be multi-factorial: patients were exposed to nephrotoxic contrast for the AE procedures and the duration of AO was longer, which likely increased the systemic inflammatory response to AO. As with time to hemostasis, the volume of contrast utilized may have been greater as this time period represented the onset of the AE learning curve in one institution.

The second most common systemic complication was ALI/ARDS, which was slightly higher than rates previously reported for REBOA patients [10], but not different between groups. The high rates of pulmonary complications suggest that the systemic inflammatory response to AO is profound, and further research is needed to identify clinical strategies to protect pulmonary function during and after AO and subsequent procedures for hemostasis.

Most patients received REBOA with a 7-Fr sheath, and among those patients the most common access-related complication was distal embolism, which was significantly higher in the RPPP group. It is unknown whether this could be due to mechanical compression on the inflow to the common femoral artery and pelvic outflow by PPP or other factors. A recent multi-institutional trial comparing access complications demonstrated that the rates of distal embolism have significantly decreased with the use of smaller introducer sheaths [8], and this is likely to continue

to improve with advances in technology that will provide lower profile devices in the future.

Several limitations exist in this study. The number of patients in each group was relatively low, which can result in type II errors for all variables. Several variables were not recorded in some institutions, such as in-dwelling sheath time and time to hemostasis, which can provide valuable information. Lastly, the three institutions were performing REBOA and resultant procedures based on their available resources. This observational study was designed primarily to address how REBOA may be used as an adjunct to hemorrhage control in different hospital settings with different resources.

CONCLUSION

Despite a longer duration of AO and higher rates of ongoing CPR at the time of AO in RAE patients, mortality rates are similar whether hemostasis is achieved after REBOA with PPP or AE. Using contemporary devices for REBOA, RPPP results in higher rates of AKI with AE, and higher rates of distal embolism with PPP. These complications appear to be independent of the duration of AO, physiology at the time of AO, use of transexamic acid, and blood products transfused. In-dwelling sheath times and/or time to definitive hemostasis may play a role in these findings; however, further study is required. Clinical strategies to protect renal and pulmonary function are required in order to maximize systemic insults from hemorrhagic shock and AO.

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

Megan Brenner and Charles Fox are Prytime Medical Inc. Clinical Advisory Board members. The remaining authors have no conflicts of interest .

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Author Contributions

MB carried out the literature search. MB, AR, and CCB were responsible for the study design. MB, LM, BZ, AS, AC, AR, CF, TS, and CCB were responsible for data collection. MB, LM, and BZ carried out data analysis. MB. LM, BZ, AS, AC, CF, TS, and CCB were responsible for data interpretation. MB, BZ, and CCB were responsible for the writing. MB, LM, CF, TS, and CCB carried out the critical revision.

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Original Article

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The Treatment of Post-Partum Bleeding with Transcatheter Arterial Embolization

Anna Maria Ierardi MD[1], Enrico Maria Fumarola MD[1], Antonio Pinto MD[2], Mariano Scaglione MD PhD[3,4] and Gianpaolo Carrafiello MD PhD[1,5]

[1]*Unità Operativa di Radiologia, Fondazione I.R.C.C.S. Cà Granda Ospedale Maggiore Policlinico, Milan, Italy*
[2]*Radiology Department, CTO Hospital, Naples, Italy*
[3]*Teesside University School of Health and Life Sciences, Middlesbrough, Tees Valley, UK*
[4]*Department of Radiology, "Pineta Grande" Hospital, Castel Volturno, CE, Italy*
[5]*Department of Health Sciences, Università degli Studi di Milano, Milan, Italy*

Background: Our aim was to assess the safety and efficacy of transcatheter embolization in the treatment of post-partum bleedings.
Methods: In a single institution, the outcome of 15 patients who underwent transarterial embolization (TAE) for post-partum hemorrhages (PPH) were retrospectively reviewed. Eleven patients presented with hemodynamic instability requiring blood transfusion (73%) and four patients were hemodynamically stable (27%). Arterial embolization was performed with gelatin sponge, particles, and coils.
Results: Mean follow-up time was 21.2 months (range 12–48 months). Technical success rate was 100%. The overall clinical success rate was 100%. No major complications that required intensive care treatment were registered during or after the procedures. No patient required emergency surgery and subsequent hysterectomy. During follow-up, four patients became pregnant after transcatheter arterial embolization and delivered full-term, healthy infants.
Conclusions: TAE is a safe method that allows for the avoidance of surgery and hysterectomy for uncontrollable PPH; a future normal pregnancy after embolization may be hypothesized.

Keywords: *Post-Partum Bleeding; PPH; Post-Partum Hemorrhages; Embolization; Interventional Radiology*

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INTRODUCTION

Life-threatening uterine hemorrhage unresponsive to conservative medical treatment is still one of the leading causes of maternal morbidity and mortality worldwide [1,2]. Among these, post-partum hemorrhage (PPH) is the emergency most commonly encountered in the perinatal clinical practice [2]. PPH has many causes, including uterine atony, lower genital tract lacerations, coagulopathy, and placental anomalies. Uterine vascular abnormalities, including pseudoaneurysms, acquired arteriovenous malformations, arteriovenous fistulas, and rupture of vessels may be caused by uterine curettage or surgical trauma [3]. Correction of coagulopathy and identification of the cause of bleeding are mainstays of treatment [1–3].

In the past, in case of failure of conservative local measures, patients traditionally underwent bilateral hypogastric artery or uterine artery ligation or surgical hysterectomy. Transcatheter embolizations are minimally invasive procedures that may prevent surgery, thus decreasing morbidity and mortality and safeguarding the patient's future fertility potential [4].

In the United Kingdom, the Royal College of Obstetricians and Gynecologists, together with the Royal College of Radiologists and the British Society of Interventional Radiology, has recommended that interventional radiology has to be taken into account in the following circumstances [5]: (a) atonic uterus; (b) surgical complications or uterine tears at the time of caesarean section; (c) bleeding while the patient is in the recovery unit or in the

Corresponding author:
Anna Maria Ierardi, Unità Operativa di Radiologia, Fondazione I.R.C.C.S. Cà Granda Ospedale Maggiore Policlinico, Via Francesco Sforza 35, 20122 Milan, Italy.
Email: amierardi@yahoo.it

Table 1 Patients and procedure characteristics.

Pt	Age	Partum	Haemodynamic Status	CT	Bleeding	Embolic Aagent	FU (m)	Successive Pregnancy
1	22	tv (p)	Stable	No	Uterine a.	Spongostan + PVA	48	Yes
2	30	Cesarean	Stable	Yes	IMA (2°)	Spongostan + coil	12	No
3	21	tv (p)	Unstable	No	Uterine a.	Spongostan + PVA	40	No
4	39	tv	Unstable	No	Uterine a.	Spongostan	32	Yes
5	28	tv (p)	Unstable	No	Uterine a.	Spongostan	32	Yes
6	33	Cesarean	Unstable	No	Pudenda a.	Spongostan + coil	20	No
7	36	Cesarean (p)	Unstable	No	Uterine a.	Spongostan (uni)	28	Yes
8	30	tv	Unstable	Yes	Uterine a. (2°)	Spongostan (uni)	12	No
9	32	Cesarean	Stable	Yes	Uterine a.	Spongostan + coil	12	No
10	27	Cesarean	Unstable	No	Uterine a.	Spongostan	12	No
11	38	Cesarean	Unstable	No	Uterine a.	Spongostan(uni)	14	No
12	40	Cesarean	Unstable	No	Uterine a.	Spongostan	12	No
13	30	tv	Stable	No	Uterine a.	Spongostan + coil	15	No
14	39	Cesarean	Unstable	No	Uterine a.	Spongostan	12	No
15	26	Cesarean	Unstable	No	Uterine a.	Spongostan	18	No

Pt: patient; CT: computed tomography; FU: follow up; m: months; tv: trans vaginal; p: primiparous; a:artery; IMA: inferior mesenteric artery; PVA: polivinyl alcohol; 2°: secondary PPH; uni: unilateral.

postnatal ward, following a natural delivery or a caesarean section; and (d) bleeding after hysterectomy [6]. In general, transarterial embolization (TAE) may be performed to treat uncontrolled bleeding associated with various obstetric conditions [4].

The aim of our study was to review our experience and to analyze, in a long-term follow up, the outcome of our cohort of patients treated with transcatheter embolization after PPHs.

METHODS

In our institution, during the past 3 years, 15 cases of post-partum arterial bleedings were diagnosed, which consisted of a pseudoaneurysm of a branch of the internal pudendal artery ($n = 1$), a blush of a branch of the inferior mesenteric artery (IMA; $n = 1$), and blushes from branches of the uterine artery ($n = 13$; Table 1). All patients were within the reproductive age group (21–40 years old) and were referred from the gynecologists to our Service of Interventional. Radiology for intractable vaginal bleeding ($n = 11$) and pelvic hematoma ($n = 4$). Hemorrhage was attributed to surgical maneuvers ($n = 9$) or to placental abnormalities (placenta previa ($n = 6$)) in accordance with gynecological report. Four patients were primiparous. TAE represented the first-choice treatment in the series described.

Five patients had natural delivery and ten patients underwent cesarean section. Primary or early PPH is defined as blood loss >500 ml (natural childbirth) and >1000 ml (cesarean section) within the first 24 h after delivery; secondary or delayed PPH occurs more than 24 h after delivery [1,7]. In all cases, the initial treatment consists of the administration of uterotonic drugs, such as oxytocin or prostaglandin E2 analogs, but if they fail, other management options should be considered. Laboratory data included platelet count, prothrombin time-international normalized ratio, fibrinogen, fibrin degradation products, and anti-thrombin-III , as well as hematocrit and hemoglobin levels. Supportive therapies for blood loss and treatment for coagulopathy were performed when necessary prior to, during, and after embolization.

Indications for diagnostic angiography and endovascular treatment included: signs and symptoms suggestive of vascular injury (such as hemodynamic instability necessitating blood transfusion, uncontrolled intraoperative blood loss, non-resolving vaginal or pelvic hematoma in a hemodynamically stable patient), and suspicious laboratory findings (low hematocrit or hemoglobin levels).

All patients underwent transabdominal and endovaginal grayscale and color Doppler ultrasound; in three cases computed tomography (CT) was performed and it revealed an arterial blush (Figure 1*a,b*). TAE was performed in 12 patients for primary PPH occurring within the first 24 h after delivery and in the remaining 3 patients for secondary PPH that occurred >24 h but <6 weeks from delivery.

Extravasation occurred in all patients. The uterine arteries, or the peripheral branches of the uterine arteries, were embolized unilaterally in 3 patients and bilaterally in 12 patients (Figure 2*a–d*). Regarding the embolization agents, absorbable gelatin sponges were used in all patients ($n = 15$), absorbable gelatin sponges and polyvinyl alcohol (PVA) particles 700–900 μm (Contour Emboli, Boston Scientific Corporation, Natick, MA) were used in two patients, absorbable gelatin sponges and microcoils in four patients (Figure 3*a–d*) and gelatin sponges alone in the remaining patients.

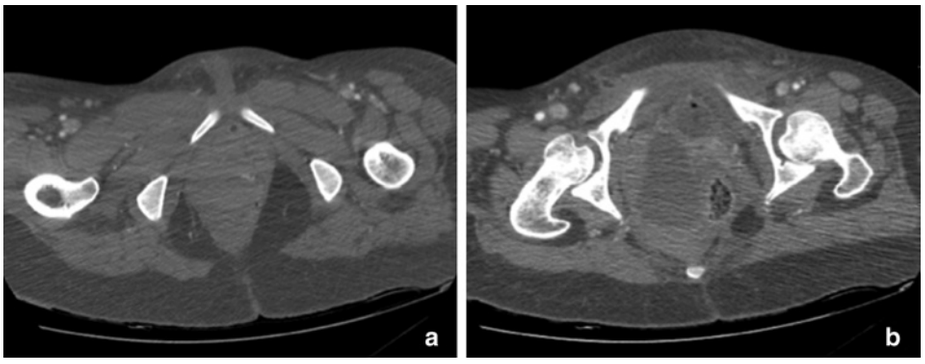

Figure 1 CT scan of a pelvic haematoma. Contrast-enhanced CT shows (**a**) the bleeding site and (**b**) pelvic hematoma.

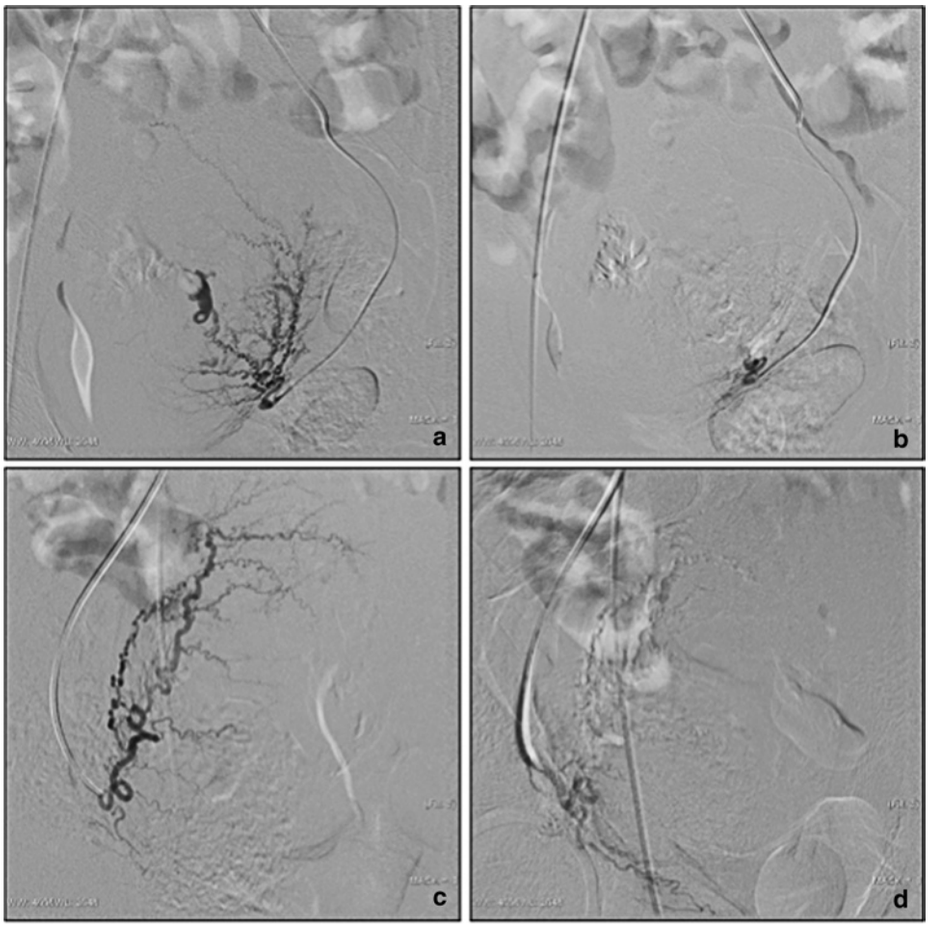

Figure 2 Selective angiograms of uterine arteries. (**a**) Contrast medium blush from branches of left uterine artery is revealed by selective angiogram. (**b**) Angiogram performed after embolization with gelatin sponge revealed complete embolization. (**c**) Angiogram of right uterine artery did not show bleeding. (**d**) Final angiogram performed after gelatin sponge embolization revealed devascularization of the treated area.

The efficacy of TAE was evaluated according to the halting of blood loss, considering both clinical and laboratory parameters. Complete hemostasis was defined based on hemodynamic parameters, hemoglobin level, and vaginal blood loss per hour.

Procedure

All endovascular procedures were performed by an interventional radiologist. Selection of embolic agents was based on the doctor's personal experience and

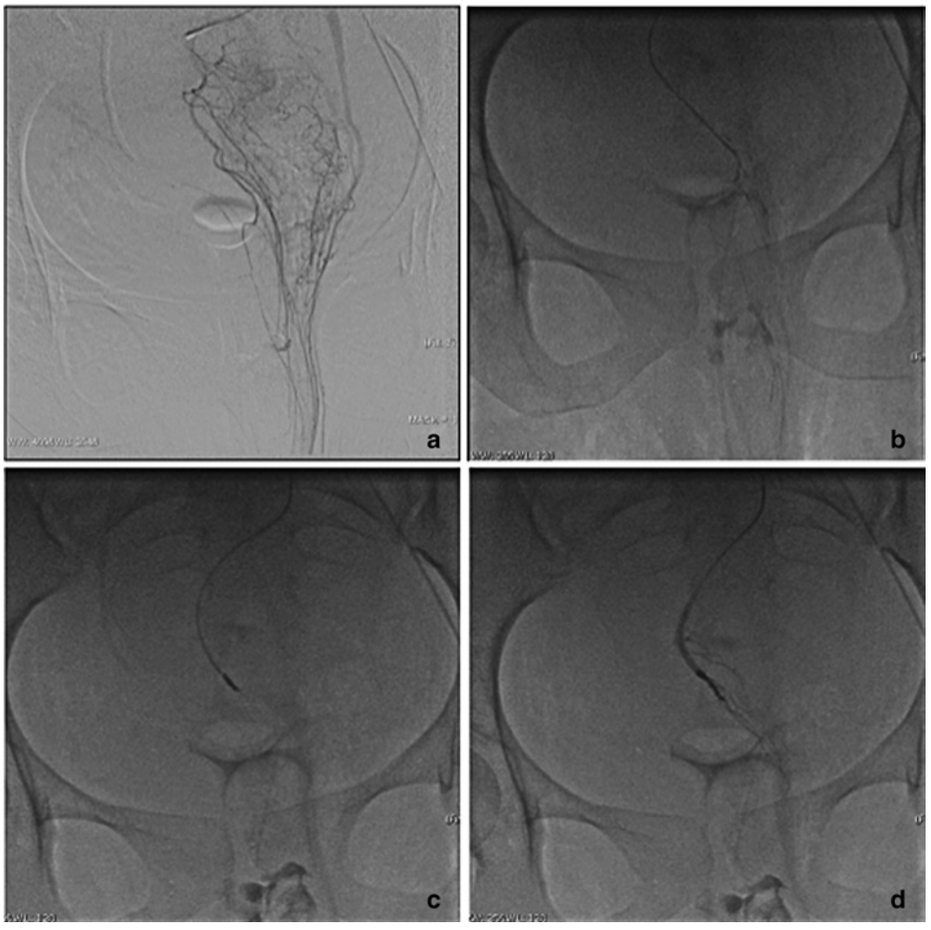

Figure 3 Selective angiogram of the inferior mesenteric artery. (a) Initial angiogram revealed bleeding from branches of inferior mesenteric artery. (b) Selective catheterization of one of the superior rectal branches permitted (c) super-selective embolization performed with coils. (d) Final angiogram revealed complete embolization.

preference, considering also site and type of vascular injury. In all cases, an anesthesiologist assisted with the procedure.

The procedure was performed in the angiography suite (GE-Innova 2100-IQ, GE Healthcare, USA) under local anesthesia and continuous cardiovascular and respiratory monitoring. Before treatment, each patient received an intravenous dose of 5% mannitol, 3 ml/kg/min of dopamine plus 600 mg of intravenous N-acetylcysteine as a protection against the ischemia-related production of free radicals and contrast medium-induced renal damage. Short-term antibiotic prophylaxis with a first-generation cephalosporin (cefazolin 2 gr) was initiated at the beginning of each endovascular procedure.

In all patients, from a common femoral approach, a bilateral selective internal iliac angiography and inferior mesenteric artery angiogram was initially performed, using a 5-F rim or a vertebral and/or a Simons 1 catheter (Cordis, Miami Lakes, FL, USA), followed by selective bleeding vessel digital subtraction angiography. Superselective embolization was carried out with a 2.7-F coaxial microcatheter (Progreat, Terumo, Tokyo, Japan). A femoral sheath was left in place for 24–48 h until hemodynamic and laboratory data confirmed patient stability.

Follow-up

All patients were closely monitored (symptoms and laboratory data) every 6 h in the first 48 h and for 1 week after the endovascular procedure. A CT scan and/or color Doppler ultrasound was performed to rule out new and/or residual bleeding, pseudoaneurysms, or fistulas in cases of incomplete hemodynamic stabilization (n = 2); in both cases a new bleeding site was not detected. The embolization procedure must be repeated if the indication persists. The interval between completion of the intervention and first imaging follow-up was in the range of 3 days to 2 months. A minimum 12-month follow-up was available for all of our patients who underwent embolization.

Outcomes

Technical success, clinical success, and complications were evaluated. Technical success was defined as the stopping of bleeding with the restoration of peripheral flow. Early clinical success was defined as cessation of symptoms and stabilization of laboratory data within 24 h and again within 1 week after endovascular procedure (i.e. absence of recurrent hemoglobin level drops <1.5 g/dl, circulatory stabilization). Late success was defined as absence of reperfusion of bleeding during follow-up, and the proportion of injuries that did not require a new endovascular treatment or subsequent surgical intervention; moreover, during follow-up, new pregnancies were registered and evaluated as late clinical success. All complications were recorded and classified according to the Society of Interventional Radiology classification [8].

Ethical Approval and Informed Consent

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

RESULTS

Hysterectomy was avoided in all cases. All patients underwent a Doppler ultrasound immediately after embolization, before discharge, and then usually at 3-month intervals for 1 year and yearly for up to 3 years. No recurrence was detected at follow-up US. Two patients underwent a new CT scan for incomplete hemodynamic stabilization, but a new bleeding site was not identified.

Technical success rate was 100% as shown by the complete exclusion of bleeding on angiography performed at the end of the procedure. After the procedure, in all patients, return to hemodynamic parameters was obtained with increased blood pressure and normalization of peripheral pulses. No patient required conversion to open surgery and none required a second treatment, whether surgical or endovascular.

Clinical success, early and late, attributed to endovascular therapy alone was documented in every patient (100%). During follow up (12–48 months), no recurrence of bleeding or sequelae related to non-target embolization was registered; moreover, four patients became pregnant again, and all of them delivered full-term, healthy infants with no abnormal delay in conception.

No major complications requiring intensive care were encountered during or after the procedure; mild post embolization syndrome was registered in four patients.

DISCUSSION

In this study, the efficacy of TAE for PPH was evaluated by analyzing the blood loss and the time interval from the end of TAE to complete hemostasis. PPH refractory to conventional procedures was well controlled by endovascular procedure alone, with a success rate of 100%.

In a literature review, the only predictive factor for the efficacy of endovascular procedure resulted in the presence or absence of coagulopathy [9]. In our series, none of the patients presented coagulopathy. In all cases, in accordance with the gynecological report, extravasation of contrast media was attributed to a surgical maneuver. The embolic agent of choice is gelatin sponge, which provides temporary occlusion with recanalization of the arterial bed in 3–6 weeks, in accordance with literature data [6]. In this particular series, absorbable gelatin sponges were used in all cases. Gelatin sponge relies on the clotting cascade and is functionally impaired in the setting of disseminated intravascular coagulation. Based on the operator's preference, coils were utilized to embolize bleeding from branches of the pudendal artery and the IMA; PVA particles were used selectively to help hemostasis when absorbable gelatin sponges were considered insufficient. Microspheres leave the capillary bed intact, and there is limited potential for recanalization. To avoid uterine necrosis, 500–900 μm particles are preferred; necrosis has been described with both absorbable and non-absorbable embolics.

The use of a permanent embolic agent for the embolization of the distal branch of the uterine artery preserved uterine perfusion and future fertility in one of our cases. Permanent agents such as particles have also been used successfully to control PPH, both alone and in combination with gelatin sponge [10].

Small embolic particles (150–250 μm) should be avoided because they can potentially increase the risk of ischemic complications [11]. Other agents, such as n-butyl-2-cyanoacrylate (NBCA) or coils, may be of particular value in genital tract tears and arteriovenous fistulae. Moreover, NBCA may be useful in cases where total vessel occlusion is necessary, such as recurrent PPH after TAE [12].

According to the localization of puerperal hematoma, it can be classified as vulvar, vulvo-vaginal, and retroperitoneal [13]. Localization of the hematoma depends on the blood vessel. One of our patients presented with bleeding from a branch of the inferior mesenteric artery; on the basis of the surgical history, this complication has been linked to an injury during the cesarean section.

In our cohort, six cases of PPH have been attributed to placenta previa, which is strongly associated with maternal hemorrhage, even though most literature focuses on morbidity in the setting of placenta accreta [14]. The fact that no cases of PPH related to placenta accreta were registered may depend on the fact that in those cases, which are considered high risk, more effective precautions are taken during pregnancy and before delivery.

TAE should be considered before surgical alternatives because arterial ligation makes subsequent TAE difficult [15] but not impossible [16,17]; moreover, embolization does not preclude later surgery.

Complications after arterial embolization are rare [6]. Postembolization syndrome should be expected and includes transient abdominal pain, fever, nausea, and mild leukocytosis.

Ischemic complications are rare but may occur if small embolic particles are used or if there is an interruption of collateral supply by previous surgical ligation of the internal iliac artery [18]. Buttock ischemia, small bowel necrosis, and uterine, vaginal, cervical, and bladder necrosis have all been reported [6,18].

Only limited data are available on the long-term follow-up of women and their future fertility after TAE [6,18,19]. In our small series, in a mean follow-up of 21.2 months, four women have become pregnant after embolization, and delivered full-term, healthy infants.

Limitations of this study are mainly its retrospective nature and the small number of patients yielding an absence of statistical power. However, the results confirm that TAE is a safe alternative method to treat uncontrollable PPH and should guarantee a normal pregnancy after embolization.

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

AMI, EMF wrote the paper and collected data. AP collected data. MS and GC reviewed the paper. All authors approved the paper.

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Case Report

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Extracorporeal Cardio-Pulmonary Resuscitation (E-CPR) in Traumatic Cardiac Arrests Caused by Penetrating Thoracic Injuries: A Series of Two Cases

Viktor A Reva MD PhD[1], David T McGreevy MD[2], Eduard A Sinyavskiy MD PhD[1], Daniil A Shelukhin MD PhD[3], Alexander N Petrov MD PhD[1], Alexander A Rud' MD PhD[1], Evgeniy N Ershov MD PhD[4], Grigory E Lysenko MD[4] and Igor M Samokhvalov MD PhD[1]

[1]Department of War Surgery, Kirov Military Medical Academy, Saint-Petersburg, Russia
[2]Department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Örebro, Sweden
[3]Nikiforov Russian Center of Emergency and Radiation Medicine, Saint-Petersburg, Russia
[4]Department of Anesthesiology and Reanimatology, Kirov Military Medical Academy, Saint-Petersburg, Russia

Background: We present two cases of thoracic penetrating injuries that necessitated extracorporeal cardiopulmonary resuscitation (E-CPR).
Methods: Two male patients were admitted to hospital within 20–25 min: one with a chest stab wound and the other with a gunshot injury. Upon ongoing CPR, patient #1 underwent resuscitative sternotomy. Bleeding from a right ventricle injury was controlled, but cardiac arrest (CA) re-occurred. Patient #2 underwent immediate surgery due to multiple rib fractures and massive hemopneumothorax, and experienced multiple CAs. Due to refractory asystole with ongoing CPR, extracorporeal membrane oxygenation (ECMO) was initiated after 100 and 135 min, respectively. Primary lactate levels in cases #1 and #2 were 8 and 20 mmol/L, respectively.
Results: In both cases, the femoral artery (17–19 Fr) and vein (25–27 Fr) were cannulated and connected to the Maquet ECMO circuit with a flow rate of 4–5 L/min. Return of spontaneous circulation was achieved within 20 min after ECMO initiation with relative stabilization. In patient #1, postoperative bleeding necessitated re-thoracotomy and hemorrhage control. In patient #2, left pulmonectomy and ligation of intercostal arteries was performed. 12/30 units of red blood cells, 16/45 units of fresh frozen plasma, and 2/8 units of platelets were given in cases #1/2, respectively. Lactate level increased to 25 mmol/L and decreased to 8 mmol/L in 5 hours, respectively. Both patients died in the ICU within 9 and 13 hours after admission due to bleeding.
Conclusions: E-CPR allows vital function protection even in traumatic CA but necessitates appropriate resuscitation. If no bleeding control is achieved, then E-CPR is futile .

Keywords: *Thoracic Injury; ECMO; Cardio-Pulmonary Resuscitation; Cannulation; Endovascular Trauma Management*

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Corresponding author:
Viktor A. Reva, Department of War Surgery, Kirov Military Medical Academy, 6 Lebedeva str. Saint-Petersburg, Russian Federation 194044.
Email: vreva@mail.ru

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INTRODUCTION

Penetrating thoracic injury remains one of the main causes of pre-hospital and early in-hospital cardiac arrest (CA) and death. Sudden deterioration can be due to either hemorrhagic or obstructive shock. The former results from uncontrolled massive bleeding into a pleural cavity, while the latter is caused by cardiac injury and intrapericardial bleeding followed by cardiac tamponade.

In the case of sudden CA caused by a penetrating thoracic injury, early resuscitative thoracotomy is considered the best option to release tamponade, cross-clamp the

aorta, and/or control bleeding. Without appropriate surgery, a standard protocol of cardio-pulmonary resuscitation (CPR) is often futile and the chance of survival in traumatic CA (TCA) is diminished. A source of hemodynamic instability has to be addressed early and controlled to maintain circulation volume and organ perfusion.

A method of veno-arterial extracorporeal membrane oxygenation (V-A ECMO) or extracorporeal CPR (E-CPR) has been proposed and implemented into clinical practice to give artificial circulatory support during non-traumatic CA [1]. It is now widely used even for out-of-hospital medical CA by emergency ECMO teams in some developed countries [1–3].

E-CPR, however, has some significant limitations in trauma associated with uncontrolled bleeding and the extensive heparin administration used to maintain the ECMO circuit. Its use in TCA is still controversial because a trauma patient has a high risk of associated traumatic brain injury, acute coagulopathy, and may have hidden hemorrhagic loci. However, some promising reports of successful V-A ECMO use in polytrauma and bleeding shock have recently been published in the literature [4–6]. While these papers describe predominantly blunt trauma, data concerning E-CPR use in penetrating injuries is lacking [6].

We present two cases of penetrating thoracic injuries with attempted E-CPR that led to intermittent return of spontaneous circulation (ROSC) but ultimately failed to restore perfusion.

Overview

The two patients suffered penetrating thoracic trauma but underwent surgery in different environments. The first patient (case #1) was stabbed in close proximity to a designated level 1 trauma center, while the second patient (case #2) received an injury from a sawn-off shotgun within a public hospital that is not a trauma center and provides only elective daily surgery. In these two cases, different door-to-surgery times but similar time to initiation of ECMO were recorded. Experienced specialists and advanced technology were used similarly in both cases. No ultrasound was used to evaluate cardiac activity.

Description of Cases

Case #1

A 25-year-old man was admitted with ongoing CPR to a trauma center within 20 min of receiving a midline chest stab injury at the base of the xyphoid process. Before admission, he was intubated, closed cardiac massage was initiated, but no intravenous (IV) access was achieved. The patient received 100% oxygen and monitoring showed pulseless electrical activity. Chest compressions were delivered using a mechanical device (Lucas 2®, Sweden) and the patient was immediately transported directly to an operation room (OR), bypassing the emergency department. An intraosseous needle (Novoplast-M®, Russia) was injected into the tibial plateau for fluid replacement therapy and surgery was initiated.

After removal of Lucas 2®, an immediate median sternotomy was performed to release cardiac tamponade and a through-and-through right ventricle injury was sutured followed by open cardiac massage (OCM; Figure 1). Both pleural cavities were simultaneously drained. Abdominal focused assessment with sonography for trauma (FAST) was negative. Aggressive administration of fluids and inotropes through established large-bore central IV-lines along with OCM resulted in a temporary ROSC followed by repeated CAs and fibrillations (6 times), requiring electrical defibrillations and OCM. Arterial blood gases (ABG) within 60 min after admission demonstrated severe acidosis: pH 6.996; base excess –19 mmol/L; lactate 8 mmol/L; partial pressure of oxygen (pO_2) 251 mmHg; partial pressure of carbon dioxide (pCO_2) 49.8 mmHg; oxygen saturation (sO_2) 99%; hemoglobin 7 g/dL; and ROTEM demonstrated severe coagulopathy (internal thromboelastometry (INTEM): clotting time CT 750 s [normal range, (NR) 100–240]; external thromboelastometry (EXTEM): CT 151 s [NR 38–79 s], α angle 33° [NR 70°–83°], Amplitude at 10 min (A10) 7 mm [NR 43–65], no other parameters were detected by the machine).

During the resuscitative efforts, including blood transfusions and CPR, secondary FAST examination showed free fluid in the abdomen that necessitated a midline laparotomy. Superficial liver lacerations were found and tight perihepatic packing was effectively performed. Shed blood from both thoracic and abdominal cavities was collected using a Haemonetics Cell Saver® 5+ Autotransfusion System (USA) and subsequently re-infused (7160 mL).

After one hour of intermittently effective resuscitative efforts requiring repeated short-term aortic cross-clamping via an additional left lateral incision (supraceliac clamping was avoided due to perihepatic packing), the decision was made to initiate ECMO to maintain perfusion of vital organs. Within 100 min after admission, the unilateral (right) femoral artery and vein were cannulated in an open fashion (the semi-Seldinger technique) by an ECMO team using 17-Fr and 25-Fr cannulas, respectively, and connected to the Cardiohelp ECMO (Maquet, Germany) circuit with a flow rate of 4–5 L/min. ROSC was achieved 28 min after ECMO initiation (2 hours after hospital admission) with relative stabilization of mean arterial pressure at 50–60 mmHg.

At this stage, ABG had improved: pH 7.263; base excess –11 mmol/L; pO_2 421 mmHg; pCO_2 33.4 mmHg; sO_2 100%; hemoglobin 8 g/dL; platelets 45×10^9/L. However, the ionized calcium level decreased from 0.61 to 0.47 mmol/L despite calcium chloride administration.

Figure 1 Emergency sternotomy and open cardiac massage along with an open femoral cutdown (for fluid replacement followed by extracorporeal membrane oxygenation cannulation) performed on patient #1 admitted with ongoing cardio-pulmonary resuscitation.

Intraoperatively, in addition to autologous transfusion, the patient received 12 units of red blood cells (RBCs), 16 units of fresh frozen plasma (FFP), and 2 units of platelets. At the end of surgery his lactate level worsened to 25 mmol/L and ROTEM continued to demonstrate hypocoagulation (INTEM: CT 1099 s, α angle 12°, A10 9 mm, (Lysis Index after 30 min) LI30 100% [NR 94–100%]; EXTEM: CT 110 s, α angle 14°, A10 12 mm, LI30 100%). Clinically, postoperative bleeding from the thoracotomy wound occurred that necessitated re-thoracotomy and hemorrhage control.

The patient was referred to the intensive care unit (ICU) where he continued to deteriorate with permanent CA, a decrease in blood pressure despite extracorporeal life support, and limited passive movements in the joints of both legs. Further care was deemed futile and discontinued within 9 hours after admission.

Case #2

A 61-year-old deputy medical director of a public hospital was assaulted by an agitated patient and suffered a gunshot injury to his left chest. He was found pale, pulseless, breathless, and unresponsive in his office by medical staff immediately after being shot. External CPR was initiated; definitive airway followed by bag ventilation was achieved before transport to an OR. Within 8 min after injury, the patient underwent resuscitative left antero-lateral thoracotomy through the fifth intercostal space. Approximately 2 L of fresh and clotted blood were evacuated from the pleural cavity. Injuries had been sustained to multiple left lung, intercostal, and left internal thoracic arteries. No cardiac injury was found after pericardiotomy and exposure of the arrested heart. OCM was initiated. For adequate fluid resuscitation, open cutdown access to both femoral veins was achieved followed by cannulation and massive fluid replacement therapy. Bleeding from multiple lung wounds re-occurred, were difficult to control, and necessitated left total pneumonectomy using a linear stapler (Ethicon Inc., USA); injured intercostal arteries were ligated. A cardiac surgeon and an ECMO team were called for a suspected blunt cardiac injury with development of cardiogenic death. A femoral artery was cannulated for intra-aortic balloon pump (IABP) insertion, and a temporary cardiac pacer was implanted. These efforts resulted in a temporary ROSC. Intermittent cardiac massage and defibrillations (19 times in total) along with attempts at hemorrhage control lasted for 2 hours. Diffuse bleeding from the ruptured muscles and vessels from the back of the pleural cavity was controlled by tight packing. Due to refractory asystole, the left femoral artery (19 Fr) and vein (an upsize from a previously inserted catheter to a 27-Fr ECMO cannula) were cannulated via the cutdown access and connected to the Rotaflow ECMO (Maquet, Germany) circuit with a flow rate of 4 L/min, 135 min after injury (Figure 2). Aggressive transfusion with 30 units of RBCs, 45 units of FFP and 8 units of platelets, and ECMO support resulted in a decrease in lactate level from 20 mmol/L upon admission to 8 mmol/L, and relative stabilization of systolic BP from around 40–50 mmHg to more than 80 mmHg. After 7 hours of surgery, the patient was referred to an ICU where he continued to deteriorate and, 13 hours after injury, care was deemed futile and withdrawn.

Ethical Approval and Informed Consent

Ethical approval was not required. Informed consent was not possible because of a clear, immediate and serious threat to patients' life and the information has been anonymized.

DISCUSSION

E-CPR with ECMO is a sophisticated treatment option which may improve outcomes in a selected patient population and, when compared with conventional CPR, yields more neurologically intact survivors [7]. Data published on the use of E-CPR is still limited and its use is often part of an aggressive approach to resuscitation. E-CPR in the trauma population remains controversial and viewed by many as challenging with the risk of hemorrhage, especially in cases of severe coagulopathy, contraindications to anticoagulant use, or traumatic brain injury [8]. Nevertheless, recent growing evidence suggests that applying ECMO as a rescue therapy in trauma patients may provide potential survival benefits [9].

Both patients in this case report suffered from TCA following penetrating thoracic trauma. They were both quickly taken to an OR and received CPR with repeated defibrillations and massive transfusion, and V-A ECMO

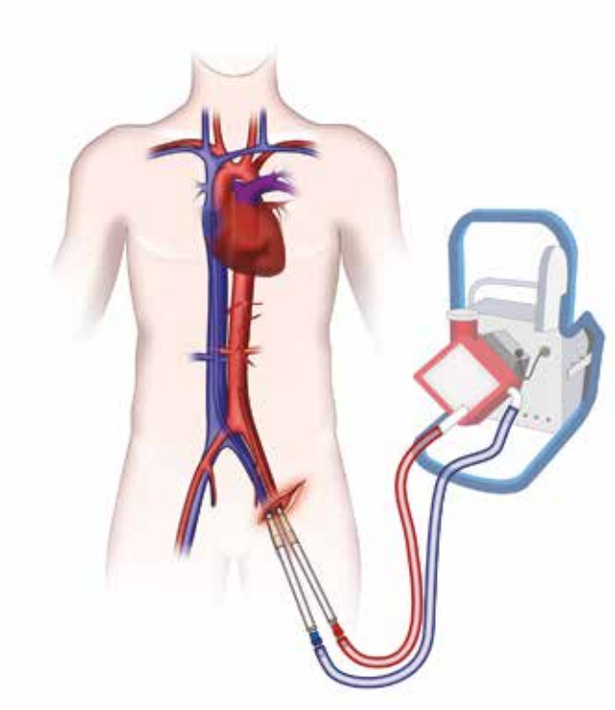

Figure 2 Schematic illustration of the extracorporeal membrane oxygenation circuit and open cannulation technique used in our patients.

was initiated within 120–135 min. However, the ECMO programs in these two hospitals differ. The patient in case #1 was taken to a level 1 trauma center and initially submitted to aortic cross clamping. This hospital has the capacity for ECMO on-site including the machine, instruments, and specialists available 24/7. Whereas in case #2, the ECMO team had to be called to the patient who received an IABP while waiting. According to the city program, this ECMO team is based at one hospital serving a whole area and has a fully equipped "ECMO-mobile" available 24/7 to be transferred to small hospitals if required.

It could be argued that resuscitative endovascular balloon occlusion of the aorta (REBOA) possibly should have been considered in both patients, if placed early during CPR and used as a bridge to ECMO; however, the use of REBOA in penetrating thoracic injury is currently considered to be contraindicated. While a REBOA-catheter was unavailable in case #2, an attempt to support hemodynamics by using the IABP was undertaken. The underlying reason was also to increase postload if blunt cardiac injury (by shock waves) took place. Other bridging techniques for severely unstable or even arrested patients have been described in the literature, such as selective aortic arch perfusion [10] and different mechanical devices, e.g. Impella (Abiomed Inc., USA) and others, that can be more suitable options as a bridge to ECMO [11]. Right-sided Impella RP® could, for example, minimize the effect of left-sided pneumonectomy (case #2) by removing blood from the inferior vena cava and ejecting it into the pulmonary artery, thus avoiding right heart failure. However, all these devices are very expensive and require fluoroscopy guidance for correct placement.

Placing the patients on ECMO allowed for the stabilization of blood pressure and relieved the heart by unloading the right atrium and ventricle, which intermittently resulted in periods of ROSC. In both cases, a high blood flow rate of 4–5 L/min was used to reduce the risk of blood clotting in the ECMO device since appropriate anti-coagulation to prevent thrombosis is contraindicated in trauma patients who are already coagulopathic as it might cause, or further contribute, to severe hemorrhage. Avoiding the use of heparin was particularly important in case #2 as attempts at hemorrhage control lasted several hours. It is, however, important to remember the severe coagulopathy that occurs after trauma and cardiac arrest with a profound alteration of hemostasis and risk of developing organ dysfunction. Cardiac arrest with the acute lack of pulsatile blood flow facilitates rapid clot formation. After CPR and ROSC there is a brief period of systemic fibrinolysis that is later replaced by a prolonged hypercoagulable state. Trauma with tissue injury causes the release of factors that are responsible for coagulopathy, fibrinolysis, and activation of inflammatory pathways. This is important during ECMO treatment and therefore continuous monitoring of prothrombin time, international normalized ratio, and activated partial thromboplastin time is necessary throughout the procedure. The balance between minimizing the risk of surgical hemorrhage by not administering anticoagulants and the risk of an ECMO circuit thrombosis due to inadequate anticoagulation is always challenging, especially in severe trauma [12]. Despite aggressive resuscitation, both patients remained in hypocoagulation status. For better control of coagulation, viscoelastic assays, e.g. thromboelastography or ROTEM, have been proposed and are now widely used for patients with hemorrhages [13]. Low EXTEM clotting time is associated with an increased bleeding tendency and indicates a likely factor deficiency. Fibrinogen is the first coagulation factor that reaches critically low levels during major hemorrhage and remains low during ECMO. The administration of tranexamic acid is regularly used in trauma because of its antifibrinolytic effect and administration can be continued with signs of bleeding during ECMO support. In case #1, ROTEM demonstrated a certain improvement over the course of treatment, with fibrinolysis at least being controlled (LI 30 turned to NR in a few hours). In case #2, however, no coagulation monitoring was available at the treatment facility.

ECMO clearly plays an important role in trauma patients; however, evidence is still lacking. The first large multicenter report of trauma patients treated with ECMO by Swol et al. [7] showed a favorable survival rate of 61%. Unfortunately, in the cases presented here,

both patients finally deceased as a result of failure to restore perfusion within an adequate time period and may have benefited from being started on ECMO earlier in the course of treatment. It is important that the decision to place a patient on ECMO is made early, as time from decision to initiation of treatment takes on average 20–30 min if the treating facility has an ECMO team on-site. In addition to an early decision to start ECMO, a few other factors can theoretically improve survival in these critically unstable patients: a dedicated team readily available 24/7, including a cardiac surgeon, anesthetist, and perfusionist; a loaded ECMO set of instruments, lines and cannulas in the emergency department; extensive monitoring; and a free approach to blood and components (even whole blood), coagulation factors, etc. The decision to start ECMO is made by both anesthetist and surgeon based on vital signs upon admission and duration of CPR. Refractory CA, defined as 10–30 min of CPR without ROSC, can be an indicator for when ECMO might be implemented. Although optimal duration of CPR for successful ROSC is unknown, Lee et al. reported a case of successful ECMO combined with hypothermia in an arrested patient who suffered from a penetrating cardiac injury previously treated with 10 to 20 min of CPR [14]. Once the decision to start ECMO is made, the initiation of the procedure should begin as early as possible. Further studies are warranted to define indications for ECMO in TCA, particularly in chest injuries.

CONCLUSION

This case report demonstrates that ROSC can be achieved in patients with penetrating traumatic injuries and TCA with the use of ECMO without the administration of heparin. It is becoming increasingly clear that E-CPR with ECMO plays an important role in the treatment of trauma patients, but the exact role that it should play is as yet unknown and further investigation is therefore needed.

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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

VAR, DM, and EAS carried out the study design, data interpretation, and manuscript writing. DAS, AAR, ANE, and GEL perfromed data analysis and interpretation. IMS and ANP carried out critical revision and work supervision.

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Narrative Review Article

The Interventional Radiology Service During the COVID-19 Pandemic: Steps for Managing the Risk of Infection

Anna Maria Ierardi MD[1], Aldo Carnevale MD[2], Melchiore Giganti MD PhD[3] and Gianpaolo Carrafiello MD PhD[1,4]

[1]Radiology Department, Fondazione IRCCS Cà Granda, Ospedale Maggiore Policlinico, Milan, Italy
[2]University Radiology Unit, Radiology Department, Arcispedale Sant'Anna, Ferrara, Italy
[3]Department of Morphology, Surgery and Experimental Medicine, Radiology Section, University of Ferrara, Ferrara, Italy
[4]Department of Health Sciences, Università degli Studi di Milano, Milan, Italy

It is imperative to ensure the safety of health-care workers in the angiographic room during the outbreak of the coronavirus disease 2019 (COVID-19). The selection criteria for interventional radiology (IR) procedures, the preparation of the staff and angiographic suite, ventilation systems, and intra- and post-procedural workflow optimization methods are detailed. The specific measures needed to protect occupational safety and health may result in higher costs, longer procedural times, and greater technical problems. However, these precautions may help to minimize the spread of COVID-19 among IR practitioners.

Keywords: *Coronavirus Disease 2019; COVID-19; Interventional Radiology; Angio Suite*

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INTRODUCTION

Worldwide, health-care systems are facing a critical situation from the coronavirus disease 2019 (COVID-19) pandemic. It is mandatory that interventional radiology (IR) services, as a major arm of radiology departments and modern health care, can be appropriately provided under these extraordinary circumstances. Indeed, essential activities should be identified and prioritized in an effort to maintain continuity of service delivery; strategic shifts should be planned to provide maximum benefit for the patients using increasingly limited resources. These essential activities in IR settings account for the whole spectrum of emergency procedures, for instance embolization for bleeding control or endovascular treatment of stroke. Other non-deferrable interventions, such as those dedicated to critical health conditions in oncology, should also not be discontinued. However, the outbreak of the novel COVID-19 pandemic may find some IR services unprepared. This paper may help IR staff to navigate through these new challenges.

COVID-19 is officially a pandemic, first recognized in December 2019 in Wuhan, China. The disease was rapidly shown to be caused by a novel coronavirus that is structurally related to the virus causing severe acute respiratory syndrome (SARS), subsequently named SARS-CoV-2. An efficient coronavirus human-to-human transmission is the cause of the rapid spread of this outbreak; to date, in Italy over 100,000 cases [1] have been reported and almost half of these are registered in our area (Lombardy) [1,2]. The virus is most likely to be transmitted via respiratory secretions in the form of droplets or aerosols [3]; fomite transmission may constitute another method of contagion [3] since the virus may remain viable for hours to days depending on the type of contaminated surface [4].

Due to the high percentage of aerosol-transmitted infections and possible permanence of the virus on surfaces, the main public health preventive advice focuses on social distancing and hygiene. These general principles are also applied to health systems and, consequently, to IR units, in light of the risk of nosocomial spread of infection. Therefore, proper preparation is crucial to reduce

Corresponding author:
Anna Maria Ierardi, Unità Operativa di Radiologia, Fondazione I.R.C.C.S. Cà Granda Ospedale Maggiore Policlinico, Via Francesco Sforza 35, 20122 Milan, Italy.
Email: amierardi@yahoo.it

exposure of health-care workers and other patients in IR. As long as possible, in regions with a heavy burden of the COVID-19 pandemic, every patient and health-care provider should be screened through real-time reverse transcription polymerase chain reaction tests for the detection of SARS-CoV-2. Patients with uncertain diagnosis should be managed as infected ones, and preventive quarantine should be applied to health-care workers also uncertainly diagnosed.

Dedicated paths to the angiographic suite should be planned for the isolated patients, including designated elevators and routes when possible, in an effort to minimize contact with other patients and staff. Indeed, few IR services are provided with distinct outpatient, inpatient, and isolation facilities; otherwise, developing a work plan based on temporal segregation to different groups of patients may be a solution. Moreover, other departments equipped with portable fluoroscopic units (i.e. operating theaters) may be temporarily made available to IR practitioners.

SELECTION OF THE PROCEDURES

A robust planning and deep reorganization of the IR workflow are fundamental, largely driven by the severity of COVID-19 dissemination in the area and local policy. First, it is pivotal to determine which procedures are non-urgent and can be delayed or rescheduled. Essential procedures for life-threatening conditions (i.e. intravascular embolization for bleeding control, thrombectomy for stroke, acute mesenteric ischemia treatment, endovascular repair for aortic rupture), urgent treatments in oncology patients (percutaneous biliary drainage, percutaneous ablation and chemoembolization in selected cases, bridging therapies for liver transplant, and a few others), and treatment of time-sensitive conditions and organ-sparing procedures (urgent diabetic foot angioplasty, percutaneous nephrostomy, prophylactic occlusion balloon placement for the prevention of postpartum haemorrhage in patients with abnormal placental implantation) must be regularly delivered. Other procedures may be discussed in a multidisciplinary team based on a case-by-case perspective. When necessary, ultrasound (US)-guided interventions should be performed at the patient's bedside in their isolation room.

The use of bedside US in the patient's isolation room to guide procedures increases safety by reducing the nosocomial spread of COVID-19. Indeed, US should be considered the modality of choice to guide an increasing number of interventions. Before entering the isolation room, the US system must be covered using transparent plastic and the probe must be protected with a sterile probe cover. The covers must be removed after the end of the procedure, before leaving the room, and the machine must be cleaned with chlorhexidine-ethanol solutions.

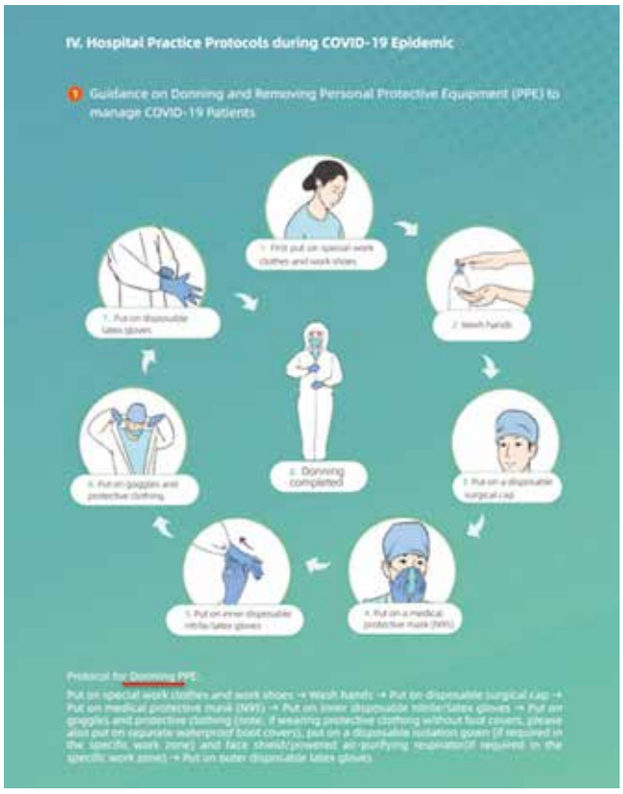

Figure 1 Guidance on donning personal protective equipment (PPE). From "Handbook of COVID-19 Prevention and Treatment". The First Affiliated Hospital, Zhejiang University School of Medicine. Compiled According to Clinical Experience. Tingbo Liang, Editor in Chief.

PREPARATION

Adequate personal protective equipment (PPE) is fundamental, and must be available on-hand and securely stored. Education on proper usage should be given to staff, particularly in the first phase of the emergence (Figure 1). All pre-procedural preparations should be completed before the arrival of the patient, aiming to minimize the unnecessary time spent in the department and possible contact with other patients and health-care professionals. Angiographic room staff should put on, use, take off, and dispose of PPE properly; this includes gowns, gloves, masks, eye protection, and shoe covers.

To avoid contamination, non-essential and mobile equipment needs to be removed from the angiographic room. Clean towels should be used to cover fixed and essential contact surfaces, whereas plastic should be preferred for control panels and changed between consecutive patients (Figure 2*a*,*b*). Proper cleaning supplies should be ensured for clean and contaminated work areas separately.

Other staff such as administrative workers should be kept at a safe distance from the patients in separate areas; they do not require PPE [5].

Health-care workers are in the front line of any outbreak response, and are subsequently exposed to hazards

Figure 2 Angiosuite fully equipped before the arrival of the patient. (**a**) Fixed and essential contact surfaces covered with clear towels. (**b**) PPE of the operator, including eye protection and lead apron, face shield, sterile gown, and gloves.

that include not only exposure to infection, but also long working hours, psychological distress, and fatigue. Consequently, the work schedule for interventional radiologists should be replanned to protect occupational safety and health, and ensure likewise the delivery of essential services. Rotating shifts (possibly per week) may be implemented to limit their exposure and prevent infection.

VENTILATION OF THE ANGIOGRAPHIC SUITE

No dedicated ventilation systems are necessary in the angiographic suite, since SARS-CoV-2, based on the available evidence [3], presents human-to-human transmission through close contact and droplets, not by airborne transmission. Modern angiosuites are usually provided with ventilation systems similar to operating rooms; nevertheless, high-efficiency particulate air filtration systems are advisable when available.

INTRA-PROCEDURAL MEASURES

Adequate PPE is recommended by the World Health Organization (WHO) [5] (Figure 3). Notably, carrying out aerosol-generating procedures on COVID-19 patients requires N95 or FFP2 respirators or equivalent. In the angiographic suite these procedures include, for instance, percutaneous gastrostomy, naso-gastric or naso-jejunal feeding tube insertion, tracheal, esophageal, gastric, or duodenal dilatation or stenting, and bronchial artery embolization [6].

All non-intubated patients who are either infected, or suspected to be, must wear a FFP2 mask in the angiosuite.

The use of the N95 or FFP2 masks must be extended to operators standing at the patient's side during the

Figure 3 Operator during the preparation.

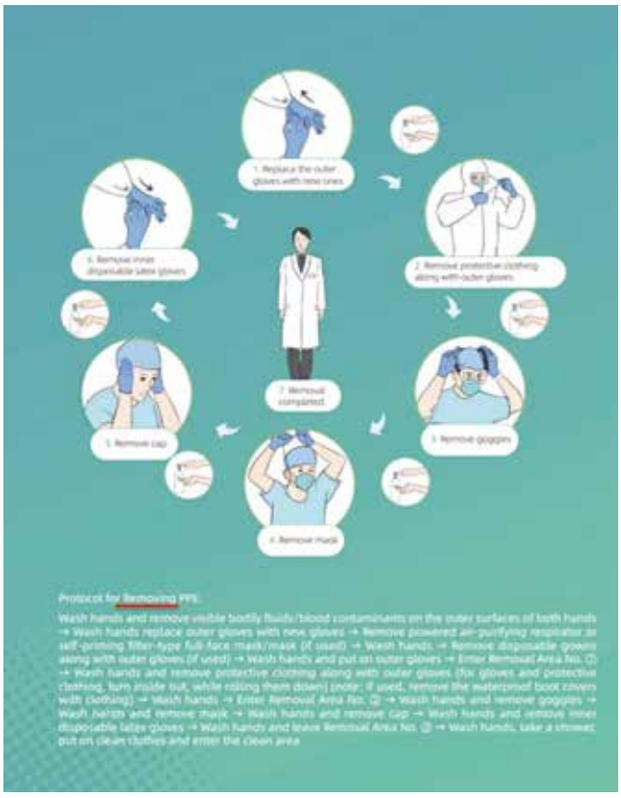

Figure 4 Guidance on removing PPE. From "Handbook of COVID-19 Prevention and Treatment". The First Affiliated Hospital, Zhejiang University School of Medicine. Compiled According to Clinical Experience. Tingbo Liang, Editor in Chief

procedure and giving specific instructions when the patient is non-intubated but is wearing an oxygen mask. During the entire procedure, the doors of the angiosuite must be kept closed. It may be advisable for the staff to stay inside the angiographic room, possibly behind lead screens, even during image acquisition. Indeed, it is essential to minimize in these circumstances the risk of cross-contamination of less adequately protected health-care workers staying outside the intervention room. Therefore, to reduce movement in and out of the potentially contaminated room, the staff wearing appropriate PPE and sterile equipment must remain close to the angiographic bed, whereas a non-sterile radiographer with full PPE could help with the angiographic table control. Communication between operators in and out the room should be done by microphone.

The measures described are expected to increase the overall complexity and time of the procedure.

POST-PROCEDURAL MEASURES

Published literature suggests that SARS-CoV-2 is stable for days on certain surfaces under experimental conditions [3]. However, although fomite transmission is plausible, at present there is no robust evidence that supports infection through contaminated surfaces. These data may have profound implications for the implementation of rationale room decontamination procedures.

Appropriate education of staff and strict personal discipline are necessary.

It is strongly suggested that health-care workers remove PPE immediately after leaving the angiographic room, in order to avoid contamination of their colleagues or themselves; an adjacent small room may be used for the PPE removal process (Figure 4) and used PPE must be collected in dedicated disposal bags.

Access to reporting rooms is permitted only after PPE removal and proper hand hygiene.

Plans for terminal cleaning of procedure rooms must be ensured and cleaners themselves are required to wear proper PPE [5,6]. Exposed surfaces including imaging equipment in the angiosuite must be cleaned with 70% ethanol or chlorhexidine-ethanol solutions, and floors cleaned with approved disinfectants (i.e. sodium hypochlorite solutions). The whole cleanup procedure takes approximately 30 min. Immediately after, the room needs to be ventilated for at least 30 min, and then it is suggested that the room is left for a further 30 min with closed doors before the next intervention.

CONCLUSION

While health systems are strained worldwide by the outbreak of the COVID-19 pandemic, adequate control measures are fundamental to reduce to a minimum the nosocomial spread of this infection even in the IR services. The specific measures needed to protect occupational safety and health may result in higher costs, longer procedural times, and greater technical difficulties. However, these precautions can help to minimize the risk of infection by the novel coronavirus among IR practitioners.

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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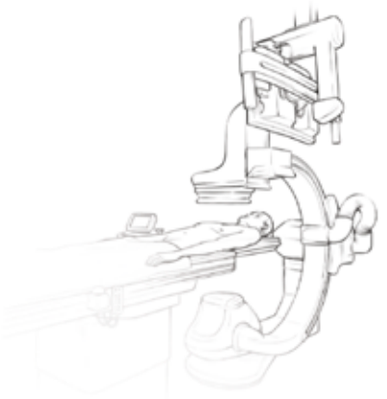


EVTM Newsletter April 2020

DURING UNPRESEDENTED TIMES…

The EndoVascular resuscitation and Trauma Management (EVTM) platform continues to grow, however, as expected, we are adjusting to the COVID-19 pandemic crisis. We are all facing difficult challenges standing on the front line of this "war" and the EVTM Society grieves with all those seriously affected.

At times when elective surgery is paused, acute cases continue to come, further stressing that this is a time to re-think "how, when and who" to treat. When the whole world's attention is on COVID-19, with health care workers around the world being limited by this enormous burden, patients are still in need of bleeding control, resuscitation and trauma management. It is highly probably that following the COVID-19 pandemic, when life starts returning to a new normal, the amount of trauma will increase. It is therefore paramount to plan ahead, to consider what can be done using endovascular methods within the EVTM concept and how we can improve.

Meanwhile, we are working intensively on the upcoming (8th) edition of the JEVTM with some exciting new topics. As many meetings around the world have been canceled or postponed, we are instead focusing on continuing…

UPCOMING EVENTS

- **ESVS/EVTM REBOA Webinar**
  17 June, 2020. (Online)
- **Pan-Pacific Trauma Congress**
  3-5 Sept, 2020. South Korea
- **EVTM Workshop**
  Sept, 2020. Örebro, Sweden
- **Carioca Vascular Meeting**
  24-26 Sept, 2020. Rio, Brazil
- **EVTM at VEITH**
  17-21 Nov, 2020. USA
- **EVTM Workshop**
  1-2 Dec, 2020. Australia

"No ego, just good science and cooperation"

...our effort to build a robust organization. This means in part by concentrating on research issues, so we would like to ask the EVTM community for help, primarily by increasing submissions to the JEVTM, joining ongoing research projects and becoming a member of the EVTM Society. Luckily, just before the COVID-19 pandemic hit Europe, members of the EVTM Society helped conduct a highly successful EVTM/REBOA workshop in Paris with the French military health service for the 2nd year in a row. Further EVTM event dates will follow and planning for the 3rd EVTM Symposium in June 2021 continues.

We would like to end by wishing each and every one of you and your families good health during this challenging time in history.

Journal of Endovascular Resuscitation and Trauma Management

Tal Hörer

EVTM Society

Örebro University
Region Örebro County
Örebro University Hospital

Journal of Endovascular Resuscitation and Trauma Management

Visit www.jevtm.com for more info on submissions

EVTM Workshop
Örebro, Sweden September 2020

Endovascular Resuscitation, Bleeding and Trauma Management (EVTM)

Hands-on Workshop

Örebro, Sweden Sept 2020 (date TBA)

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

Target: Surgeons, Vascular, Trauma, IR, ED, Intensivists and Military with interest in trauma/bleeding/resuscitation, emergency & pre-hospital teams.
Cost (cover expenses only): 600€, 500€ for EVTM Society members
Workshop Director: Dr. Tal Hörer MD, PhD, Associate Professor of Surgery
Workshop Secretary / Registration: Åsa Strandberg (asa.strandberg@regionorebrolan.se)

EVTM Workshop
Örebro, Sweden September 2020

The aim of this WS 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 WS. It is built on an individual, professional level and we will together explore different methods for resuscitation, bleeding control and trauma management, some with great experience and some that have never been practiced anywhere before.

- 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
- 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 both dry models as well as live tissue
- Basics for building a "REBOA / 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 EUCME and acknowledged by the European Society for Trauma and Acute Care Surgery and in cooperation with other relevant societies.

Day 1 Clinical Training Center (KTC), USÖ

- EVTM algorithm and up-to-date world experience
- Theory and methods for vascular access; Basic and advanced
- Practical physiology of REBOA/pREBOA/iREBOA and literature
- Use of access, aortic/arterial balloon occlusion, endografts, embolization and other tools for the bleeding and unstable patients
- Dry model training and simulator training
- Group discussion of participant cases and ABOTrauma Registry cases
- Building an EVTM service and initiating REBOA use per center
- Discussions/cases
- Current data updates
- New technologies in endo tools and imaging; what's hot, what's next?

11:40 Gathering at the Clinical Training Center (2 nd floor)
11:40-12:20 Lunch, welcome and general information
12:30-17:30 8-minute presentations and short discussions (coffee served during sessions)
Minor changes may follow.
17:30-19:00 Practical discussions/exchange of information and training in stations and cases with scenario training on model.

EVTM Workshop
Örebro, Sweden September 2020

Day 2 Animal lab training & research center, USÖ

07:00 Gathering/changing at the Clinical Training Center (2 nd 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)
08:40-09:15 Breakfast with the industry (Clinical Training Center); short presentations as needed/time limitations
09:20-14:30 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, Cut down techniques, Endoshunts (and shunts), Hybrid procedures, Puncture methods, Seldinger technique, The failing access - alternatives, Venous access and Ultrasound

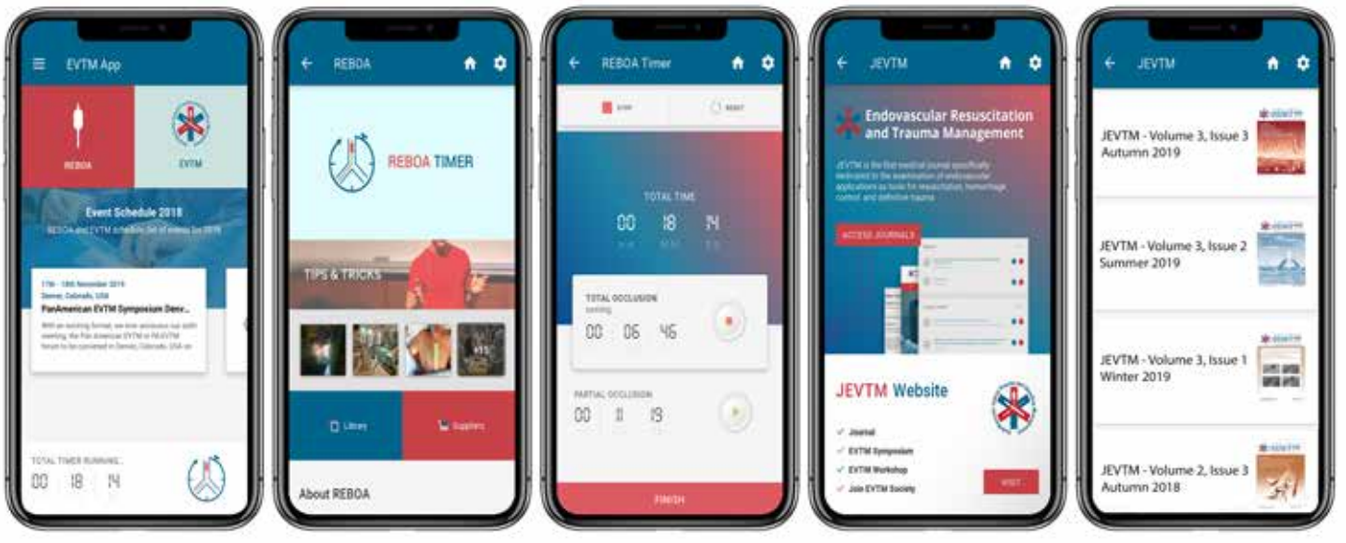
3. Upgrading/introducers/guide wires
4. REBOA
   Material and REBOA kit
   Deflation and re-positioning
   Ongoing bleeding practice
   CPR procedures and pending areas
   Intermittent/Partial inflation (MAP as target - iREBOA/pREBOA)
5. ECMO
6. Embolization and grafts (Basic/advanced)
   Material
   Coils
   Onyx/Phil
   Endografts

As times allows and based on individual level:
7. Balloon in alternate locations (Iliac, Subclavian, Brachiocephalic trunk/Zone 1 neck)
8. Aortography and Angiography considerations (type, volume etc.)
9. Pelvic bleeding, Advanced ultrasound

14:30 -15:00 End of workshop and evaluation

"No ego, just good science and cooperation"

The EVTM App

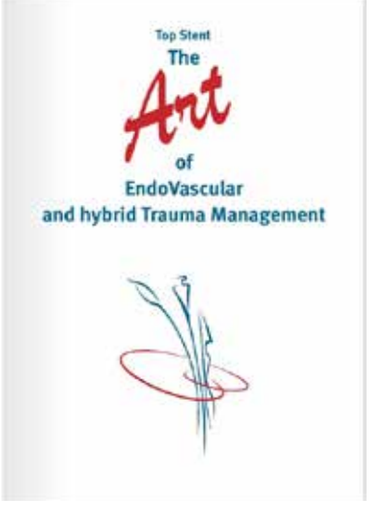


- **Stay up-to-date with all the EVTM events around the world**
- **Access all editions of JEVTM**
- **Read Top Stent wherever you are**
- **Use the REBOA Timer to keep track of occlusion time**
- **Listen to trauma related podcasts**
- **Discuss EVTM with others in our Open Forum**
- **…and much much more!**

Available for both iPhone and Android

jevtm.com/evtm-app/

The Top Stent work manual



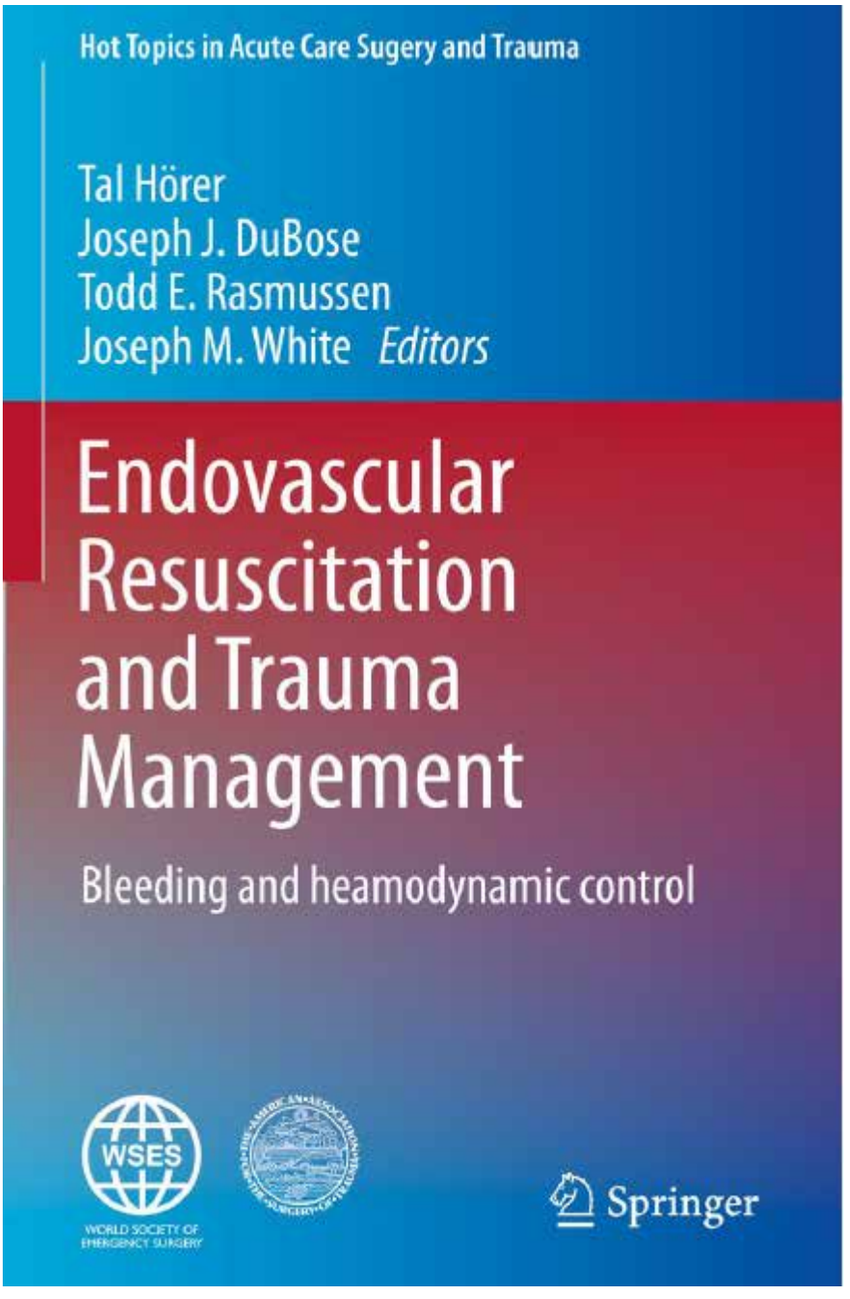
The Top Stent project is a multidisciplinary work manual for EVTM. 28 experts from around the world give tips and tricks for EVTM and REBOA.

The manual is distributed as a non-profit project at production costs of 302 SEK with addition to delivery by post.

If interested, send an e-mail to: asa.strandberg@regionorebrolan.se and state: number of books, address of shipment and address for invoice.

You can also access Top Stent for free in the EVTM App.

Now Available at Springer



This book focuses on endovascular methods for resuscitation and trauma management. Written by highly qualified and clinically active physicians from around the world, it shares information gathered over the past decade, providing a comprehensive database of clinical knowledge for a wide range of practicing clinicians and researchers.

Moreover, it describes basic methods for vascular access, methods for REBOA (Resuscitative Endovascular Balloon Occlusion of the Aorta), endo-grafts and embolization methods, as well as other, more advanced methods for endovascular and hybrid resuscitation (CPR REBOA, ECHMO etc.) from the pre-hospital to the post-surgical phase. As the body of literature in this field has grown considerably over the past five years, the book also focuses on summarizing what is known, what the clinical and research evidence is, and "how to actually use" the various methods. It will help readers understand basic and advanced modern techniques for bleeding control and modern resuscitation, and how to apply them in clinical practice.