JEVTM

Journal of Endovascular Resuscitation and Trauma Management

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Issue Highlights

Hybrid techniques for a transhepatic gunshot injury

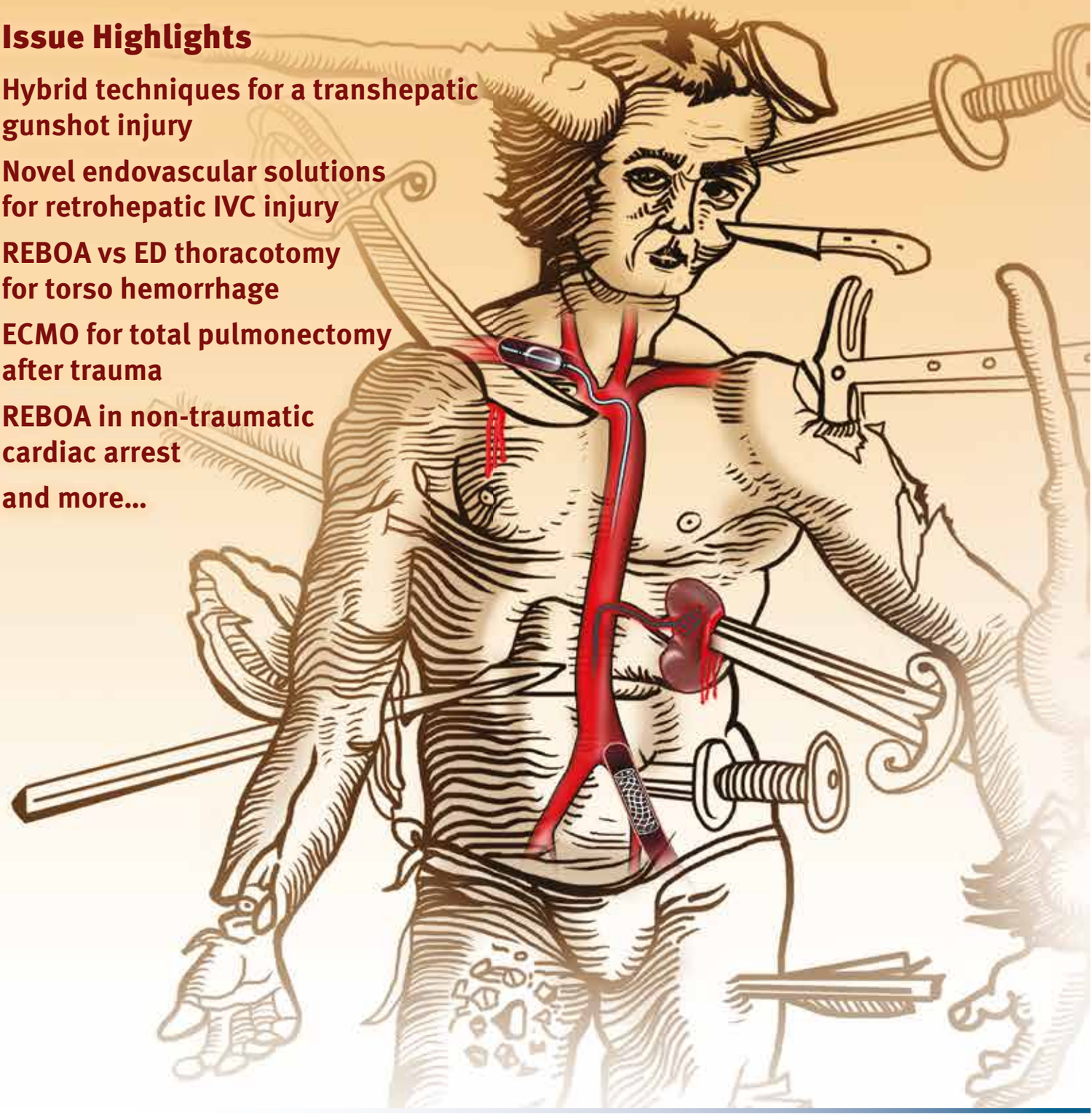
Novel endovascular solutions for retrohepatic IVC injury

REBOA vs ED thoracotomy for torso hemorrhage

ECMO for total pulmonectomy after trauma

REBOA in non-traumatic cardiac arrest

and more...



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

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

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

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

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

JEVTM is indexed in Scopus and Web Of Science.

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

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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:
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Author Guidelines

A manuscript submitted to the Journal must constitute a unique piece of work that is not under consideration for publication, in part or whole, by another journal. Submissions should preferably be produced using Microsoft Word, although other formats will be considered.

The submission process requires three discreet documents:

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

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

1. The type of manuscript submission (Original Article, Review Article etc)
2. A sentence or two on the subject of the study.
3. Confirmation that the study is not under consideration for publication by another journal.
4. Confirmation that all of the authors have made a substantial contribution to the manuscript and that they have seen and approved the submission draft.
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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
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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.

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Where there is a topic within the subject area of endovascular hemorrhage control that has a substantial evidence base, a Systematic Review with/without a Meta-Analysis is considered more appropriate than a narrative review article. These articles should follow the methodology established by PRISMA. Submission should be a maximum of 5000 words and authors should include a PRISMA checklist in their submission. The overall aim is to provide a pooled analysis that enables firm conclusions to be drawn on a particular subject.

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

Author Guidelines

Images of Interest
Rather than accept case reports, the Journal will prefere images of interest, which include a short commentary. The aim of this section is to demonstrate and illustrate an educational message, rather than just to demonstrate dramatic pathology. Images can be submitted as a multi-panel with a series of scans/photographs in order to support the message presented in the narrative. The submission should be a maximum of 250 words.

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

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

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

An example article:

Stannard W, Rutman A, Wallis C, O'Callaghan C. Central microtubular agenesis causing primary ciliary dyskinesia. Am J Respir Crit Care Med. 2004;169:634.
Where there are more than six authors, the first three should be included followed by et al .

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

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

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

Detailed ethical guidelines

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

- The manuscript should not be submitted to more than one journal for simultaneous consideration.
- The submitted work should be original and should not have been published elsewhere in any form or language (partially or in full), unless the new work concerns an expansion of previous work. (Please provide transparency on the re-use of material to avoid the concerns about text-recycling ('self-plagiarism').
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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.

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(continued)

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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.

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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

Special issue in collaboration with the Damage Control Resuscitation (DCR) group

Editorial

Vol. 4, No. 2; 2020; pp 75–76
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DCR and EVTM: The Future of Trauma Research and Training

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The term *damage control* comes from the United States Navy's system of rapidly deploying measures to maintain or restore a ship's integrity when damaged, to allow it to safely exit from hostile environments, and to definitively repair damages so that it might 'live to fight another day.' The individuals responsible for delivering damage control aboard such vessels are called damage controlmen and are described within their manuals as *emergency repair specialists*. These individuals provide efforts related to damage control, ship stability, and more. They also instruct other naval personnel in the methods of damage control and in the repair of damage control equipment and systems. The damage control manuals are exhaustive as is the training of these individuals.

Following on from this philosophy, the trauma community adopted the damage control surgery approach [1] to major haemorrhages resulting from penetrating abdominal trauma. This soon gained traction in managing all patients who had suffered significant physiological insult after major trauma. The concept was a major diversion at the time, going against the traditional teachings of restoring anatomy at the initial (and only) surgery. Damage control focused on restoration of physiology first, irrespective of the degree of anatomical insult.

Internationally, over the past few decades, surgery has become more and more specialised with individuals losing their general surgical skills. This, alongside the reduction in hours, affects the delivery of comprehensive care to the trauma patient as individuals may lack both the clinical skills and relevant exposure to the vast array of traumatic insults [2]. To help mitigate this phenomenon and to aid the appropriate theoretical and manual training of this philosophy, the Damage Control Resuscitation (DCR) organisation was established. The purpose of the organisation is to promote trauma and emergency surgery as a specialty, where possible, and to promote the tenets of DCR through a multi-disciplinary team in areas where a singular specialty is not sustainable. To accomplish both, the DCR organisation has set out to establish best practices based on up to date scientific research and expert consensus statements.

Up until the turn of the century, the mainstay of control of the haemorrhaging vessel remained extravascular with extra-luminal compression or clamping. DCR recognises that in order to optimally manage the patient, all 'arrows in the quiver' must be utilised. To this end, a collaboration was established with the Endovascular Resuscitation and Trauma Management (EVTM) organisation, who are internationally renowned in pioneering and promoting evidence based endovascular management of trauma. This relationship has already made important contributions to the literature [3–7], and will no doubt continue to do so. The joint aim remains to restore the field to 'Big T' status, training surgeons to care for any injury, head to toe, and help them achieve full *Emergency Repair Specialist* status.

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.

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Conflicts of Interest

The authors declare that they have no conflicts of interest.

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REFERENCES

[1] Rotondo MF, Schwab CW, McGonigal MD, et al. 'Damage control': an approach for improved survival in exsanguinating penetrating abdominal injury. J Trauma. 1993;**35**(3):375–82, discussion 382–3.

[2] Khan MA and M. McMonagle. Trauma: code red: companion to the RCSEng definitive surgical trauma skills course. Boca Raton, FL: CRC Press; 2018.

[3] Duchesne J, Taghavi S, Houghton A, et al. Prehospital mortality due to hemorrhagic shock remains high and unchanged: a summary of current civilian EMS practices and new military changes. Shock. 2020; *In Press*. doi: 10.1097/SHK.0000000000001522.

[4] Hörer TM, Pirouzram A, Khan M, et al. Endovascular resuscitation and trauma management (EVTM)-practical aspects and implementation. Shock. 2020; *In Press*. doi: 10.1097/SHK.0000000000001529.

[5] Kauvar D, Cotton B, Khan M, et al. Circulatory trauma: a paradigm for understanding the role of endovascular therapy in hemorrhage control. Shock, 2020; *In Press*. doi: 10.1097/SHK.0000000000001513.

[6] Kauvar D, Cotton B, Khan M, et al. Challenges and opportunities for endovascular treatment of hemorrhage in combat casualty care. Shock, 2020; *In Press*. doi: 10.1097/SHK.0000000000001514.

[7] Tatum D, Duchesne J, Pereira B, et al. Time to hemorrhage control in a hybrid er system: is it time to change? Shock. 2020; *In Press*. doi: 10.1097/SHK.0000000000001539.

Editorial

Vol. 4, No. 2; 2020; pp 77–79
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ECMO in Trauma Patients Requiring Total Pulmonectomy: Could This be a New Approach in the Era of Hybrid Management?

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Most traumatic chest injuries can be safely managed conservatively by chest thoracotomy and respiratory support. Only 10–20% of chest injuries require surgery, mostly due to haemodynamic instability and/or a massive uncontrolled air leak [1]. In the vast majority of cases undergoing surgery, the haemostasis or leak control may be achieved by relatively simple lung sparing techniques such as suturing, tractotomy or non-anatomical wedge resection [2]. The real need for formal lung resection remains unclear, accounting for 10–30% of operative cases [3,4]. In a study on 143 chest trauma patients undergoing surgery, Karmy-Jones et al. demonstrated that each step that increases the complexity of the surgical technique and the volume of resected lung tissue is an independent risk factor for mortality [5]. Aiolfi et al. reported similar results in their recent large study on 3,107 patients [6].

In very rare cases of massive bronchial leak or bleeding from the region of the pulmonary root, closure of the lung hilum is mandatory. Temporary vascular clamping or lung twisting may achieve temporary control. In these cases, total pneumonectomy is considered a last resort due to the associated mortality rates that reach 75–100% in most series [7,8]. The main reasons for a patient's death are uncontrolled bleeding, appearance of the death triad and the rapid development of fulminant right heart failure unresponsive to medical therapy [9]. Although the right heart is still functioning after a pneumonectomy, the thin-walled structure is unable to pump effectively against rapid pressure increases, resulting from redistribution of pulmonary bed circulation after closure of one of the pulmonary hilums [10]. In most extremely unstable patients requiring total pulmonectomy, the patient is probably unsalvageable. However, in some cases patients undergo explorative thoracotomy due to massive haemothorax or persistent ongoing bleeding while initial physiologic parameters are still relatively stable. Under such circumstances, deterioration after chest opening and exploration is expected. In these select patients, we believe that veno-arterial Extracorporeal Membrane Oxygenation (ECMO) may be a promising solution for this currently unresolved problem.

ECMO is a form of cardiopulmonary life-support, first described in the 1970s. For many years, ECMO has been indicated for supportive therapy of severe cardiopulmonary disease in patients unresponsive to medical treatment for hypoxemic respiratory failure, mainly resulting from Acute Respiratory Distress Syndrome (ARDS) and lung contusion [11]. In a large randomized controlled study on 188 adults with severe acute respiratory failure, Peek et al. demonstrated that treatment with ECMO was associated with significantly reduced mortality rates compared with conventional protocols [12]. Since the publication of this study, ECMO gained popularity, with physicians worldwide accumulating wide experience using this method of treatment. ECMO is usually used in one of the two following ways: the veno-venous (VV) configuration when the blood is drained and replaced in the venous system, or alternatively, the veno-arterial (VA) configuration when the blood is drained from the venous system and returned to the arterial system providing both respiratory and cardiac support [13]. Indications for ECMO include cardiac support (VA ECMO), respiratory support (VV ECMO) or a combination of both (VA ECMO).

Little is known about the feasibility of ECMO in acute trauma settings. Some studies describe the use of ECMO for ARDS or lung contusion in severely injuries trauma patients [14,15]. The major concern about ECMO use in trauma is the estimated risk of bleeding

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complications due to use of anticoagulation. However, in a study on 52 trauma patients, Kruit et al. have shown that ECMO in trauma patients does not exacerbate the primary traumatic injury, regardless of anticoagulation initiation. Nevertheless, in their study, initiation of ECMO treatment was performed on average 3 days after the initial therapeutic procedures [16].

In this editorial, we discuss the feasibility of ECMO use in patients in whom the single option for bleeding control is pulmonectomy. In our proposed protocol, ECMO placement will be done as soon as possible and anticoagulation strategy should be adapted accordingly. Therefore, we propose using a minimizing heparin dose strategy described by Wu et al. This approach avoids pre-cannulation heparin dose and provides continuous maintenance dose of heparin after 48 hours of ECMO when a near-normal activated partial thromboplastin time (<40 s) is the therapeutic goal [17].

Peripheral percutaneous ultrasound-guided VA cannulation is the preferred technique for cannulation of the femoral artery and vein using a modified Seldinger technique. This method is associated with lower bleeding and infection rates, compared with open surgical techniques. However, these claims are not based on studies that involve severely hypovolemic patients, with concomitant venous congestion due to RV congestion/failure and arterial vasoconstriction due to hypovolemia. Such conditions might severely impair the ability for ultrasound-guided access.

After ultrasound identification of both vessels, vascular access is gained, avoiding a lateral or back wall puncture. Subsequently, the wire is advanced to the abdominal aorta and the cannula (15–19 Fr) is inserted. The venous drainage is achieved by the cannula (23–25 Fr) in the femoral vein with the tip positioned at the level of the right atrium. The preferred way for the confirmation of guidewire route is fluoroscopy. Transthoracic echocardiography alone is insufficient to avoid vessel injury or dislocation because it cannot identify kinking of the guidewire during the dilation or insertion of the cannula. In addition, the pitfalls of cannulation include vascular complications or ischaemia of the corresponding extremity, blood loss and/or relocation of cannulas, hypoxia of the upper body [18]. Deoxygenated blood will be drained at the right atrium and oxygenated blood will be returned retrogradely into the aorta. [19,20]. In this way, peripheral VA-ECMO configuration will partially (up to 90%) bypass the pulmonary vascular bed. This bypass will potentially 'buy time' that will enable the addressing of the bleeding as well as enable the right ventricle to adapt to the pulmonectomy.

The main advantage of peripheral VA-ECMO is the relative simplicity and speed of initiation of ECMO. For example, Yannopoulos et al. reported a mean initiation time of 6.3+2 min [21]. Routine use of a distal cannula is also recommended after control of the thoracic bleeding to minimize the risk of distal limb ischaemia. This may be performed by accessing the superficial femoral artery with an antegrade needle access, using a 5–6 Fr sheath [22].

The evidence mentioned above supports the feasibility of ECMO use in acute trauma patients. In our opinion, VA-ECMO may potentially improve outcomes in trauma victims previously considered unsalvageable. This concept requires the immediate availability of both ECMO equipment and properly trained staff. In addition, awareness of the trauma surgeon is necessary to allow early use of ECMO in trauma victims. Possible methods that may enable initiating ECMO before total pulmonectomy include intermittent lung twisting, alternating lung hilum clamping and use of balloon technique for temporary proximal and distal control. Despite the technical evolution and today's improved protocols, current data regarding ECMO use is mainly based on observational and mostly retrospective studies. It should be highlighted that there is no data regarding the efficacy of ECMO use before, during or after surgery. The question whether ECMO should always precede pulmonectomy remains unanswered. Therefore, the proper timing of initiation of ECMO is controversial and an adequate strategy should be developed in the future. We believe that animal studies followed by prospective controlled trials are urgently needed in order to generate evidence on safety and efficacy of ECMO support in acute trauma settings.

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

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no financial support for this work.

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REFERENCES

[1] Mattox KL, Wall MJ, Tsai P. Trauma thoracotomy: principles and techniques. In: Mattox KL, Moore EE, Feliciano DV, editors. Trauma, 7th ed. New York: McGraw-Hill; 2013. pp. 461–7.
[2] Velmahos GC, Baker C, Demetriades D, Goodman J, Murray JA, Asensio JA. Lung-sparing surgery after

penetrating trauma using tractotomy, partial lobectomy, and pneumonorrhaphy. Arch Surg. 1999;134(2):186–9.
[3] Martin MJ, McDonald JM, Mullenix PS, Steele SR, Demetriades D. Operative management and outcomes of traumatic lung resection. J Am Coll Surg. 2006; 203(3):336–44.
[4] Garcia A, Martinez J, Rodriguez J, et al. Damage-control techniques in the management of severe lung trauma. J Trauma Acute Care Surg. 2015;78(1):45–50.
[5] Karmy-Jones R, Jurkovich GJ, Shatz DV, et al. Management of traumatic lung injury: a Western Trauma Association Multicenter review. J Trauma. 2001;51(6): 1049–53
[6] Aiolfi A, Inaba K, Martin M, et al. Lung resection for trauma: a propensity score adjusted analysis comparing wedge resection, lobectomy, and pneumonectomy. Am Surg. 2020;1;86(3):261–5.
[7] Alfici R, Ashkenazi I, Kounavsky G, Kessel B. Total pulmonectomy in trauma: a still unresolved problem-our experience and review of the literature. Am Surg. 2007; 73(4):381–4.
[8] Matsushima K, Aiolfi A, Park C, et al. Surgical outcomes after trauma pneumonectomy: revisited. J Trauma Acute Care Surg. 2017;82(5):927–32.
[9] Baumgartner F, Omari B, Lee J, et al. Survival after trauma pneumonectomy: the pathophysiologic balance of shock resuscitation with right heart failure. Am Surg. 1996;62(11):967–72.
[10] Phillips B, Turco L, Mirzaie M, Fernandez C. Trauma pneumonectomy: a narrative review. Int J Surg. 2017; 46:71–4.
[11] Parekh M, Abrams D, Brodie D. Extracorporeal techniques in acute respiratory distress syndrome. Ann Transl Med. 2017;5(14):296.
[12] Peek GJ, Mugford M, Tiruvoipati R, et al. Efficacy and economic assessment of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR): a multicentre randomized controlled trial. Lancet. 2009;374(9698): 1351–63.
[13] Marasco SF, Lukas G, McDonald M, McMillan J, Ihle B. Review of ECMO (extra corporeal membrane oxygenation) support in critically ill adult patients. Heart Lung Circ. 2008;17 Suppl 4:S41–7.
[14] Raff L, Kerby JD, Reiff D, G et al. Use of extracorporeal membranous oxygenation in the management of refractory trauma-related severe acute respiratory distress syndrome: a national survey of the Eastern Association for the Surgery of Trauma. Trauma Surg Acute Care Open. 2019;4(1):e000341.
[15] Menaker J, Tesoriero RB, Tabatabai A, et al. Venovenous extracorporeal membrane oxygenation (VV ECMO) for acute respiratory failure following injury: outcomes in a high-volume adult trauma center with a dedicated unit for VV ECMO. World J Surg. 2018; 42(8):2398–403.
[16] Kruit N, Prusak M, Miller M, Barrett N, Richardson C, Vuylsteke A. Assessment of safety and bleeding risk in the use of extracorporeal membrane oxygenation for multitrauma patients: a multicenter review. J Trauma Acute Care Surg. 2019;86(6):967–73.
[17] Wu MY, Chou PL, Wu TI, Lin PJ. Predictors of hospital mortality in adult trauma patients receiving extracorporeal membrane oxygenation for advanced life support: a retrospective cohort study. Scand J Trauma Resusc Emerg Med. 2018;26(1):14.
[18] Rupprecht L, Lunz D, Philipp A, Lubnow M, Schmid C. Pitfalls in percutaneous ECMO cannulation. Heart Lung Vessel. 2015;7(4):320–6.
[19] Lamperti M, Bodenham AR, Pittiruti M, et al. International evidence-based recommendations on ultrasound-guided vascular access. Intensive Care Med. 2012;38(7): 1105–17
[20] Rao P, Khalpey Z, Smith R, Burkhoff D, Kociol RD. Venoarterial extracorporeal membrane oxygenation for cardiogenic shock and cardiac arrest. Circ Heart Fail. 2018;11(9):e004905.
[21] Yannopoulos D, Bartos JA, Martin C, et al. Minnesota Resuscitation Consortium's advanced perfusion and reperfusion cardiac life support strategy for out-of-hospital refractory ventricular fibrillation. J Am Heart Assoc. 2016;5(6):e003732.
[22] Bonicolini E, Martucci G, Simons J, et al. Limb ischemia in peripheral veno-arterial extracorporeal membrane oxygenation: a narrative review of incidence, prevention, monitoring, and treatment. Crit Care. 2019; 23(1):266.

Original Article

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To Ultrasound or not to Ultrasound: A REBOA Femoral Access Analysis from the ABOTrauma and AORTA Registries

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Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is becoming a standardized adjunct in the management of non-compressible hemorrhage. Ultrasound (US)-guided femoral access has been taught as the best practice for femoral artery cannulation. However, there is a lack of evidence to support its use in patients in extremis with severe hemorrhage. We hypothesize that no differences in outcome will exist between US-guided and to blind percutaneous or cutdown access methods.
Methods: This was an international, multicenter retrospective review of all patients managed with REBOA from the ABOTrauma Registry and the AORTA database. REBOA characteristics and outcomes were compared among puncture access methods. Significance was set at $P < 0.05$.
Results: The cohort included 523 patients, primarily male (74%), blunt injured (77%), with median age 40 (27–58), and an Injury Severity Score of 34 (25–45). Percutaneous using external landmarks/palpation was the most common femoral puncture method (53%) used followed by US-guided (27.9%). There was no significant difference in overall complication rates (37.4% vs 34.9%; $P = 0.615$) or mortality (47.8% vs 50.3%; $P = 0.599$) between percutaneous and US-guided methods; however, access by cutdown was significantly associated with emergency department (ED) mortality ($P = 0.004$), 24 hour mortality ($P = 0.002$), and in-hospital mortality ($P = 0.007$).
Conclusions: In patients with severe hemorrhage in need of REBOA placement, the percutaneous approach using anatomic landmarks and palpation, when compared with US-guided femoral access, was used more frequently without an increase in complications, access attempts, or mortality.

Keywords: *Resuscitative Balloon Occlusion of the Aorta; Femoral Artery; Arterial Access; Non-compressible Torso Hemorrhage*

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INTRODUCTION

Uncontrolled hemorrhage after severe trauma leads to cardiovascular collapse and ultimately death if not managed and controlled in a timely manner [1,2]. As a consequence of anatomic location, non-compressible torso hemorrhage (NCTH) is the leading cause of potentially preventable death in both military and civilian populations, accounting for 30–40% of trauma-related mortality [3–5]. Hemorrhage within the torso is particularly challenging to control because the injured area(s) is/are

not amendable to compression as in an extremity injury and require(s) invasive intervention such as surgery or angioembolization to prevent exsanguination.

Resuscitative balloon occlusion of the aorta (REBOA) has become a widely used resuscitation adjunct to temporize NCTH and buy time for definitive hemorrhage control. Like its predecessor, resuscitative thoracotomy with aortic cross-clamping (RTACC), REBOA serves to support proximal pressure and stem hemorrhage, thus acting as a bridge to definitive control [6,7]. The procedure involves maneuvering a compliant balloon into the aorta where it is then inflated, obstructing blood flow into distal circulation [8]. The rate limiting and crucial first step of the procedure is arterial access, usually via the common femoral artery (CFA). In trauma situations, arterial access is typically gained in one of three ways: a "blind" percutaneous approach using anatomic landmarks and palpation, ultrasound (US)-guided percutaneous access, or surgical cutdown to facilitate direct visualization and access. Currently, US-guidance is recommended for successful cannulation of the CFA in all REBOA procedures. For elective, non-emergent interventions, US-guided access should be the gold standard approach for arterial access; however, its superiority in patients with NCTH has not been demonstrated. We hypothesize that no differences in outcomes will exist between US-guided in comparison with the blind percutaneous access method in a trauma patient population.

METHODS

Study Design and Data Sources

This was a retrospective, pooled data analysis of two prospectively collected, de-identified REBOA registries. The ABOTrauma registry is an international, multicenter, prospective observational database funded and maintained by the Department of Cardiothoracic and Vascular Surgery at Örebro University Hospital in Örebro, Sweden and the EVTM research group. The subjects included in the registry were enrolled between July 2014 and June 2018. The Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry is an American Association for the Surgery of Trauma sponsored multi-center, prospective observational examination of the utilization of aortic occlusion in the acute resuscitation of trauma and acute care surgery patients in shock. Subjects from the AORTA registry included in the present analysis were enrolled between November 2013 and September 2018. The two registries were combined to create a pooled database. Variables defined and collected similarly in each database were combined. Vital signs such as heart rate and systolic blood pressure (SBP) were reported as categorical values in the ABOTrauma registry and as continuous values in AORTA. Therefore, AORTA variables were converted to categorical in order to combine the datasets. Variables that were differently defined or collected were excluded. For example, the ABOTrauma registry captures transfusion products for the first 24 hours following REBOA, whereas the AORTA database captures transfusion products for the first 24 hours, including the time before aortic occlusion. Therefore, data regarding transfusion products were not examined. Subjects who were dead on arrival (DOA) to the emergency department (ED) or with missing femoral access method were excluded.

Data Elements and Definitions

Demographic and clinical data elements collected included: age, gender, Injury Severity Score (ISS), admission vital signs and lab values, injury descriptors, puncture method of REBOA placement, zone of aortic balloon deployment, SBP pre- and post-balloon insertion, complications, and ED, 24 hour, and in-hospital mortality. Access complications included primary access failure, access site hematoma, and conversion to open aortic occlusion. In-hospital complications included sepsis, pulmonary failure, multiorgan dysfunction syndrome, renal failure, distal embolism, and extremity ischemia. Polytrauma was defined as two or more anatomic regions injured. Subjects were classified as DOA if first ED SBP and post-aortic occlusion (AO) SBP were both zero.

Statistical Analysis

Categorical variables were reported as frequencies and represented as *n* (%) and examined using univariate chi square analysis, while continuous variables were described using median and interquartile range (IQR) and examined using the independent samples Mann–Whitney *U* test. Univariate and multivariate logistic regression analyses were performed to examine associations of patient, injury, and femoral access variables with odds of mortality. Significance was set at the level of $P < 0.05$. All analyses were executed using IBM SPSS, version 26.0 (Armonk, NY).

Ethical Approval and Informed Consent

The study was determined exempt from Institutional Review Board (IRB) oversight, as collaborating centers obtained approval from their local IRB or ethics boards prior to enrolling patients.

RESULTS

The initial iteration of the pooled study population included 655 patients (Figure 1). Of those, 113 were excluded as DOA and 19 were excluded for missing femoral access method. The remaining 523 subjects were included in the present analysis and are described in Table 1. The population was primarily male (74.2%), blunt injured (78.1%), with median (IQR) age and ISS

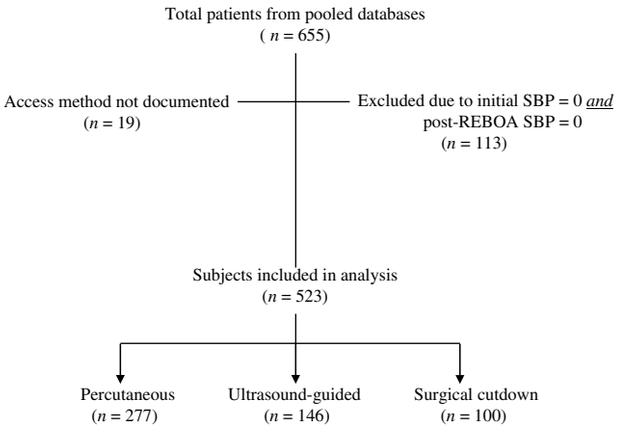

Figure 1 Study flow chart.

of 40 years (27–58) and 34 (25–45), respectively. Abdominal/pelvic (66.3%) injury was the most common followed by thoracic injury (50.7%). Polytrauma occurred in 56.2% of the cohort. Percutaneous using external landmarks/palpation was the most common femoral puncture method used (53.0%) followed by US-guided (27.9%). The anatomic location of injury and ISS did not differ between groups. The proportion of obese patients (body mass index (BMI) ≥30) did not differ between access groups. Median (IQR) hemoglobin was 11.1 (9.2–12.9) and did not reach a level of significance between groups (P = 0.052). Similarly, median (IQR) lactate (7.0 (4.4–11.3)) and international normalized ratio (1.4 (1.2–1.7)) were not different between groups (P = 0.082 and P = 0.380, respectively). Subjects who underwent cutdown to facilitate direct visualization for femoral access prior to REBOA were younger and more likely to be injured by the penetrating mechanism than their counterparts in the percutaneous or US-guided subgroups. The cutdown cohort was also frequently more severely hypotensive (SBP <50 mmHg), bradycardic, and had lower median pH compared to the other access groups. The cutdown group was also significantly more likely to have received cardiopulmonary resuscitation (CPR) pre-hospital and upon arrival to an ED (P = 0.004 and P = 0.013, respectively). Median (IQR) time from injury to arrival was 45 min (28–77) and did not differ between groups (P = 0.655). The number of intensive care unit (ICU) and ventilator days were significantly lower in the cutdown group (P < 0.001 for both), but there was no statistical difference in ICU days or ventilator days between percutaneous and US-guided cohorts (P = 0.374 and P = 0.372, respectively). The overall in-hospital complication rate was 35.6%. The complication most often incurred was renal failure (17.0%) followed by multiorgan dysfunction syndrome (15.9%). Hematoma at access site, distal embolism, and extremity ischemia were relatively infrequent with overall incident rates of 2.1%, 4.2%, and 5.4%, respectively. The incidence of individual complications did not differ between access methods. Overall mortality was 52%. Access by cutdown had significantly higher ED (P = 0.004), 24 hour (P = 0.005), and in-hospital mortality (P = 0.007).

Procedural descriptors for the different access method groups are described in Table 2. Aortic occlusion was primarily performed in the ED for all three access groups. However, femoral access by surgical cutdown was more commonly performed in an operating room compared with the other groups. Attending trauma surgeons were the most common operator (68.4%) and were more likely to utilize US-guidance for percutaneous CFA access. ED/ICU attending physicians were the second most common operators (12.7%) and were more likely to obtain femoral artery access via the blind percutaneous approach than other methods. Overall primary access success was 88.1%. Cutdown was associated with significantly higher access success with a rate of 97.0% (P = 0.007). Initial attempt success rates did not differ significantly between the blind and US-guided percutaneous groups (P = 0.436). Primary access failure was then examined by the operator for each access technique. ED/ICU physicians failed on the initial access attempt in 69.8% (37/53) of patients undergoing blind percutaneous access, while attending surgeons were the least likely to fail the initial attempt in this cohort, requiring a second attempt in only 4.2% (7/168) of patients (P <0.001). There were no overall significant differences in primary failure attempts by the operator in the US-guided cohort (P = 0.130). However, attending surgeons failed primary attempts significantly less than ED/ICU physicians (10.4% vs 25.0%, respectively; P <0.050). No differences in initial attempt failure rate existed among operators in the surgical cutdown cohort (P = 0.703). BMI examined as a continuous variable was not significantly associated with primary access success (P = 0.076), and as a categorical variable, BMI ≥ 30 did not increase risk of primary access attempt failure (relative risk 0.929, 95% confidence interval 0.849–1.017; P = 0.147). Conversion to open aortic occlusion occurred significantly more in the US-guided group (P = 0.007), but frequency did not differ between operators (P = 0.634). A subgroup analysis of 350 patients from the AORTA registry revealed median (IQR) time from admission to successful aortic occlusion to be significantly shorter in the surgical cutdown cohort (21 (13–36) min vs 36 (21–31) min for blind percutaneous and 30 (19–55) min for US-guided; P = 0.005). Comparison of time to successful AO between US-guided access and percutaneous using anatomic landmarks was not statistically different (P = 0.220).

The relative risks for specific complications and mortality in US-guided femoral artery access versus percutaneous using anatomic landmarks and palpation are detailed in Table 3. There was no significant difference in overall complication rates (37.4% vs 34.9%; P = 0.615) or mortality (47.8% vs 50.3%; P = 0.599) between percutaneous and US-guided arterial access methods. Event

Table 1 Cohort demographic and clinical descriptors of study population.

	Total (n = 523)	*Percutaneous (n = 277, 53.0%)*	*US-guided (n = 146, 27.9%)*	*Cutdown (n = 100, 19.1%)*	*P*
Descriptor					
Age, years‡	40 (27–58)	44 (28–60)	42.5 (28–56)	30.5 (23–47)	<0.001
Male gender	388 (74.2)	201 (72.6)	117 (80.1)	70 (70.0)	0.136
BMI ≥30	108 (25.5)	56 (24.0)	37 (28.5)	15 (24.6)	0.641
ISS‡	34 (25–45)	36 (26–45)	34 (25–43)	34 (25–48)	0.162
MOI					
Blunt	404 (78.1)	225 (82.1)	124 (84.9)	55 (56.7)	<0.001
Penetrating	110 (21.3)	47 (17.2)	22 (15.1)	41 (42.3)	
Both	3 (0.6)	2 (0.7)	0	1 (1.0)	
Injury location					
Abdominal/pelvic	347 (66.3)	188 (67.9)	95 (65.1)	64 (64.0)	0.726
Thoracic	265 (50.7)	144 (52.0)	79 (54.1)	42 (42.0)	0.143
Head	232 (44.4)	122 (44.0)	70 (47.9)	40 (40.0)	0.463
Polytrauma	294 (56.2)	159 (57.4)	84 (57.5)	51 (51.0)	0.505
PH GCS	3 (3–14)	3 (3–14)	3 (3–14)	3 (3)	<0.001
PH CPR	90 (17.5)	43 (15.8)	19 (13.1)	28 (28.0)	0.004
ED arrival					
Time from injury to arrival, minutes‡	45 (28–77)	43 (27–73)	42.5 (30–81)	51 (30–82)	0.655
CPR in progress	67 (13.6)	32 (12.1)	14 (10.3)	21 (23.1)	0.013
No pupil response	198 (39.8)	100 (39.5)	96 (34.2)	51 (51.5)	0.082
pH‡	7.17 (7.04–7.27)	7.19 (7.06–7.30)	7.17 (7.04–7.26)	7.13 (6.97–7.23)	0.023
HR, bpm					
None	21 (4.0)	8 (2.9)	1 (0.7)	12 (12.0)	<0.001
<50	7 (1.3)	3 (1.1)	2 (1.4)	2 (2.0)	
50–100	133 (25.4)	67 (24.2)	44 (30.1)	22 (22.0)	
101–119	105 (20.1)	62 (22.4)	33 (22.6)	10 (10.0)	
120+	208 (39.8)	113 (40.8)	60 (41.1)	35 (35.0)	
SBP, mmHg					
<50	85 (16.3)	44 (15.9)	10 (6.8)	31 (31.0)	<0.001
51–80	165 (31.5)	80 (28.9)	54 (37.0)	31 (31.0)	
81–100	90 (17.2)	48 (17.3)	37 (25.3)	5 (5.0)	
>100	143 (27.3)	77 (27.8)	41 (28.1)	25 (25.0)	
Unmeasurable	27 (5.2)	17 (6.1)	4 (2.7)	6 (6.0)	
Not recorded	13 (2.5)	11 (4.0)	0	2 (2.0)	
Outcomes					
ICU LOS, days‡	4 (1–13)	4 (1–13)	6 (1–15)	1 (0–6.25)	<0.001
Ventilator days‡	2 (1–8)	2 (1–9)	3 (1–12)	1 (1–4)	<0.001
Complication	186 (35.6)	104 (37.5)	51 (34.9)	31 (31.0)	0.494
In-hospital mortality	271 (52.0)	132 (47.8)	73 (50.3)	66 (66.0)	0.007
24-hour mortality	174 (33.2)	85 (30.7)	42 (28.8)	47 (47.0)	0.005
ED mortality	42 (8.1)	19 (6.9)	7 (4.8)	16 (16.0)	0.004

All values are frequencies reported as n (%) unless denoted by ‡, which indicates median (IQR). BMI: body mass index; ISS: Injury Severity Score; MOI: mechanism of injury; PH: pre-hospital; GCS: Glasgow Coma Score; CPR: cardiopulmonary resuscitation; ED: emergency department; HR: heart rate; bpm: beats per minute; SBP: systolic blood pressure ICU: intensive care unit; LOS: length of stay.

Table 2 REBOA procedural descriptors and access outcomes.

Descriptor	*Total (n = 523)*	*Percutaneous (n = 277)*	*US-guided (n = 146)*	*Cutdown (n = 100)*	*P*
Pre-AO insufflation SBP‡	64 (49–80)	65 (50–85)	66 (50–80)	50 (16–70)	0.001
Post-AO insufflation SBP‡	110 (90–129)	110 (94–130)	108 (90–124)	100 (85–130)	0.065
Femoral access location					
Pre-hospital	2 (0.4)	2 (0.7)	–	–	<0.001
Emergency Department	357 (68.4)	189 (68.5)	114 (78.1)	54 (54.0)	
Operating room	134 (25.7)	65 (23.6)	24 (16.4)	45 (45.0)	
Angiohybrid	18 (3.4)	14 (15.1)	3 (2.1)	1 (1.0)	
Intensive care unit	1 (0.2)	1 (0.4)	–	–	
Floor/Other	10 (1.9)	5 (1.8)	5 (3.4)	–	
Zone of deployment					
Zone 1	354 (68.1)	205 (74.3)	66 (45.8)	83 (83.0)	<0.001
Zone 2	10 (1.9)	8 (2.9)	1 (0.7)	1 (1.0)	
Zone 3	156 (30.0)	639 (22.8)	77 (52.5)	16 (16.0)	
Operator					
ED/ICU Attending	65 (12.7)	53 (19.3)	12 (8.6)	-	<0.001
Attending Surgeon	351 (68.4)	168 (61.1)	106 (75.7)	77 (77.0)	
Vascular surgeon	39 (7.6)	17 (6.2)	3 (2.1)	19 (19.0)	
IR	22 (4.2)	14 (5.1)	8 (5.7)	0	
ED/ICU + IR	1 (0.2)	1 (0.4)	–	–	
Surgery resident/fellow	35 (6.8)	22 (8.0)	11 (7.9)	2 (2.0)	
Primary access success	461 (88.1)	241 (87.0)	123 (84.2)	97 (97.0)	0.007
Access site hematoma	11 (2.1)	4 (1.4)	5 (3.4)	2 (2.0)	0.401
Conversion to open AO	23 (4.4)	8 (2.9)	13 (8.9)	2 (2.0)	0.007

All values are frequencies reported as n (%) unless denoted by ‡, which indicates median (IQR). REBOA: resuscitative balloon occlusion of the aorta; AO: aortic occlusion; SBP: systolic blood pressure; ED: Emergency department; ICU: intensive care until IR: interventional radiology.

Table 3 Relative risk for complications in ultrasound-guided femoral access versus percutaneous access for REBOA.

	Event Rate for Percutaneous (%)	*Event Rate for US-guided (%)*	*Relative Risk*	*95% Confidence Interval*
Complication				
Initial access failure	13.0	15.8	0.825	0.509–1.338
Conversion to open AO	2.9	8.9	1.074	1.018–1.133
Access site hematoma	1.4	3.4	0.420	0.115–1.541
Renal failure	17.6	20.5	0.858	0.571–1.290
MODS	15.8	11.6	1.359	0.806–2.292
Respiratory failure	13.4	11.0	1.214	0.700–2.107
Sepsis	14.6	8.9	1.640	0.899–2.976
Extremity ischemia	5.1	6.8	0.735	0.335–1.614
Distal embolism	3.2	6.8	0.473	0.196–1.137
Mortality				
ED	6.9	4.8	1.426	0.614–3.313
24-hour	30.9	29.2	1.060	0.777–1.445
In-hospital	47.8	50.3	0.947	0.722–1.160

REBOA: resuscitative balloon occlusion of the aorta; US: ultrasound; AO: aortic occlusion; MODS: multiorgan dysfunction syndrome; ED: emergency department.

rates of individual complications also did not differ significantly between the two groups.

DISCUSSION

Mortality from severe hemorrhage often occurs in the first 3–6 hours following injury, particularly in the setting of NCTH [9–12]. Shorter times to hemostatic intervention and definitive surgical control can preserve volume not yet lost and reduce mortality from exsanguination [13,14]. In the setting of REBOA, achieving CFA access is the rate limiting step to aortic occlusion and volume preservation. A 2013 study analyzed continuous video recordings to compare times to aortic occlusion

with REBOA and RTACC, including and excluding the time required for cannulation of the CFA. The study reported that time to aortic occlusion was longer with REBOA when considering the time consumed to obtain CFA access, which accounted for 50% of the overall procedure time [15]. However, once arterial access was achieved, time to AO was significantly faster with REBOA, highlighting the importance of rapid CFA access. A more recent analysis found no difference between REBOA and open approaches such as RTACC to time of successful aortic occlusion, potentially suggesting that increasing use of the procedure and dedicated competency training of the endovascular approach have improved efficiency [16–18].

Obtaining arterial access can result in serious complications and poor outcomes for patients. The traditional mainstay of CFA access has been a percutaneous approach using anatomic landmarks and palpation [19,20]. However, with the advent of portable, affordable US devices, physicians gained the ability to locate the artery under direct guidance in patients with weak or absent arterial pulses as well as in obese patients with larger leg circumferences [20,21]. US-guided puncture of the CFA has been reported to reduce the number of attempts and time to access in central venous cannulation compared with other techniques [20–23]. As each attempt at CFA access increases risk of complications, successful cannulation on the initial attempt is optimal, particularly in a time critical illnesses such as NCTH. While pooled data was not available to compare the total number of attempts, our findings demonstrated no difference in requirement for a second access attempt between the percutaneous approaches. In addition, obesity was not associated with access approach utilized or with primary access failure.

A third approach, surgical cutdown to facilitate direct visualization and access, has been reported to be a more reliable method than blind or US-guided percutaneous access [24]. Our results align with previous reports. Low et al. reported a success rate of 91.7% in hypotensive patients, a rate similar to the 97.0% demonstrated by our analysis [24]. However, our results revealed this method to be associated with a higher incidence of mortality compared with the percutaneous approaches. This may be due not to the femoral access approach, but rather to the severity of the illness, as surgical cutdown was the preferred approach for patients who presented severely hypotensive, had undergone CPR in the field, or were undergoing CPR upon ED arrival. This preference possibly suggests a higher degree of confidence in this approach among providers to locate and cannulate the CFA when faced with a patient in extremis [15,16].

In the setting of severe hemorrhage, each minute of unabated blood flow leads to increased volume depletion. A delay in femoral access for patients who are REBOA candidates is a delay of both hemostasis and resuscitation. Previous data has revealed no difference in time to compete CFA cannulation between percutaneous and surgical cutdown approaches or guided percutaneous access vs blind [15,25]. Here, a subgroup examination of 350 patients contributed by the AORTA registry revealed no difference in time to successful aortic occlusion across puncture methods. This is not a direct measure of time to cannulation; however, similar overall time to balloon insufflation across access methods suggests that access can be obtained with comparable efficiency. This lends support to the supposition that proficiency across methods has increased as REBOA use has become more widespread and as endovascular hemostatic skills have been taught by dedicated courses to trauma surgeons and emergency medicine physicians.

There is a lack of consensus in the existing literature regarding incidence of complications with US-guided access vs other methods. Some reports state US-guided puncture of the CFA reduces complications compared with other access techniques, while other studies report no difference [19,21,23,26]. Our analysis aligned with the latter and revealed no difference in overall complication rates, rates of specific complications, or relative risk of developing complications. Discrepancy among reports may be due, at least partly, to population differences, both in terms of patient population and primary operators. Previous reports that demonstrated lower complication rates in US-guided access have often been in scheduled diagnostic or interventional coronary or peripheral procedures in which the operators were cardiologists or interventional radiologists [19,23]. In trauma situations, the primary operator is most often a trauma surgeon, and the procedure is unplanned, emergent, and often conducted in the chaos of the trauma resuscitation room [16]. In addition, ultrasonography is well known to be user dependent, and differences in level of proficiency may contribute to variation in reported complication rates.

This report has several important limitations. The most significant is due to the pooled analysis, which combined two large REBOA registries. This provided the advantage of a larger study population, as most REBOA studies are limited by small sample sizes. However, the tradeoff is loss of granularity of detail, as some variables are collected differently in each database and could not be combined for analysis. Resuscitation requirements were one such variable as there were differences in how blood products were reported in each registry. Other variables such as need for amputation or time to aortic occlusion were only captured by one database, also precluding pooled analysis. Another limitation is that each database is based on data collected from various institutions in different regions and countries and was not standardized for all data points. Lastly, there was no data available to assess variations in risk factors, procedure volume, or outcomes by center.

In summary, US-guided puncture of the CFA has been promoted as best practice to improve primary access

success and reduce complications compared to other techniques. However, in hypotensive patients with ongoing NCTH who are suitable for REBOA, the percutaneous approach was used more frequently without an increase in complications, access attempts, or mortality compared with US-guided femoral access. Future prospective randomized study is necessary to further evaluate these findings.

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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

MB is on the clinical advisory board for Prytime Medical Inc., a medical device company which manufactures the ER-REBOA catheter. TER holds patents in REBOA and REBOA-like technologies. He has no financial conflicts of interest to disclose and receives no consulting fees, travel support, stocks, or other financial support for these patents.

The other authors have no conflicts to declare.

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Author Contributions

J Duchesne and DT contributed to the study conception and design. DM, J DuBose, KN, and TH were responsible for the acquisition of data. DT, J Duchesne, DM, TH, KN, MB, and J DuBose were responsible for the analysis and interpretation of the data. DT, J Duchesne, TH, KN, and DM were involved in the drafting of the manuscript. J Duchesne, DT, TH, KN, J DuBose, DM, MB, and TER were responsible for critical revision.

REFERENCES

[1] Peitzman AB, Billiar TR, Harbrecht BG, Kelly E, Udekwu AO, Simmons RL. Hemorrhagic shock. Curr Probl Surg. 1995;32(11):925–1002.
[2] Cannon JW. Hemorrhagic Shock. New Engl J Med. 2018;378(4):370–9.
[3] Stannard A, Morrison JJ, Scott DJ, Ivatury RA, Ross JD, Rasmussen TE. The epidemiology of noncompressible torso hemorrhage in the wars in Iraq and Afghanistan. J Trauma Acute Care Surg. 2013;74(3):830–4.
[4] Morrison JJ, Stannard A, Rasmussen TE, Jansen JO, Tai NR, Midwinter MJ. Injury pattern and mortality of noncompressible torso hemorrhage in UK combat casualties. J Trauma Acute Care Surg. 2013;75(2 Suppl 2): S263–8.
[5] Kisat M, Morrison JJ, Hashmi ZG, Efron DT, Rasmussen TE, Haider AH. Epidemiology and outcomes of non-compressible torso hemorrhage. J Surg Res. 2013; 184(1):414–21.
[6] Assar AN, Zarins CK. Endovascular proximal control of ruptured abdominal aortic aneurysms: the internal aortic clamp. J Cardiovasc Surg. 2009;50(3):381–5.
[7] Malina M, Veith F, Ivancev K, Sonesson B. Balloon occlusion of the aorta during endovascular repair of ruptured abdominal aortic aneurysm. J Endovasc Ther. 2005;12(5):556–9.
[8] Morrison JJ, Galgon RE, Jansen JO, Cannon JW, Rasmussen TE, Eliason JL. A systematic review of the use of resuscitative endovascular balloon occlusion of the aorta in the management of hemorrhagic shock. J Trauma Acute Care Surg. 2016;80(2):324–34.
[9] Morrison JJ. Noncompressible Torso Hemorrhage. Crit Care Clin. 2017;33(1):37–54.
[10] Holcomb JB, del Junco DJ, Fox EE, et al.; PROMMTT Study Group. The prospective, observational, multicenter, major trauma transfusion (PROMMTT) study: comparative effectiveness of a time-varying treatment with competing risks. JAMA Surg. 2013;148(2):127–36.
[11] Tien HC, Spencer F, Tremblay LN, Rizoli SB, Brenneman FD. Preventable deaths from hemorrhage at a level I Canadian trauma center. J Trauma. 2007;62(1):142–6.
[12] Demetriades D, Murray J, Charalambides K, et al. Trauma fatalities: time and location of hospital deaths. J Am Coll Surg. 2004;198(1):20–6.
[13] Asensio JA, Arroyo H, Jr., Veloz W, et al. Penetrating thoracoabdominal injuries: ongoing dilemma-which cavity and when? World J Surg. 2002;26(5):539–43.
[14] Clarke JR, Trooskin SZ, Doshi PJ, Greenwald L, Mode CJ. Time to laparotomy for intra-abdominal bleeding from trauma does affect survival for delays up to 90 minutes. J Trauma. 2002;52(3):420–5.
[15] Romagnoli A, Teeter W, Pasley J, et al. Time to aortic occlusion: it's all about access. J Trauma Acute Care Surg. 2017;83(6):1161–4.
[16] DuBose JJ, Scalea TM, Brenner M, et al.; AAST AORTA Study Group. The AAST prospective Aortic Occlusion

for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). J Trauma Acute Care Surg. 2016;81(3):409–19.

[17] Brenner M, Hoehn M, Pasley J, Dubose J, Stein D, Scalea T. Basic endovascular skills for trauma course: bridging the gap between endovascular techniques and the acute care surgeon. J Trauma Acute Care Surg. 2014;77(2):286–91.

[18] Villamaria CY, Eliason JL, Napolitano LM, Stansfield RB, Spencer JR, Rasmussen TE. Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS) course: curriculum development, content validation, and program assessment. J Trauma Acute Care Surg. 2014;76(4):929–35.

[19] Gedikoglu M, Oguzkurt L, Gur S, Andic C, Sariturk C, Ozkan U. Comparison of ultrasound guidance with the traditional palpation and fluoroscopy method for the common femoral artery puncture. Catheter Cardiovasc Interv. 2013;82(7):1187–92.

[20] Maecken T, Grau T. Ultrasound imaging in vascular access. Crit Care Med. 2007;35(5 Suppl):S178–85.

[21] Dudeck O, Teichgraeber U, Podrabsky P, Lopez Haenninen E, Soerensen R, Ricke J. A randomized trial assessing the value of ultrasound-guided puncture of the femoral artery for interventional investigations. Int J Cardiovasc Imaging. 2004;20(5):363–8.

[22] Hind D, Calvert N, McWilliams R, et al. Ultrasonic locating devices for central venous cannulation: meta-analysis. BMJ. 2003;327(7411):361.

[23] Seto AH, Abu-Fadel MS, Sparling JM, et al. Real-time ultrasound guidance facilitates femoral arterial access and reduces vascular complications: FAUST (Femoral Arterial Access With Ultrasound Trial). JACC Cardiovasc Interv. 2010;3(7):751–8.

[24] Low RB, Longmore W, Rubinstein R, Flores L, Wolvek S. Preliminary report on the use of the Percluder occluding aortic balloon in human beings. Ann Emerg Med. 1986;15(12):1466–9.

[25] Abu-Fadel MS, Sparling JM, Zacharias SJ, et al. Fluoroscopy vs. traditional guided femoral arterial access and the use of closure devices: a randomized controlled trial. Catheter Cardiovasc Interv. 2009;74(4):533–9.

[26] Brass P, Hellmich M, Kolodziej L, Schick G, Smith AF. Ultrasound guidance versus anatomical landmarks for subclavian or femoral vein catheterization. Cochrane Database Syst Rev. 2015;1:Cd011447.

Original Article

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A Research Protocol and Case Report of Emergency Department Endovascular Aortic Occlusion (REBOA) in Non-traumatic Cardiac Arrest

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Background: There are over 395,000 out-of-hospital cardiac arrests (OHCA) annually in the United States with an estimated 70–90% mortality rate and fewer than 10% surviving with a favorable neurologic outcome. Research in animal models and early human studies suggests that resuscitative endovascular balloon occlusion of the aorta (REBOA) may play a role in augmenting coronary perfusion during OHCA by reducing blood flow to the lower body and re-directing it towards the heart and the brain. We describe our initial case and research protocol to investigate the feasibility of REBOA in the emergency department for OHCA as an adjunct to advanced cardiac life support.
Methods: We plan to enroll 20 patients in a single-arm interventional device study utilizing an exception from informed consent over a 2-year period. The primary outcome is feasibility, with secondary outcomes assessing for hemodynamic changes pre- and post-aortic occlusion.
Results: Enrollment began in January 2020 and is ongoing. For the initial patient, an emergency physician (EP) obtained common femoral arterial access under chest compressions, followed by advancement of the REBOA catheter by an interventional radiologist. Immediately after aortic occlusion, investigators noted a substantial improvement in mean arterial pressure (37 mmHg to 50 mmHg) and end tidal carbon dioxide (33 mmHg to 50 mmHg), with transient but non-sustained return of spontaneous circulation.
Conclusion: This is the first research protocol and case report describing successful REBOA placement in the emergency department (ED) involving EPs for non-traumatic OHCA as an adjunct to advanced cardiac life support.

Keywords: *Resuscitative Endovascular Balloon Occlusion of the Aorta; REBOA; Resuscitation; Aortic Occlusion; Cardiac Arrest; Out-of-Hospital Cardiac Arrest; Non-traumatic Cardiac Arrest*

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INTRODUCTION

There are an estimated 395,000 out-of-hospital cardiac arrests (OHCAs) annually in the United States, with fewer than 10% surviving with a favorable neurologic outcome. Despite advances in resuscitative strategies over the past several decades, patient-centered outcomes have remained frustratingly poor [1].

Resuscitative endovascular balloon occlusion of the aorta (REBOA) involves the use of a balloon tipped catheter to occlude the aorta and prevent distal blood flow. REBOA was initially developed for the management of non-compressible intra-abdominal hemorrhage to temporize further blood loss and bridge the patient to definitive operative repair [2]. To perform REBOA, an introducer sheath is placed in the common femoral artery (CFA) and a balloon-tipped catheter is advanced through the sheath retrograde into the aorta. When the intra-aortic balloon is inflated, the thoracic aorta is occluded, preventing distal blood flow and increasing blood pressure in the aortic arch and coronary arteries [3]. Intra-vascular aortic procedures are typically performed by endovascular specialists; however, a recent report demonstrated that anesthesiologists could be trained to safely perform REBOA during OHCA [4]. In the United States, REBOA is typically performed by trauma surgeons and its use by emergency physicians (EPs) has been limited. In Europe, the majority of REBOA procedures are performed by non-surgical specialties (e.g. emergency medicine, critical care, anesthesiology) [5].

While REBOA has been employed primarily in traumatic bleeding, the increase in blood pressure in the aortic arch may be beneficial in patients suffering from OHCA to increase cardiac and cerebral perfusion. Cardiac output generated by chest compressions during OHCA is often inadequate to maintain sufficient coronary and cerebral perfusion pressure [6]. Aortic occlusion may compensate for this by reducing the effective circulating area of a patient's blood and redirecting flow towards the heart and the brain. Numerous pre-clinical studies demonstrate the effectiveness of REBOA during non-traumatic cardiac arrest [7,8]. Clinical research involving REBOA used as an adjunct to advanced cardiac life support (ACLS) in OHCA is limited and, to our knowledge, has not been reported in the *emergency medicine* literature [8,9]. Demonstration of feasibility by EPs and non-specialists is essential, as the majority of OHCAs present to smaller hospitals without in-house specialist coverage. A recent study of 10 patients undergoing REBOA for prolonged OHCA in the field demonstrated statistically significant improvements in end tidal carbon dioxide ($ETCO_2$) after aortic occlusion, with return of spontaneous circulation (ROSC) in six patients and one patient discharged with a favorable neurologic status. These results are promising, especially given the prolonged mean down-time prior to REBOA. We hope to build upon this study by assessing for real-time improvements in diastolic blood pressure (a surrogate for coronary perfusion pressure) pre- and post-aortic occlusion.

METHODS

In January 2020, we began the implementation of the first emergency department (ED)-based REBOA protocol involving EPs as part of single-arm early feasibility trial

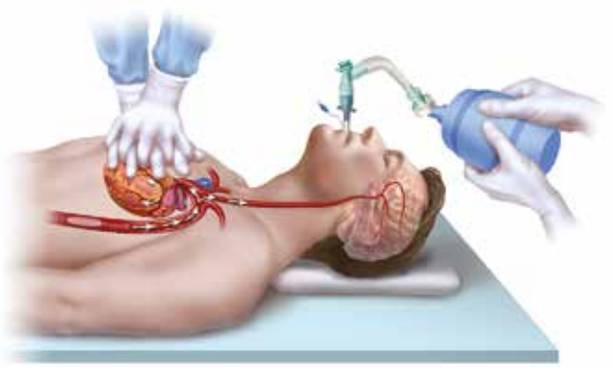

Figure 1 Thoracic aortic balloon occlusion as adjunct to ACLS. Thoracic aortic balloon occlusion during cardiac arrest with bag-valve mask ventilation and manual chest compressions demonstrating the re-direction of blood flow with aortic occlusion.

with and planned enrollment of 20 patients (ClinicalTrials.gov identifier: NCT03703453). Our goal is to demonstrate that REBOA for OHCA is feasible and that EPs can be successfully trained to perform this procedure during chest compressions (Figure 1). The primary outcome is feasibility, defined as successful intra-aortic balloon inflation in greater than 70% of cases, with secondary procedural, hemodynamic, and clinical outcomes (Figure 2). To be included, the patient must have had a witnessed cardiac arrest with bystander cardiopulmonary resuscitation (CPR) (Figure 3). Upon patient enrollment, the REBOA procedure will be performed as rapidly as possible, with a maximum total aortic occlusion time of 15 min (while ACLS is continued). If ROSC is obtained, the intra-aortic balloon will be deflated step-wise as rapidly as possible to avoid subjecting the recovering heart to increased afterload and to minimize lower body ischemic time.

Enrollment occurs during defined times when a research assistant and EP investigator are present. Eight EP investigators completed the cadaveric-based basic endovascular skills for trauma (BEST) course with additional OHCA-focused training in our simulation laboratory. ED nurses and technicians underwent REBOA training involving in-situ simulation as it is essential that all staff know their role, their expected location, and have an understanding of the procedure so they may better assist during REBOA. Figure 4 depicts our staff and room setup for a right-handed procedural physician. Once a patient is enrolled, the EP investigator (separate from the EP leading the resuscitation) prepares all necessary equipment on a sterile field (Figure 5). The EP investigator will then place a 7 Fr introducer sheath into the CFA under ultrasound guidance during chest compressions. CFA access is typically the most difficult and rate-limiting step of the REBOA procedure [5]. To improve the probability of procedural success and patient safety, the US Food and Drug Administration (FDA) has required that EP investigators enlist the assistance of interventional radiologists (IR) to

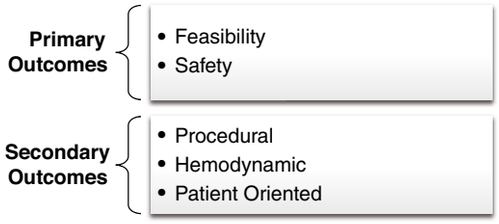

Figure 2 Study primary and secondary outcomes. Primary outcomes are feasibility, defined by successful supra-celiac placement of the intra-aortic balloon in at least 70% of patients. Safety is measured as a composite score of five pre-determined adverse events. Secondary outcomes are procedural (e.g. time to balloon placement), will assess for hemodynamic changes before and after balloon inflation, and are patient oriented (e.g. proportion of patients discharged with a favorable neurologic outcome).

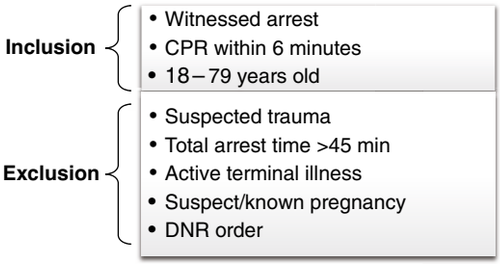

Figure 3 Patient inclusion and exclusion criteria. Inclusion and exclusion criteria of out-of-hospital cardiac arrest patients eligible for ED-initiated REBOA. DNR: Do not resuscitate.

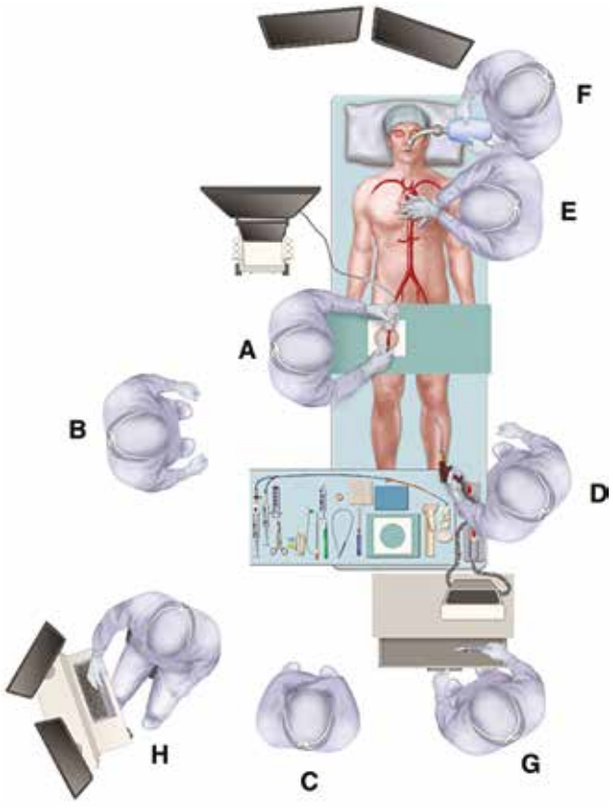

Figure 4 Resuscitation room setup. Emergency department staff performing REBOA as an adjunct to ACLS in a non-traumatic cardiac arrest patient. (**A**) Primary proceduralist. (**B**) Procedural/research assistant. (**C**) Code team leader. (**D**) Nurse obtaining intra-osseous access. (**E**) Chest compressor. (**F**) Respiratory therapist. (**G**) medications nurse. (**H**) Documenting nurse.

insert and manipulate the actual REBOA catheter. For the initial patients in the trial, EPs will obtain CFA access with ultrasound guidance and the supporting IR will then advance the REBOA catheter and inflate the intra-aortic balloon. For the subsequent patients, as EPs gain experience, we plan to file a study protocol amendment with the FDA to permit EP advancement of the REBOA catheter with IR in a supporting role. Subjects will undergo aortic occlusion for no longer than a total of 15 min. This time period was decided on through expert opinion; 15 min is likely enough time for the intervention to induce a beneficial effect, while still well under the generally accepted maximum aortic occlusion time in an attempt to mitigate any ischemic damage. If ROSC is not obtained after 15 min of aortic occlusion, the resuscitation will cease due to perceived futility.

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. The study was granted an investigational device exemption under the FDA and an exception from informed consent (EFIC).

RESULTS

A 77-year-old male had a witnessed OHCA with bystanders providing basic life support including chest compressions within several minutes of his collapse. He had a past medical history significant for congestive heart failure (baseline ejection fraction 40%), atrial fibrillation, hypertension, diabetes, and chronic renal disease (baseline creatinine 1.8 mg/dl).

When paramedics arrived, they found the patient in sinus bradycardia with a faintly palpable pulse. He was prepared for transport to the ED and subsequently suffered a ventricular fibrillation (VF) cardiac arrest. Paramedics began ACLS, attempted defibrillation unsuccessfully, and intubated the patient. Several minutes after his arrival to the ED, the patient had ROSC with sinus bradycardia. Then, 3 min after that, he suffered a repeat VF arrest and the decision was made to activate the ED-REBOA protocol.

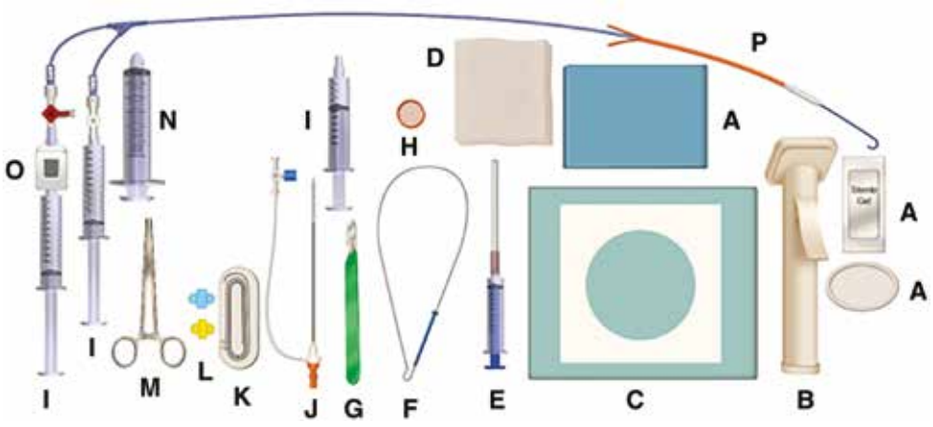

Figure 5 Essential equipment and setup for the REBOA procedure. Items are prepared in the order of their use, from right to left. (**A**) Sterile gel and probe cover and kit. (**B**) Antiseptic sponge. (**C**) Patient drape. (**D**) Gauze. (**E**) Cannulation needle and syringe. (**F**) Guide wire. (**G**) Scalpel. (**H**) Needle holder. (**I**) Sterile saline flushes. (**J**) 7 Fr sheath. (**K**) Sutures. (**L**) Catheter clamps. (**M**) Needle driver. (**N**) Empty syringe. (**O**) Centurion Compass® (Mirador Biomedical) pressure monitoring device. (**P**) ER-REBOA™ catheter.

A "REBOA alert" was sent to on-call EM and IR trial investigators. The patient was enrolled as he had multiple positive prognostic factors despite his comorbidities: his initial rhythm of ventricular fibrillation, ROSC in the ED just prior to enrollment, rapid bystander CPR, and an $ETCO_2$ of 35 mmHg on arrival. Per protocol, an exemption from informed consent was utilized.

Approximately 10 min after his arrival in the ED, an EP investigator began to obtain right CFA access using ultrasound guidance to place the 7 Fr introducer sheath in preparation for ER-REBOA™ (Prytime Medical Devices) catheter insertion. Sheath insertion was successful on the first needle puncture and required approximately 4 min to complete. Arterial placement was then confirmed post-procedure with bedside ultrasound.

IR subsequently advanced the REBOA catheter 45 cm from the insertion site into the thoracic aorta. Investigators did not encounter any difficulty when rapidly advancing the REBOA catheter. The EP performed a bedside ultrasound of the aorta which confirmed placement of the intra-aortic balloon superior to the celiac artery (Figure 5) and the balloon was subsequently inflated with 8 ml of saline. Inflation of the balloon occurred approximately 17 min after ED arrival, and 30 min after his initial arrest.

Significant improvements in the patient's hemodynamics were noted almost immediately after aortic occlusion. A total of 30 s after balloon inflation, the patient's mean arterial pressure (MAP) had increased from 37 mmHg to 50 mmHg and $ETCO_2$ had increased from 35 mmHg to 50 mmHg. ROSC with sinus bradycardia was obtained for approximately 60 s post-balloon inflation, but then devolved into ventricular fibrillation. Defibrillation with 200 J was attempted but on the subsequent pulse check the patient was once again in asystole. Investigators continued ACLS with aortic occlusion for 15 min in total per protocol but the patient never regained cardiac function and was declared deceased. The patient's MAP ranged from 50 to 60 mmHg and $ETCO_2$ from 50 to 57 mmHg for the entirety of the aortic occlusion period.

DISCUSSION

While the use of REBOA in the setting of trauma is becoming more common, we are not aware of any literature describing REBOA placement in the ED for OHCA involving EPs, although there are two similar reports from Europe involving critical care physicians [4,8]. This report provides evidence that the performance of REBOA by an EP lead team during OHCA is feasible and some encouraging hemodynamic data that it may be an effective adjunct to ACLS.

In the United States, when patients suffer trauma or an OHCA, the first physician they typically encounter is an EP. If REBOA eventually proves to be effective at improving perfusion to the heart and brain, its application soon after patient presentation will be crucial. In order for early application of REBOA to be possible in most cases, it is imperative that EPs are adept at utilizing REBOA as an adjunct to current standard of care, as the majority of US hospitals lack around-the-clock in-house intra-vascular specialist coverage.

This report provides early evidentiary support that EPs can build a REBOA program and perform the REBOA procedure for OHCA in conjunction with IR assistance. In this case, the EP was able to successfully perform the most difficult aspect of the procedure: accessing the CFA during chest compressions and achieving first pass success in under 5 min [10]. Correct CFA placement is crucial as unintentional placement in the femoral vein or distal to the CFA bifurcation in the femoral artery could cause sig-

nificant morbidity. While the EP did not advance the actual REBOA catheter due to protocol restrictions, it is unlikely that they would have had difficulty doing so, given the ease with which IR performed this step. We hope to confirm this suspicion in subsequent enrollments.

The physiologic hypothesis supporting the use of REBOA in OHCA is innovative and straight forward: by limiting blood flow to the lower body, one might maximize the perfusion of the brain and heart, in particular the coronary arteries, during OHCA. REBOA is unique in that it seeks to redistribute the cardiac output generated during chest compressions in a more effective manner and may improve cardiac function by improving coronary perfusion. We chose to occlude the aorta in Zone 1, above the level of the celiac artery, because it seemed more likely to provide the desired hemodynamic improvements than placement distally (e.g. Zone 3, distal to the renal arteries). A recent study in swine demonstrated improvements in coronary perfusion with aortic occlusion in Zone 1 compared with Zone 3, which did not improve coronary perfusion (measured through diastolic blood pressure) [11]. There are important ethical considerations when depriving most of the body of needed blood flow, as placement in Zone 1 will potentially cause more ischemic injury than Zone 3. It is our hope that by limiting aortic occlusion time to no more than 15 min, we may mitigate the risk of any resulting ischemic damage. However, patients enrolled in the trial have already undergone at least 15 min of standard ACLS, and evidence has demonstrated that by that point they are highly unlikely to survive with standard care alone [12].

This report provides evidence that EP-initiated REBOA in conjunction with IR assistance is feasible and may improve cardiac perfusion and chest compression quality, as evidenced by immediate improvements in the patient's MAP and $ETCO_2$, respectively. These improvements were maintained for the subsequent 15 min throughout the period of aortic occlusion, save for expected decreases in MAP when chest compressions were paused for pulse checks. Prior to aortic occlusion, the patient had been pulseless for approximately 20 min and then subsequently regained a pulse soon after aortic occlusion was initiated (although this was not sustained). While the patient ultimately died, the temporal association of the patient's hemodynamic improvements and ROSC with aortic occlusion suggests that REBOA may prove to be an effective adjunct to ACLS. It is possible that these hemodynamic improvements could lead to improved patient-centered outcomes, although a much larger controlled study would be required to provide any certainty regarding this hypothesis.

Our initial experience demonstrates that REBOA for OHCA appears to be feasible and associated with a positive hemodynamic effect. The EP-initiated application of REBOA in this case seemed to induce sustained increases in $ETCO_2$ and MAP, and a brief period of ROSC. These changes temporally correlated with aortic balloon inflation, suggesting a causal relationship. Furthermore, this was an important step in demonstrating the feasibility of an EP-initiated pathway for REBOA in OHCA. Significant preparation and staff training enabled an EP lead team to perform the procedure without undue difficulty. However, the involvement of two EPs and one IR makes it unlikely that smaller EDs would be able to enact this protocol as currently written. If future evidence supports the use of REBOA for OHCA, our goal would be to then investigate the feasibility of a single-physician protocol that could be utilized in smaller EDs. Given the positive hemodynamic response and this initial demonstration of feasibility, ED-initiated REBOA may prove to be an effective adjunct to ACLS. Due to the potential complications of REBOA and its promising but uncertain effectiveness, we believe that further research on a much larger scale is warranted before this technique should be widely applied for OHCA patients.

Ethics Statement

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

Conflicts of Interest

The primary author, JD, would like to declare a potential conflict of interest. JD received funding in the form of a research grant from Prytime Inc., the manufacturer of the ER-REBOA™ catheter used in this trial. JD has no other financial relationship with the company and does not personally receive payments of any kind. Prytime Inc. has not viewed this manuscript and had no part in its preparation or the design of the trial.

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Author Contributions

AJ and CM should be considered joint senior authors. All authors have substantially contributed to the study and manuscript writing.

REFERENCES

[1] Jentzer JC, Clements CM, Wright RS, White RD, Jaffe AS. Improving survival from cardiac arrest: a review of contemporary practice and challenges. Ann Emerg Med. 2016;68(6):678–89.

[2] Morrison JJ, Galgon RE, Jansen JO, Cannon JW, Rasmussen TE, Eliason JL. A systematic review of the use of resuscitative endovascular balloon occlusion of the aorta in the management of hemorrhagic shock. J Trauma Acute Care Surg. 2015;80(2):324–34.

[3] Dogan E, Beskow L, Calais F, Horer T, Birger A, Nilsson K. Resuscitative endovascular balloon occlusion of the aorta in experimental cardiopulmonary resuscitation: aortic occlusion level matters. Shock. 2019;52(1):67–74.

[4] Brede JR, Lafrenz T, Krüger AJ, et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA) in non-traumatic out-of-hospital cardiac arrest: evaluation of an educational programme. BMJ Open. 2019;9(5):1–8.

[5] Bekdache O, Paradis T, Shen YBH, et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA): indications: advantages and challenges of implementation in traumatic non-compressible torso hemorrhage. Trauma Surg Acute Care Open. 2019;4(1):e000262–e000262.

[6] Meaney PA, Bobrow BJ, Mancini ME, et al. Cardiopulmonary resuscitation quality: improving cardiac resuscitation outcomes both inside and outside the hospital: a consensus statement from the American heart association. Circulation. 2013;128(4):417–35.

[7] Daley J, Morrison JJ, Sather J, Hile L. The role of resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct to ACLS in non-traumatic cardiac arrest. Am J Emerg Med. 2017;35(5):731–36.

[8] Coniglio C, Gamberini L, Lupi C, et al. Resuscitative endovascular balloon occlusion of the aorta for refractory out-of-hospital non-traumatic cardiac arrest – a case report. Prehosp Disaster Med. 2019;34(5):566–8.

[9] Brede JR, Lafrenz T, Klepstad P, et al. Feasibility of pre-hospital resuscitative endovascular balloon occlusion of the aorta in non-traumatic out-of-hospital cardiac arrest. J Am Heart Assoc. 2019;8(22):e014394.

[10] Romagnoli A, Teeter W, Pasley J, et al. Time to aortic occlusion: it's all about access. J Trauma Acute Care Surg. 2017;83(6):1161–4.

[11] Nowadly CD, Hoareau GL, Grayson JK, Johnson MA. Zone 3 REBOA does not provide hemodynamic benefits during nontraumatic cardiac arrest. Am J Emerg Med. 2020;38(9):1915–20.

[12] Grunau B, Reynolds J, Scheuermeyer F, et al. Relationship between time-to-rosc and survival in out-of-hospital cardiac arrest ecpr candidates: when is the best time to consider transport to hospital? Prehosp Emerg Care. 2016;20(5):615–22.

Original Article

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Pediatric Sized REBOA Catheter Testing in a Pulsatile Aortic Flow Model

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Background: Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in the management of pediatric abdomino-pelvic hemorrhage from trauma or iatrogenic injury is limited by a lack of appropriately sized balloon catheters that can be delivered through a less than 7-Fr sheath.
Methods: We bench tested the occlusion capability of eight commercially available balloon catheters deliverable through 4-Fr, 5-Fr, and 6-Fr sheaths in an anatomic pulsatile flow model of the pediatric aorta with variable luminal diameters (5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, and 12 mm). Inflated balloon migration and the deflated balloon's effect on aortic flow were recorded. The flow chamber was calibrated to an approximate size-appropriate physiologic aortic blood flow.
Results: Seven of the eight devices were able to occlude the test lumen diameter corresponding to their manufactured specifications. Deflated luminal flow restriction in the smallest test lumen was lowest in the Fogarty devices (0–3%) followed by Cordis (8–10%) and Numed (14–26%) devices. The Fogarty devices demonstrated the most distal migration (10–15 mm) followed by Numed (1–5 mm). Device migration was undetectable in the Cordis devices.
Conclusion: There are commercially available balloon catheters, deliverable through smaller than 7-Fr sheaths, which can occlude pediatric sized aortic test lumens in the setting of physiologic pulsatile flow. While the use of these catheters for occlusion represents off-label use, these results will help inform future research, device development, and practice in the field of pediatric REBOA.

Keywords: *Pediatric REBOA; Trauma, Balloon Occlusion Resuscitation; Pulsatile Flow Model*

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INTRODUCTION

Trauma remains the leading cause of mortality for children, and contributes to 30–50% of deaths for children greater than 1 year of age [1]. The majority of deaths occurring within the first hour after presentation to a trauma center are attributable to hemorrhage [2]. Thus, the development of immediately available and rapidly deployable adjuncts to control exsanguinating hemorrhage as a bridge to surgical therapy are essential. For appropriately selected adult patients presenting with abdomino-pelvic hemorrhage, resuscitative endovascular balloon occlusion of the aorta (REBOA) is a promising adjunct to temporize patients until operative source control can be obtained [3,4]. Utilizing percutaneous or cut-down vascular access, REBOA catheters can be inserted through the common femoral artery (CFA) into the descending aorta and inflated to obtain either complete or partial occlusion, thereby decreasing distal blood flow and augmenting proximal pressure to the brain and heart. Adaptation of this technology to

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children with hemorrhage from trauma or iatrogenic injury during high-risk operations may be beneficial.

The use of REBOA in pediatric patients remains controversial with only limited evidence. Recent models of pediatric trauma using 20–30 kg swine have demonstrated the feasibility of REBOA in a pediatric population [5,6]. Norii et al. published a case series using data from the Japan Trauma Data Bank of 54 patients aged 5–17 years who underwent placement of REBOA for trauma [7]. They demonstrated that these patients had equal survival rates to adult trauma patients who underwent REBOA. While most patients were adolescents, the authors recognized that this early clinical use in children was likely increased with the commercial availability of balloon catheters deployed through a 7-Fr sheath instead of a 12-Fr sheath. While this was a significant improvement in device profile, there remains concern regarding morbidity related to access sheath size in young children.

A "one balloon fits all" approach, as utilized in adults, may not be appropriate in the adaptation of REBOA to the pediatric population given the normal morphometric differences amongst children of different ages [8]. In addition, there is greater potential for iatrogenic vessel injury and loss of blood flow to the distal extremity when placing sheaths with a diameter greater than 50% of the vessel luminal diameter [9]. Sheaths and balloons of varying size will be necessary until a child is large enough to safely undergo femoral cannulation with a 7-Fr sheath. While purpose-built REBOA catheters have not been developed for the pediatric population, or for deployment through a sheath smaller than 7-Fr, existing balloon catheters designed for alternative uses may be applicable to these patients' anatomy. Utilizing a benchtop flow chamber, we sought to evaluate readily available balloon catheters deployable through 4-Fr, 5-Fr, and 6-Fr sheaths. We evaluated their ability to maintain appropriate occlusion throughout a range of aortic diameters and their impact on baseline flow when fully deflated.

METHODS

Benchtop Flow Chamber

Our lab developed a benchtop pulsatile flow chamber in order to test occlusion catheters and devices for other experiments related to REBOA (Figure 1). This consisted of an anatomic central arterial circuit with water propelled by a pump. An intermittent solenoid valve controlled by an Arduino microcontroller (Arduino AG, Somerville, MA) with a potentiometer provided pulsatile flow past the main inflow valve. An adjustable bypass segment was placed above the aortic position to allow simulated collateral flow which was titrated with a Hoffman tubing clamp. An in-line flow meter and monitor (Transonic ME 10 PXN and TS410, Transonic Systems Inc., Ithaca, NY) was placed above the aortic occlusion position and pressure was measured both proximal and distal to the aortic position. Replaceable aortic segments were made from polyvinyl chloride tubing of various internal diameters (5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, and 12 mm) to approximate different aortic diameters in children. A 21-Fr sheath was used as the circuit access point for device placement.

Flow Chamber Calibration

For each series of testing, the sized aortic segment was installed and pressure and flow were calibrated to estimated physiologic maximums without an occlusion balloon in place. All balloons were tested at a mean arterial pressure (MAP) of 60 mmHg to mimic the upper range of normal blood pressure with the expectation that hypotensive pressures are less likely to result in balloon occlusion failure. Aortic flow was calibrated based on 50 ml/kg/min using the expected upper limit of weight for each aortic diameter. To fully recapitulate human aortic occlusion physiology, the bypass circuit clamp was adjusted so that during periods of complete aortic segment occlusion with a clamp, the distal systolic blood pressure (SBP) was approximately 10% of the proximal SBP. The calibration parameters for each aortic segment diameter can be found in Table 1.

Balloon Catheter Testing

We selected eight devices from three manufacturers (Cordis, Edwards Lifesciences, Numed) deployable through 4-Fr, 5-Fr, and 6-Fr sheaths with balloon diameters of 8 mm to 12 mm to be tested in the pulsatile flow chamber (Table 2). During testing, each device was evacuated of air and advanced into the aortic position. Aortic flow with the balloon deflated was noted and used to calculate a percent decrease compared with baseline flow. The balloon was then inflated with water using a computerized syringe pump in 0.05 ml increments until flow past the balloon ceased. Inflation volumes were recorded, and the balloon was left in this position for 1 min to evaluate for migration or loss of occlusion. Each balloon was observed for migration and any changes in structure or wall apposition during inflation. The Fogarty embolectomy catheter (PN 120804F) only has a balloon channel and was advanced into position without wire guidance. All other devices were inflated with the guidewire extended at least 30 mm from the tip of the device. If the syringe pump was unable to drive the balloon to occlusion or rupture, manual syringe inflation was attempted. If a device ruptured or failed to occlude the aortic lumen, it was excluded from testing on subsequent aortic sizes.

Ethical Approval and Informed Consent

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

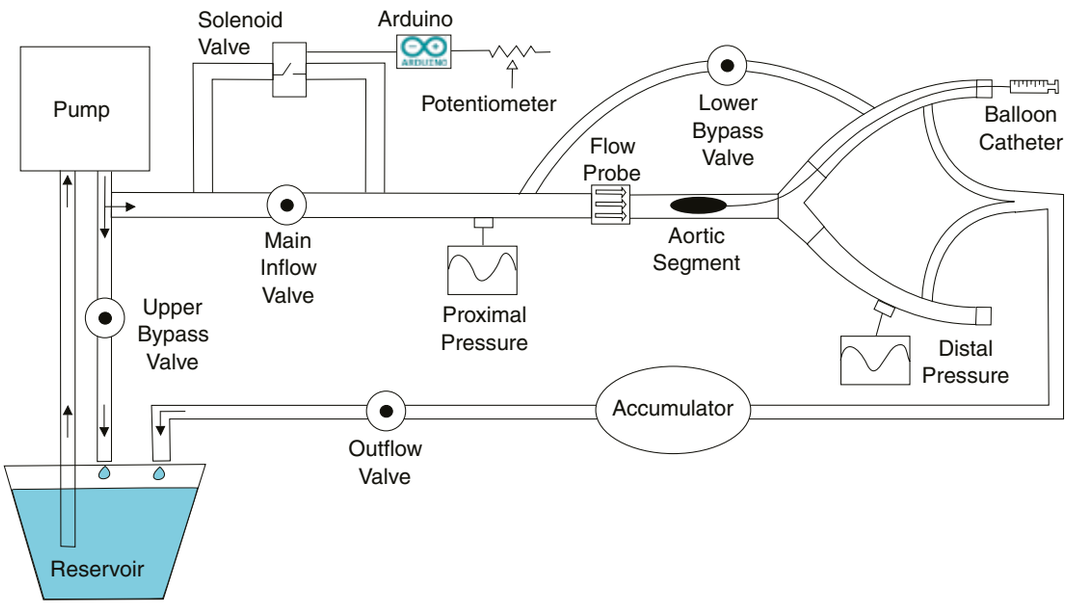

Figure 1 Diagram of pulsatile flow chamber used for occlusion balloon catheter testing.

Table 1 Pulsatile flow chamber settings for aortic occlusion balloon catheter testing.

Aortic Lumen Size (mm)	*Representative Weight (kg)*	*Goal Flow (ml/min)**	*Actual Flow (ml/min)*	*MAP (mmHg)*	*SBP Proximal to Balloon (mmHg)*	*SBP Distal to Balloon (mmHg)*	*Distal: Proximal % Bypass*
5	9	450	490	60	95	10	10.5
6	14	700	700	63	100	10	10.0
7	18	900	900	62	83	6	7.2
8	23	1,150	1,150	59	95	10	10.5
9	29	1,450	1,430	60	100	10	10.0
10	36	1,800	1,800	60	100	9	9.0
12	40	2,000	2,000	60	100	10	10.0

**Calculated as representative weight × 50 ml/kg/min. MAP: mean arterial blood pressure; SBP: systolic blood pressure.*

RESULTS

The results from occlusion catheter testing are summarized in Table 3. All but one device (Cordis 4401004S) were able to occlude the lumen commensurate with their manufacture specifications. There were no instances of loss of occlusion after inflation. In three instances, the balloons were inflated beyond manufacturer specifications resulting in device failure with ruptured balloon. The Fogarty 120804F failed at 2.2 ml of inflation, the Fogarty 12TLW804F failed during device removal after occluding the 10 mm lumen, resulting in tear of the balloon, and the Numed PDC408 ruptured during manual inflation when a 12 mm occlusion was not obtained using the syringe pump. Table 4 displays the percent decrease in flow when the catheters were fully deflated while positioned in the test lumen. The deflated Fogarty catheters had the least amount of luminal flow restriction (0–3%). Deflated Numed devices demonstrated up to a 26.5% decrease in flow in the smaller lumens with lower baseline flows. As expected, all devices, when deflated, trended toward having less of an impact on flow as lumen diameter and flow increased. Balloon migration was limited to the first 15 s following occlusion across all devices. The Fogarty devices demonstrated 10–15 mm of distal migration at the upper limits of testing with significant intraluminal device vibration just prior to occlusion when tested at flow rates over 1,400 ml/min. Numed devices demonstrated 1–5 mm of migration at the upper limits of testing and the Cordis devices did not migrate.

DISCUSSION

The use of REBOA has great potential in the management of traumatic abdominal or pelvic hemorrhage and in prophylactic placement for operations with a

Table 2 Selected occlusion balloon manufacture specifications.

Brand	*Part Number*	*Introducer Sheath (Fr)*	*Balloon Diameter (mm)*	*Balloon Length (mm)*	*Guidewire Diameter (inches)*
Fogarty	120804F	4	9	10	None
Fogarty	12TLW804F	5	9	10	0.025
Fogarty	12TLW805F35	6	11	15	0.035
Numed	PDC408	4	10	40	0.014
Numed	PDC507	5	12	30	0.025
Numed	PDC508	6	12	40	0.035
Cordis	4400808S	5	8	80	0.035
Cordis	4401004S	6	10	40	0.035

Table 3 Occlusion balloon catheter occlusion volume in various lumen diameters.

Balloon Catheter		*Balloon Occlusion Volume (ml)*						
Brand	*Part Number*	*5 mm*	*6 mm*	*7 mm*	*8 mm*	*9 mm*	*10 mm*	*12 mm*
Fogarty	120804F	0.80	1.10	0.90	1.05	1.35	1.95	No occlusion
Fogarty	12TLW804F	0.85	0.95	1.00	1.10	1.15	1.45	NT
Fogarty	12TLW805F35	0.95	0.95	1.10	1.15	1.00	1.35	1.85
Numed	PDC408	1.30	1.40	1.80	2.30	2.90	4.00	No occlusion
Numed	PDC507	1.35	1.60	1.80	2.30	2.65	3.25	4.6
Numed	PDC508	1.70	1.75	2.05	2.40	3.20	3.85	5.75
Cordis	4400808S	2.80	2.90	3.35	3.85	No occlusion	NT	NT
Cordis	4401004S	1.80	2.55	2.50	2.95	3.55	No occlusion	NT

NT: not tested due to failure in previous lumen diameter.

high-risk of severe bleeding such as sacrococcygeal or retroperitoneal tumor resection. This potential is tempered by concern for access site complications and the lack of appropriately sized, purpose built pediatric REBOA catheters. The purpose of this study was to evaluate off-the-shelf balloon catheters that could be used for REBOA in pediatric research and practice.

Anatomical Considerations

If REBOA is to be used in smaller than adult sized children, balloon catheters must be able to be delivered through sheaths smaller than 7 Fr. Alexander et al. identified an increased incidence of loss of lower extremity pulse ipsilateral to the access sheath in children undergoing cardiac catheterization when the sheath outer diameter (OD) was more than 50% of the arterial luminal diameter (AD) [9] During previous work examining pediatric aortic morphometry and preparing a height based adjunct to the Broselow Tape, we concluded that a child of 122 cm or 4 feet should have a CFA large enough to accept a 7-Fr sheath while maintaining a <50% OD/AD ratio [8]. When time permits, besides simply using height, ultrasound evaluation of the CFA prior to cannulation is prudent and can help with sheath and catheter selection.

With normal aortic anatomy, Zone I extends from the origin of the left subclavian to the level of the celiac axis and Zone III starts at the lowest renal artery and ends at the aortic bifurcation [3]. The length of these REBOA landing zones will decrease as the size of the patient decreases. Properly sized devices should not occlude the renal arteries or the celiac axis when correctly positioned. The two most common adult occlusion balloons, ER-REBOA (Prytime Medical, Boerne, TX) and CODA (Cook Medical, Bloomington, IN) have balloon lengths of 37 mm and 35 mm. In adults, the median length of Zone I and Zone III are 210 mm and 97 mm, respectively [10]. In comparison, angiographic measurements of the length of Zone I in 2-year-old children is only 66 mm and Zone 3 measurement data are lacking [11]. Catheters used for pediatric REBOA in Zone III must be of adequate length to prevent flow past the balloon, but short enough to avoid occlusion of the renal arteries.

Device Considerations

Ideal aortic occlusion balloons provide complete 360-degree apposition to the vessel wall, have structural longitudinal rigidity to avoid migration, and are deliverable through a sheath that is appropriately sized for the patient's CFA diameter. Due to concerns for migration

Table 4 Occlusion balloon catheter luminal flow reduction when positioned and fully deflated in various lumen diameters.

Balloon Catheter		*% Decrease in Luminal Flow When Deflated*						
Brand	*Part Number*	*5 mm*	*6 mm*	*7 mm*	*8 mm*	*9 mm*	*10 mm*	*12 mm*
Fogarty	120804F	0.0	1.4	1.1	1.7	0.7	1.1	1.0
Fogarty	12TLW804F	2.0	1.4	1.1	1.7	0.7	0.6	NT
Fogarty	12TLW805F35	3.1	2.9	2.2	2.6	1.4	0.6	0.5
Numed	PDC408	22.4	7.1	4.4	3.5	2.1	0.6	0.5
Numed	PDC507	26.5	11.4	5.6	4.3	2.8	1.7	2.0
Numed	PDC508	14.3	17.1	4.4	4.3	3.5	2.2	2.0
Cordis	4400808S	8.2	8.6	5.6	8.7	4.2	NT	NT
Cordis	4401004S	10.2	10.0	4.4	4.3	3.5	2.2	NT

NT: Not tested due to failure in previous lumen diameter.

and "flipping" of the balloon, we primarily selected "over the wire" balloon devices for testing. In addition, balloon catheters should have a low profile to not only allow passage through a smaller sheath, but also to limit the effects on flow if the balloon is positioned prophylactically and kept deflated. Fogarty devices demonstrated the lowest impact on baseline flow when deflated but were the most apt to migrate when inflated at higher flow rates. Numed devices had less migration and the largest balloon diameter for each of the introducer sheaths tested, but demonstrated the largest decrease in baseline flow when deflated in small vessels with low flow. It is important to note that water was used in the pulsatile flow model which is less viscous than blood. Balloon catheters with significant deflated luminal flow restriction in our model would be expected to have a compounded effect on flow in-vivo.

Balloon compliance plays an important role in occlusion catheters; the most common REBOA catheters (ER-REBOA and CODA) utilize compliant or semi-compliant balloons. While material specifications are proprietary to each manufacture, we are able to comment on the general compliance of the devices tested. The Fogarty catheters, which are typically used as embolectomy catheters, demonstrated compliance similar to that of a Foley catheter balloon with a deflated profile, which most closely approximates the shaft of the catheter without any wrinkles in balloon material. This is good for limiting flow obstruction while deflated, but the balloon lengths were small leading to short segment lumen contact and more migration during testing. The Numed catheters tested are designed for pediatric valvuloplasty and as such are somewhat less compliant than the Fogarty balloons. The overall inflated profile more closely approximated the ER-REBOA with good apposition of the lumen walls and minimal migration. This profile resulted in a 14–26% decrease in flow when deflated in our smallest aortic model. The Cordis catheters used are intended for percutaneous transluminal angioplasty and are specifically designed to be non-compliant. These were the stiffest balloons tested and while they performed well with minimal decrease in aortic flow while deflated and boasted the highest burst pressures, their non-compliant materials may make them more prone to injuring a small vasoconstricted aorta. For the purpose of animal model research, we selected Fogarty balloon catheters for our pediatric swine hemorrhage model and occlusion tolerance studies and would select a similarly designed catheter for clinical applications when indicated.

Table 5 lists the tested catheters by introducer sheath size and their ability to occlude lumens of various sizes and may be used as a guide for catheter selection when these or similar devices are available. The diameter and access sheath size of the commonly used adult occlusion balloon catheters are included for comparison. While these were not tested in our pediatric sized aortic lumens, they have performed well in adult sized conduit at greater pressures and would be expected to provide satisfactory occlusion in smaller lumens.

Limitations

There are several limitations in this in-vitro analysis of occlusion balloon performance. The tubing used in the replaceable aortic segment is less complaint than that of the young human aorta and lacks the vasoconstriction and vasodilation expected in response to shock and endoluminal manipulation. The test duration for each device was limited to 1 min of occlusion. In a static inorganic model this would not be expected to change device dynamics after the initial loading of the balloon and catheter body which occurred within 15 s in our testing. In a dynamic in-vivo model, we would anticipate increased potential for migration due to changes in proximal blood pressure, aortic compliance, and catheter body loading during patient movement. In our model we did not explore partial REBOA which is used to mitigate the metabolic effects of complete occlusion.

Table 5 Select balloon catheter specifications and occlusion capabilities organized by sheath size.

Balloon Catheter Characteristics				*Device Capable of Occlusion?*						
Brand	*Part Number*	*Sheath (Fr)*	*Balloon Diameter (mm)*	*5 mm*	*6 mm*	*7 mm*	*8 mm*	*9 mm*	*10 mm*	*12 mm*
Fogarty	120804F	4	9	Yes*	Yes*	Yes*	Yes*	Yes*	Yes*†	No
Numed	PDC408	4	10	Yes‡	Yes	Yes	Yes	Yes	Yes	No
Fogarty	12TLW804F	5	9	Yes*	Yes*	Yes*	Yes*	Yes*	Yes*†	No
Numed	PDC507	5	12	Yes‡	Yes‡	Yes	Yes	Yes	Yes	Yes
Cordis	4400808S	5	8	Yes	Yes	Yes	Yes	No	No	No
Fogarty	12TLW805F35	6	11	Yes	Yes*	Yes*	Yes*	Yes*	Yes*	Yes†*
Numed	PDC508	6	12	Yes‡	Yes‡	Yes	Yes	Yes	Yes	Yes
Cordis	4401004S	6	10	Yes‡	Yes‡	Yes	Yes	Yes	No	No
Prytime	ER-REBOA	7	32	Included for diameter and sheath comparison						
Cook	CODA 32	12	32	Not tested in this study						
Cook	CODA 40	14	40							

**Balloon fill volume during occlusion is outside manufacture specifications. †Occlusion diameter outside manufacture specifications. ‡Greater than 10% flow decrease when in position and deflated. (Note: there are no FDA approved devices for REBOA in pediatric patients.)*

Partial occlusion may change the action of the balloon catheter, leading to dynamic changes in balloon profile, migration, and vibration. We did not test each catheter over a range of pressures and instead selected 60 mmHg as a baseline MAP above which it is doubtful a patient would need endovascular occlusion. Alteration in balloon dynamics are possible with the augmented proximal pressure associated with aortic occlusion; however, this was not investigated. We tested a limited number of catheters from suppliers that were readily available in the United States. It is possible a superior performing catheter is available that we are unaware of or do not have access to in our market. Finally, each series of tests were performed with the same set of devices that are generally intended to be used once. It is possible that some of the devices failed due to "wear and tear" from being advanced through the sheath several times and may have performed better if a new device was used each time. It was not financially feasible to obtain multiple of the same device for testing. We mitigated device damage by using a 21-Fr access sheath, minimizing contact between the balloon and sheath during withdrawal.

CONCLUSION

The lack of size appropriate balloon occlusion catheters is a roadblock to the use of REBOA in the pediatric population for the management of life-threatening bleeding after trauma and during high-risk operations. This study demonstrates the occlusion capabilities of eight off-the-shelf catheters, deliverable through 4-Fr, 5-Fr, and 6-Fr sheaths, in a pulsatile flow aortic model. While the use of these catheters for REBOA represents an off-label use, this study helps inform catheter selection, pediatric trauma model research, and device design in the management of pediatric traumatic or iatrogenic hemorrhage.

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

MAJ and TKW are stakeholders and cofounders of Certus Critical Care Inc. The other authors declare that they have no conflicts of interest .

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Author Contributions

ED, FT, AJD, JJD, MAJ, TKW, and JS were responsible for the conception and design. ED and FT performed data acquisition. ED performed data analysis and interpretation. ED drafted the manuscript. ED, FT, AJD, JJD, MAJ, TKW, and JS were involved in critical revision of the manuscript. ED has responsibility for the content.

REFERENCES

[1] National Center for Health Statistics. National Vital Statistics System: Mortality Tables 1999–2015. https://www.cdc.gov/nchs/nvss/mortality/lcwk3.htm. Accessed 1 October 2020.

[2] Kauvar DS, Lefering R, Wade CE. Impact of hemorrhage on trauma outcome: an overview of epidemiology, clinical presentations, and therapeutic considerations. J Trauma. 2006;60(6 Suppl):S3–11.

[3] Stannard A, Eliason JL, Rasmussen TE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for hemorrhagic shock. J Trauma. 2011; 71(6):1869–72.

[4] Morrison JJ, Galgon RE, Jansen JO, Cannon JW, Rasmussen TE, Eliason JL. A systematic review of the use of resuscitative endovascular balloon occlusion of the aorta in the management of hemorrhagic shock. J Trauma Acute Care Surg. 2016;80(2):324–34.

[5] Yamashiro KJ, Galganski LA, Grayson JK, et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA) in a pediatric swine model: is 60 minutes too long?. J Trauma Acute Care Surg. 2020; In Press doi: 10.1097/TA.0000000000002620.

[6] Yamashiro KJ, Wishy AM, Beyer CA, et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA) in a pediatric swine liver injury model: a pilot study. J Pediatr Surg. 2020;55(2):346–52.

[7] Norii, T, Miyata S, Terasaka Y, Guliani S, Lu SW, Crandall C. Resuscitative endovascular balloon occlusion of the aorta in trauma patients in youth. J Trauma Acute Care Surg. 2017;82(5):915–20.

[8] DeSoucy ES, Trappey AF, Wishy AM, et al. Approximation of pediatric morphometry for resuscitative endovascular balloon occlusion of the aorta. J Endovasc Resusc Trauma Manag. 2019;3(3):97–103.

[9] Alexander J, Yohannan, T, Abutineh I, et al. Ultrasound-guided femoral arterial access in pediatric cardiac catheterizations: a prospective evaluation of the prevalence, risk factors, and mechanism for acute loss of arterial pulse. Catheter Cardiovasc Interv. 2016;88:1098–107.

[10] Stannard A, Morrison JJ, Sharon DJ, Eliason JL, Rasmussen TE. Morphometric analysis of torso arterial anatomy with implications for resuscitative aortic occlusion. J Trauma Acute Care Surg. 2013;75(2 Suppl 2):S169–72.

[11] Steinberg C, Weinstock DJ, Gold JP, Notterman DA. Measurements of central blood vessels in infants and children: normal values. Cathet Cardiovasc Diagn. 1992; 27:197–201.

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Invited Review

Hybrid Trauma Management: Is It the Way We Are Heading?

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Background: Hybrid trauma management, namely the combination of open and endovascular techniques and/or the application of endovascular methods in the operating/emergency room, is a quickly growing concept worldwide. However, its implications are not well established. We aimed to review the current data regarding hybrid trauma management in medical literature.

Methods: A review of the medical literature published between 2000 and 2020 using PubMed, Cochrane, Embase and Medline databases was performed in search of clinical studies regarding hybrid trauma treatments. Case-reports were excluded from this review. The manuscripts were analyzed regarding the mechanism, location, and type of injury, endovascular and surgical techniques utilized, and the outcome.

Results: In total, 14 studies reporting hybrid trauma management in a total of 1,049 patients met the inclusion criteria and were analyzed. Blunt trauma was the leading trauma mechanism (87.1%) and the most common procedure was transcatheter arterial embolization, performed in 29.7% of patients. The overall mortality was 15.2%. Regarding case-control studies, 85.7% have shown hybrid trauma management to be associated with a shorter time from arrival to intervention, 42.9% reported lower rates of unfavorable outcome, and 28.6% reported reduced requirement for red blood cell transfusion as compared with conventional management.

Conclusions: Accumulating data suggests that hybrid management may be associated with a shorter time from arrival to intervention, lower rates of unfavorable outcomes and a reduced requirement for red blood cell transfusion as compared with conventional management of trauma patients.

Keywords: *EVTM; Hybrid Trauma Management; Hybrid ER; Hybrid OR*

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INTRODUCTION

The concept of endovascular resuscitation for trauma management represents an attractive alternative treatment paradigm for trauma cases previously treated with open surgery [1,2]. Percutaneous trauma procedures may be used to achieve rapid hemorrhage control and urgent repair of damaged vessels [3]. Recent publications have demonstrated lower complication and mortality rates among patients treated by endovascular techniques [4–6].

Hybrid emergency and operating rooms have been reported in patient management in different medical fields, including management of cerebrovascular disease [7,8], cardiac surgery [9,10], and orthopedic surgery [11]. Utilizing hybrid rooms for the management of trauma patients is a new, rapidly progressing concept. Management of hemorrhage, in the setting of acute trauma, by endovascular and combined open-endo techniques has been reported frequently over the past few years [12]. This new approach, used for both hemodynamically stable and unstable patients, is named endovascular resuscitation and trauma management (EVTM) [12]. The foundation of the EVTM society in 2017 enables the sharing of information on advanced bleeding control methods and thus plays an important role in the evolution and growth of the field of hybrid trauma management. The management of trauma patients in different types of hybrid emergency and operating rooms has been described, including management of subclavian artery injury [13], innominate artery injury [14], aortic rupture [15], and tracheobronchial injury [16]. Due to the promising results of hybrid trauma management, installation of newly developed hybrid rooms for trauma management has been reported in recent years [17–19].

These hybrid rooms may eliminate the need to choose between interventional radiology techniques and surgical

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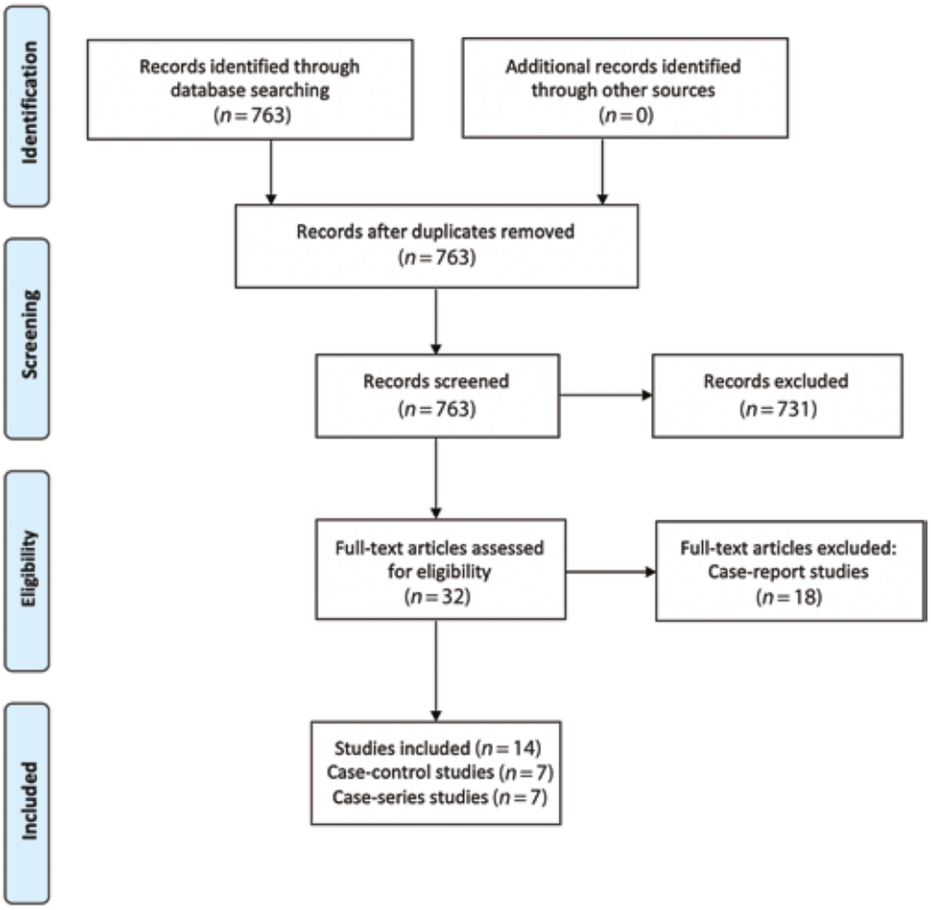

Figure 1 Flow chart of search results. *n* = number of studies.

management and enable the management of trauma patients with combined definitive trauma interventions in a single suite. In addition, hybrid rooms may shorten the time interval from arrival to intervention in acute trauma patients by elimination of transfer time from the resuscitation room to an intervention suite [20]. Fehr et al. [20] assessed the potential benefit of hybrid trauma management and found that up to 7% of persistently hypotensive trauma patients may benefit from the utilization of a hybrid room for trauma management.

However, the hospital preparedness for hybrid trauma management requires sophisticated and expensive equipment, high-level professional skills, and commitment [21]. In addition, management of trauma patients in a hybrid room, combining open and endovascular techniques, is a concept that is still not well established and evidence supporting this type of management is relatively limited.

The aim of this review was to assess the evidence of advantages, risks and results of hybrid management of acute trauma patients, and to summarize the cumulative experience from this concept through a review of the currently available English medical literature.

MATERIALS AND METHODS

A systematic review of the English medical literature was conducted using the Pubmed service of the National Library of Medicine/National Institutes of Health, Cochrane, Embase, and OVID Medline databases to identify all clinical studies regarding hybrid trauma management reported during 2000–2020. Separate search queries were performed using the following terms: "trauma" AND "hybrid" AND "endovascular"; "hybrid emergency room"; "endovascular and hybrid trauma management"; "hybrid operating environment" AND "trauma"; "hybrid operating suite" AND "trauma"; "EVTM"; "RAPTOR" (Resuscitation with Angiography, Percutaneous Techniques and Operative Repair).

Only publications regarding acute trauma patients were included. The following criteria were used to select studies to be included in the analysis: adequate information regarding the mechanism, location, and type of the injury; location and type of hybrid management; surgical intervention; and follow up. Case-reports were excluded from this study as well as clinical studies describing iatrogenic or delayed traumatic event complications.

Methods of descriptive statistics were used to analyze the investigated studies regarding patients' characteristics; mechanism, location, and type of injury; endovascular and surgical techniques utilized; and outcomes. All continuous variables are presented as means + standard deviation or median with interquartile range. All categorical variables are expressed as percentages.

RESULTS

The use of hybrid management in acute trauma patients was described in 32 articles, published during 2000–2020. After exclusion of all case-report descriptive studies (18 studies), 14 studies were included in this review. There were seven case-control studies defined as level III studies and seven case-series defined as level IV studies (Figure 1).

The total number of patients treated in a hybrid emergency room or operating room was 1049, aged 11–79, with an injury severity score ranging between 16 and 75. Blunt trauma was the leading indication for hybrid trauma management comprising 87.1% (914/1049) of cases. Penetrating trauma comprised 9.4% (103/1049) of cases. For 32 cases, the mechanism of trauma was not reported.

Trauma patients were managed in different types of hybrid rooms: 76.6% (804) of the patients were treated in a hybrid emergency room, 6.2% (65) of the patients were treated in a hybrid operating theater, 16.1% (169) of the patients were treated in a RAPTOR suite, and 1.1% (11) of the patients were treated in a combined computed tomography (CT) and angiography suite with a single pivoting table. Results for case-series studies are presented in Table 1. The hybrid techniques utilized in the reviewed studies included different combinations of laparotomy – 19.3% (202 patients), thoracotomy – 3.8% (40 patients), craniotomy – 17.9% (188 patients), preperitoneal pelvic packing – 1.6% (17 patients), neck exploration – 1.4% (15 patients), extremity vascular procedure – 2.6% (27 patients), transcatheter arterial embolization – 29.7% (312 patients), resuscitative endovascular balloon occlusion of the aorta – 0.9% (9 patients), temporary balloon occlusion – 1.1% (11 patients), and stenting – 5.3% (56 patients). The preferred site for endovascular procedure was the femoral artery, although this information was not detailed in many of the studies included in this review.

For trauma patients treated in a hybrid room, an overall mortality of 15.2% (159 patients) was found, ranging between 0% and 60% in different studies. For patients treated conventionally, an overall mortality of 27.8% (239 patients) was found, ranging between 15% and 47% in different studies. The reported endovascular procedure-related complications included a retroperitoneal hematoma in one patient and recurrent bleeding in one patient.

Results for case-control studies are presented in Table 2. Hybrid trauma management was associated with a significantly shorter time from patient arrival to intervention in 85.7% of case-control studies. The mean time to intervention in patients treated in a hybrid room ranged between 45 and 63 min, whereas the mean time to intervention in patients treated conventionally was 64–148 min.

In addition, 42.9% of the case-control studies demonstrated significantly lower rates of unfavorable outcome for patients treated in a hybrid room as compared with controls. However, the remaining 57.1% of case-control studies did not report a significant difference in rates of unfavorable outcome. Rates of unfavorable outcome in hybrid trauma management ranged between 15% and 41% compared with 22–47% for patients treated in a conventional room. Unfavorable outcome was defined as in-hospital mortality or 28-day mortality in four and two studies, respectively. One study, reporting results for patients with traumatic brain injury, defined unfavorable outcome as unfavorable functional outcomes at 6 months after injury, as assessed by the Glasgow Outcome Scale-Extended.

Moreover, two studies, which constitute 28.6% of case-control studies, showed hybrid trauma management was associated with a reduced red blood cell (RBC) transfusion requirement as compared with conventional trauma management. One of these studies [22] reported a mean RBC transfusion volume of 2 units of packed cells for patients treated in a hybrid room, compared with 4 units for patients treated conventionally (p=0.011). The other study [23] reported that the rate of RBC transfusion requirement for patients treated in a hybrid room and patients treated conventionally was 16% and 25% respectively (p=0.04).

DISCUSSION

Following review of the current literature, results suggest possible significant advantages of hybrid trauma management. The survival rate for trauma patients treated in a hybrid room ranged between 40% and 100%. In addition, the endovascular procedure-related complication rate found in this review, including one patient with a retroperitoneal hematoma and one patient who suffered from recurrent bleeding [24 ,25], is significantly lower than the complication rate reported in current endovascular literature. For example, Desai et al. reported an overall complication rate of 21% for patients undergoing endovascular repair of arterial trauma [26]. Similarly, Asaid et al. reported that endovascular repair of traumatic aortic injury was associated with a 20% complication rate, including common femoral artery thrombosis, access-related vessel thrombosis, and endoleaks [27].

Another promising aspect of hybrid trauma management, found in this review, is a decreased rate of unfavorable outcome, found by 42.9% of the analyzed case-control studies [22,28,29]. However, when looking

Table 1 Case-series studies.

	Type of Hybrid OR/ER	*No. of Patients*	*Injury Type*	*Intervention*	*Type of Embolization*	*Time to Intervention (Median and IQR)*	*RBC Transfusion (Mean + SD)*	*Complications (Procedure Related)*	*Survival Rate*
Hörer TM [24]	Angiography table in the surgical suite	7	Penetrating/ blunt trauma, ISS >16 and hemodynamic instability	ABO	–	–	–	Retroperitoneal hematoma - 14.3%	–
Tan H [35]	One-stop hybrid operating room	3	Vascular injury of lower extremity	Endovascular & open debridement, temporary artery blocking, surgical repair	Steel coils, gelatin sponge particles	–	–	None	100%
Teo LT [36]	TAE suite in the OR	32	Severe trauma (ISS>9) with active arterial bleeding	TAE, surgery, pelvic ext. fixation	Coils, gel foams	–	–	None	46.9%
Kinoshita T [32]	HERS	10	Blunt poly-trauma requiring concurrent bleeding control and ICP monitoring	Surgery, TAE, REBOA, intracranial surgery for ICP monitoring,	–	Bleeding control: 29 (22–42) min Neurosurgical intervention: 39 (31–53) min	–	–	40%
Cherry RA [37]	Digital subtraction fluoroscopy unit in the OR	12	Pelvic fracture with hemodynamic instability	Intra-operative TAE	Gel foam slurry	–	–	None	50%
Morozumi J [33]	DSA device and an angiography table in the ER	29	Blunt trauma with pelvic injury	TAE	Platinum coils and/or gelatin sponge	Hemodynamically stable: 27 (23–35) min Hemodynamically unstable: 31 (25–39) min	Hemodynamically stable: 1,259 + 2,021ml Hemodynamically unstable: 2,367ml + 2,358 ml	None	82.8%
Kos X [25]	CT and angiography suite with a single pivoting table	11	Blunt trauma	TAE	Coils, polyvinyl alcohol particles	–	–	Recurrent bleeding (9.1%)	100%

Continuous variables are expressed as the median and interquartile range (25th and 75th percentiles) or as means + standard deviation. Categorical variables are expressed as %. ABO: aortic balloon occlusion; CT: computed tomography; DSA: digital subtraction angiography; ER: emergency room; HERS: hybrid emergency room system; ICP: intracranial pressure; ISS: injury severity score; OR: operating room; RBC: red blood cells; REBOA: resuscitative endovascular balloon occlusion of the aorta; TAE: transcatheter arterial embolization.

Table 2 Case-control studies.

	Type of Hybrid OR/ER	*No. Cases (Hybrid ER/OR)*	*No. Controls (Conventional ER/OR)*	*Injury Type*	*Intervention*	*Type of Embolization*	*Time to Intervention (Cases vs Controls)*	*RBC Transfusion (Median/Rate) (Cases vs Controls)*	*Unfavorable Outcome (Cases vs Controls)*
Kataoka Y [38]	Digital subtraction angiography device in the OR	13	45	Abd. injuries, multiorgan injuries	Surgery, TAE, TBO, stenting	Gelatin sponge strip, steel coils, NBCA	–	4,174 (2,576–5,772) ml vs 5,832 (4,515–7,149) ml ($p = 0.24$, NS)	In-hospital mortality: 15% vs 36% ($p = 0.31$, NS)
Ito K [30]	HERS	24	72	Pelvic fractures	AE, REBOA	–	AE: 46 (5–75) min vs 103 (2–690) min ($p < 0.01$) REBOA: 63 (10–480) min vs 81 (56–213) min (no *p*-value data)	12 (0–130) U vs 8 (0–84) U ($p = 0.58$, NS)	In-hospital mortality: Total: 13% vs 15% ($p = 0.52$, NS) REBOA: 43% vs 75% (no *p*-value data)
Kinoshita T [28]	Hybrid ER with IVR-CT unit	70	88	TBI	Intracranial surgery, bleeding control surgery	–	50 (42–55) min vs 64 (57–70) min ($p < 0.001$)	–	Adjusted unfavorable outcome at 6 months (Odds ratio): 0.42 (0.18–0.93)
Kinoshita T [31]	Hybrid ER with IVR-CT unit	336	360	Non-penetrating severe trauma (ISS ≥16)	DCS, TAE, craniotomy	–	47 (37–57) min vs 68 (51–85) min ($p < 0.0001$)	0 (0–4) U vs 0 (0–4) U ($p = 0.18$, NS)	28-day mortality: Total: 15% vs 22% ($p = 0.028$) Exsanguination: 3% vs 8% ($p = 0.007$)
Harmsen AMK [22]	Hybrid resuscitation room	282	219	Blunt & penetrating Severe trauma (ISS >15)	Surgery, IVR	–	–	2 (2–5) U vs 4 (2–9) U ($p = 0.011$)	In-hospital mortality: 41% vs 47% ($p = 0.043$)
Carver D [23]	RAPTOR suite	169	169	Severe trauma (ISS >12)	Surgery, AE, aortic endostenting	–	82min vs 148min (IVR), 101min (OR) ($p < 0.05$) (no IQR data)	16% vs 25% ($p = 0.04$)	In-hospital mortality: 14% vs 15% ($p = 0.76$, NS)
Wada D [29]	Hybrid ER with IVR-CT system	21	27	Blunt trauma requiring emergency bleeding control	TAE, surgery	–	Surgery: 45 (37–65) min vs 108 (81–129) min ($p = 0.004$) TAE: 54 (42–66) min vs 75 (58–105) min ($p = 0.007$)	10 (2–16) U vs 14 (8–24) U ($p = 0.335$ NS)	28-day mortality: 24% vs 19% ($p = 0.729$, NS)

Continuous variables are expressed as the median and interquartile range (25th and 75th percentiles) or as means + standard deviation. Categorical variables are expressed as %. Abd.: abdominal; AE: angioembolization; CT: computed tomography; DCS: damage control surgery; ER: emergency room; HERS: hybrid emergency room system; IVR: interventional radiology; ISS: injury severity score; NBCA: n-butyl-2-cyanoacrylate; NS: not significant; OR: operating room; RBC: red blood cells; REBOA: resuscitative endovascular balloon occlusion of the aorta; TAE: transcatheter arterial embolization; TBI: traumatic brain injury; TBO: temporary balloon occlusion; U: units.

at the ranges of rates of unfavorable outcome in hybrid vs. conventional management (15–41% and 22–47%, respectively), the ranges do not appear to be very different. A possible explanation for this finding is that this review includes studies with a wide range of injury type and severity level. Thus, rates of unfavorable outcome are highly variable across different studies included in this review, making comparison of the studies very limited. In addition, this review has found a reduced RBC transfusion volume requirement in patients treated in a hybrid room, reported in two of the studies analyzed [22,23]. These findings may be partially attributed to the significantly shorter time from patient arrival to intervention for patients treated in a hybrid room as compared with conventional management, as reported in some of the studies reviewed [23,28–31].

An interesting aspect of our review is that it revealed a wide range of different types of hybrid rooms used for trauma management. In several studies, the type of hybrid emergency room used for trauma management was a hybrid emergency room system (HERS) which consists of a trauma resuscitation room equipped with a CT scanner, fluoroscopy equipment, and an operating room setup [28,30–32]. The HERS was installed in Osaka, Japan in 2011 and was first reported by the founding members of the Japanese Association for Hybrid Emergency Room System [17]. The HERS is equipped with a sliding CT scanner system with interventional radiology features and was created in order to facilitate both diagnostic and therapeutic interventions in a single room [17]. One study included in this review reported the use of an intensive care unit designed for surgical intervention and equipped with a mobile digital subtraction angiography device [33]. In two other studies, the hybrid emergency room used for trauma management was a RAPTOR suite [22,23]. The new concept and establishment of a RAPTOR suite was first described by Kirkpatrick et al. [34]. This suite, which entered clinical service in March 2013, was designed to provide the ultimate setting to prevent exsanguination and eliminate delays in hemorrhage control in trauma patients. This pioneer suite was equipped with a ceiling mounted single-planar angiography, coupled with a hybrid surgical operating table, and integrated with an operating room integration system [34]. Other hybrid operating rooms used for trauma management were operating rooms equipped with a digital subtraction angiography device [24,35–38]. One study included in this review, reported results of trauma patients' management in an angiography suite equipped with a spiral CT [25].

These new hybrid rooms present exciting new possibilities for the management of trauma patients. On the other hand, the benefits of hybrid trauma management must be weighed against the high cost and human resource demand of these rooms and workflows [20]. Furthermore, the limited availability of hybrid rooms should be taken into consideration since hybrid rooms are used not only for trauma management, but for a wide range of procedures as well, such as treatment of neurovascular disease [8], which is mainly performed in elective surgery settings. Similarly, new approaches for aortic valve replacement utilize hybrid operating rooms in some medical centers and are also performed electively [10]. Therefore, these hybrid rooms and the operating team needed to operate them may not be available for trauma patients on a 24 h basis.

While the results of the reviewed studies are promising, a number of limitations of this review must be highlighted. One important limitation is the fact that all case-control studies have compared management of trauma patients in a single center before and after installation of a hybrid room. It is important to recognize that throughout the years, other than the installation of a hybrid room, many other changes must have been implemented in these medical centers alongside worldwide advancements in trauma care. Therefore, the promising results of these studies may reflect not only the advantages of installation and utilization of hybrid rooms, but also the different improvements which have evolved in the care of trauma patients.

Another limitation is the retrospective nature of the reviewed studies, which are therefore subject to selection bias and information bias. When discussing our results, it is important to note that no randomized controlled or prospective studies were found. Thus, this review included studies with a level of evidence of III and IV, and no level I or II studies were analyzed.

Lastly, limited comparability of the analyzed studies must be taken into account. The reviewed studies differ greatly with regard to patients' injury type and severity. Furthermore, this review included studies performed in different centers worldwide. Hence, the differences in therapeutic approach, capabilities, and level of expertise between different trauma centers must be taken into consideration.

CONCLUSIONS

The existing studies show promising results regarding the outcomes of hybrid trauma management, including decreased rates of unfavorable outcome, shorter time from arrival to treatment, and reduced requirement for blood transfusion in different studies. However, the published studies to date are observational and retrospective studies with a low level of evidence. Interestingly, some centers have already adopted hybrid trauma management as a standard of care. Future data collected from these centers may further support the use of this approach in the future as a standard of care worldwide.

We believe findings of this review justify the urgent need for further prospective studies to better understand the possible advantages of and indications for hybrid trauma management. These future studies should also

address the high cost and resource demand of this promising new approach.

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

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no financial support for this work.

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Author Contributions

MP was responsible for the drafting of the manuscript, data acquisition, data analysis and interpretation. BK was responsible for study conception and design, data analysis and interpretation, critical revision.

REFERENCES

[1] Pryor JP, Braslow B, Reilly PM, Gullamondegi O, Hendrick JH, Schwab CW. The evolving role of interventional radiology in trauma care. J Trauma. 2005;59(1): 102–4.
[2] Zealley IA, Chakraverty S. The role of interventional radiology in trauma. BMJ. 2010;340:c497.
[3] Ball CG, Kirkpatrick AW, D'Amours SK. The RAPTOR: Resuscitation with angiography, percutaneous techniques and operative repair. Transforming the discipline of trauma surgery. Can J Surg. 2011;54(5):E3–4.
[4] Branco BC, DuBose JJ, Zhan LX, et al. Trends and outcomes of endovascular therapy in the management of civilian vascular injuries. J Vasc Surg. 2014;60(5):1297–307.e1.
[5] Branco BC, Boutrous ML, DuBose JJ, et al. Outcome comparison between open and endovascular management of axillosubclavian arterial injuries. J Vasc Surg. 2016;63(3):702–9.
[6] Romagnoli AN, Zeeshan M, Joseph B, Brenner ML. Utilization of endovascular and open surgical repair in the United States: A 10-year analysis of the National Trauma Databank (NTDB). Am J Surg. 2019;218(6): 1128–33.
[7] Jeon HJ, Lee JY, Cho BM, Yoon DY, Oh S-M. Four-year experience using an advanced interdisciplinary hybrid operating room: Potentials in treatment of cerebrovascular disease. J Korean Neurosurg Soc. 2019;62(1): 35–45.
[8] Choi E, Lee JY, Jeon HJ, Cho B-M, Yoon DY. A hybrid operating room for combined surgical and endovascular procedures for cerebrovascular diseases: A clinical experience at a single centre. Br J Neurosurg. 2019;33(5):490–4.
[9] Singh A, Mehta Y, Parakh R, Kohli V, Trehan N. Role of hybrid operating room in surgery for the right atrial thrombus, pulmonary thrombi, and ventricular septal rupture after myocardial infarction. Ann Card Anaesth. 2016;19(4):717–21.
[10] Spaziano M, Lefèvre T, Romano M, et al. Transcatheter aortic valve replacement in the catheterization laboratory versus hybrid operating room: Insights from the FRANCE TAVI registry. JACC Cardiovasc Interv. 2018; 11(21):2195–203.
[11] Richter PH, Yarboro S, Kraus M, Gebhard F. One year orthopaedic trauma experience using an advanced interdisciplinary hybrid operating room. Injury. 2015;46 Suppl 4:S129–34.
[12] Hörer TM, Pirouzram A, Khan M, et al. Endovascular Resuscitation and Trauma Management (EVTM) - practical aspects and implementation. Shock. 2020; *In Press*. doi: 10.1097/SHK.0000000000001529
[13] Karkos CD, Mair R, Markose G, Fishwick G, London NJM, Naylor, AR. Hybrid procedures combining open and endovascular surgical techniques for the management of subclavian artery injuries. J Trauma. 2007;63(5): E107–10.
[14] Bilos L, Pirouzram A, Toivola A, Vidlund M, Cha SO, Hörer T. EndoVascular and Hybrid Trauma Management (EVTM) for blunt innominate artery injury with ongoing extravasation. Cardiovasc Intervent Radiol. 2017;40(1):130–4.
[15] Schmid FX, Philipp A, Link J, Zimmerman M, Birnbaum DE. Hybrid management of aortic rupture and lung failure: Pumpless extracorporeal lung assist and endovascular stent-graft. Ann Thorac Surg. 2002;73(5):1618–20.
[16] Wada D, Hayakawa K, Maruyama S, et al. A paediatric case of severe tracheobronchial injury successfully treated surgically after early CT diagnosis and ECMO safely performed in the hybrid emergency room. Scand J Trauma Resusc Emerg Med. 2019;27(1):49.
[17] Founding members of the Japanese Association for Hybrid Emergency Room System (JA-HERS). The hybrid emergency room system: A novel trauma evaluation and care system created in Japan. Acute Med Surg. 2019;6(3):247–51.
[18] Watanabe H, Shimojo Y, Hira E, et al. First establishment of a new table-rotated-type hybrid emergency room system. Scand J Trauma Resusc Emerg Med 2018;26(1):80.
[19] Wada D, Nakamori Y, Kanayama S, et al. First installation of a dual-room IVR-CT system in the emergency room. Scand J Trauma Resusc Emerg Med. 2018;26:17.
[20] Fehr A, Beveridge J, D'Amours SD, Kirkpatrick AW, Ball CG. The potential benefit of a hybrid operating environment among severely injured patients with persistent hemorrhage: How often could we get it right? J Trauma Acute Care Surg. 2016;80(3):457–60.
[21] Tatum D, Duchesne J, Pereira B, et al. Time to hemorrhage control in a hybrid ER system: Is it time to

change? Shock. 2020; *In Press*. doi: 10.1097/SHK.0000000000001539.
[22] Harmsen AMK, Giannakopoulos GF, Terra M, de Lange de Klerk ESM, Bloemers FW. Ten year maturation period in a level-I trauma center, a cohort comparison study. Eur J Trauma Emerg Surg. 2017;43(5):685–90.
[23] Carver D, Kirkpatrick AW, D'Amours S, Hameed SM, Beveridge J, Ball CG. A prospective evaluation of the utility of a hybrid operating suite for severely injured patients: Overstated or underutilized? Ann Surg. 2020;271(5):958–61.
[24] Hörer TM, Skoog P, Pirouzram A, Nilsson KF, Larzon T. A small case series of aortic balloon occlusion in trauma: Lessons learned from its use in ruptured abdominal aortic aneurysms and a brief review. Eur J Trauma Emerg Surg. 2016;42(5):585–92.
[25] Kos X, Fanchamps JM, Trotteur G, Dondelinger RF. Radiologic damage control: Evaluation of a combined CT and angiography suite with a pivoting table. Cardiovasc Intervent Radiol. 1999;22(2):124–9.
[26] Desai SS, DuBose JJ, Parham CS, et al. Outcomes after endovascular repair of arterial trauma. J Vasc Surg. 2014;60(5):1309–14.
[27] Asaid R, Boyce G, Atkinson N. Endovascular repair of acute traumatic aortic injury: experience of a level-1 trauma center. Ann Vasc Surg. 2014;28(6):1391–5.
[28] Kinoshita T, Hayashi M, Yamakawa K, et al. Effect of the hybrid emergency room system on functional outcome in patients with severe traumatic brain injury. World Neurosurg. 2018;118:e792–9.
[29] Wada D, Nakamori Y, Yamakawa K, Fujimi S. First clinical experience with IVR-CT system in the emergency room: positive impact on trauma workflow. Scand J Trauma Resusc Emerg Med. 2012;20:52.
[30] Ito K, Nagao T, Tsunoyama T, et al. Hybrid emergency room system improves timeliness of angioembolization for pelvic fracture. J Trauma Acute Care Surg. 2020;88(2):314–9.
[31] Kinoshita T, Yamakawa K, Matsuda H, et al. The survival benefit of a novel trauma workflow that includes immediate whole-body computed tomography, surgery, and interventional radiology, all in one trauma resuscitation room: A retrospective historical control study. Ann Surg. 2019;269(2):370–6.
[32] Kinoshita T, Yamakawa K, Yoshimura J, et al. First clinical experiences of concurrent bleeding control and intracranial pressure monitoring using a hybrid emergency room system in patients with multiple injuries. World J Emerg Surg. 2018;13:56.
[33] Morozumi J, Homma H, Ohta S, et al. Impact of mobile angiography in the emergency department for controlling pelvic fracture hemorrhage with hemodynamic instability. J Trauma. 2010;68(1):90–5.
[34] Kirkpatrick AW, Vis C, Dubé M, et al. The evolution of a purpose designed hybrid trauma operating room from the trauma service perspective: the RAPTOR (Resuscitation with Angiography Percutaneous Treatments and Operative Resuscitations). Injury. 2014;45(9):1413–21.
[35] Tan H, Zhang LY, Guo QS, et al. "One-stop hybrid procedure" in the treatment of vascular injury of lower extremity. Indian J Surg. 2015;77(1):75–8.
[36] Teo LT, Punamiya S, Chai CY, et al. Emergency angio-embolisation in the operating theatre for trauma patients using the C-Arm digital subtraction angiography. Injury. 2012;43(9):1492–6.
[37] Cherry RA, Goodspeed DC, Lynch FC, Delgado J, Reid SJ. Intraoperative angioembolization in the management of pelvic-fracture related hemodynamic instability. J Trauma Manag Outcomes. 2011;5:6.
[38] Kataoka Y, Minehara H, Kashimi F, et al. Hybrid treatment combining emergency surgery and intraoperative interventional radiology for severe trauma. Injury. 2016;47(1):59–63.

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Narrative Review Article

Endovascular Versus Open: Emergency Department Resuscitative Endovascular Balloon Occlusion of the Aorta or Thoracotomy for Management of Post-Injury Non-compressible Torso Hemorrhage

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Non-compressible torso hemorrhage (NCTH) (i.e. bleeding from anatomical locations not amenable to control by direct pressure or tourniquet application) is a leading cause of potentially preventable death after injury. In select trauma patients with infra-diaphragmatic NCTH-related hemorrhagic shock or traumatic circulatory arrest, occlusion of the aorta proximal to the site of hemorrhage may sustain or restore spontaneous circulation. While the traditional method of achieving proximal aortic occlusion included Emergency Department thoracotomy (EDT) with descending thoracic aortic cross-clamping, resuscitative endovascular balloon occlusion of the aorta (REBOA) affords a less invasive option when thoracotomy is not required for other indications. In this article, we review the innovation, pathophysiologic effects, indications for, and technique of EDT and partial, intermittent, and complete REBOA in injured patients, including recommended methods for reversing aortic occlusion. We also discuss advantages and disadvantages of each of these methods of proximal aortic occlusion and review studies comparing their effectiveness and safety for managing post-injury NCTH. We conclude by providing recommendations as to when each of these methods may be best, when indicated, to manage injured patients with NCTH.

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INTRODUCTION

Non-compressible torso hemorrhage (NCTH) (i.e. bleeding from anatomical locations not amenable to control by direct pressure or tourniquet application) is a leading cause of potentially preventable death after injury [1–5]. In 2012, Morrison and Rasmussen defined NCTH as torso hemorrhage from one of four anatomic sites (lung, abdominal solid organ, major vascular, or the pelvis) in patients with signs of hemorrhagic shock (blood pressure (BP) <90 mmHg or lactate >4 mmol/L) and/or the need for immediate open or endovascular hemorrhage control [5,6]. In one retrospective cohort study, approximately 70% of included trauma patients with NCTH were reported to be bleeding from an anatomic site within the abdomen or pelvis and the primary cause of death was exsanguination, often occurring 2 hours following presentation [7].

In select trauma patients with infra-diaphragmatic NCTH-related hemorrhagic shock or traumatic circulatory arrest, occlusion of the aorta proximal to the site of hemorrhage may sustain or restore spontaneous circulation [8,9]. While the traditional method of achieving proximal aortic occlusion included Emergency Department thoracotomy (EDT) with descending thoracic aortic cross-clamping [8,9], resuscitative endovascular balloon occlusion of the aorta (REBOA) affords a less invasive option when thoracotomy is not required for other indications (e.g. cardiac tamponade) [10]. REBOA requires that the common femoral artery (CFA) be accessed percutaneously or via femoral cutdown. A catheter with a compliant balloon near its tip is then inserted into the aorta through a femoral sheath and partially, intermittently, or completely inflated in aortic zone 1 (located between the left subclavian and celiac artery) or zone 3 (located between the lowest renal artery and aortic bifurcation) (Figure 1) [10].

In this article, we review the innovation, pathophysiologic effects, indications for, and technique of EDT and partial, intermittent, and complete REBOA in injured patients, including recommended methods for reversing aortic occlusion. We also discuss advantages and disadvantages of these methods of proximal aortic occlusion and review studies comparing their effectiveness and safety for managing post-injury NCTH. We conclude by providing recommendations as to when each of these methods may be best, when indicated, to manage injured patients with NCTH.

Ethical Approval and Informed Consent

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

PATHOPHYSIOLOGIC EFFECTS OF PROXIMAL AORTIC OCCLUSION

Proximal aortic occlusion has several potentially beneficial pathophysiologic effects among hemodynamically unstable patients [11–14]. Zone 1 aortic occlusion increases preload, systematic vascular resistance, central aortic BP, and coronary (the aortic diastolic-to-right atrial pressure difference during myocardial relaxation) and cerebral perfusion [15]. In contrast, zone 3 aortic occlusion causes only a mild increase in mean arterial pressure [15]. Finally, proximal aortic occlusion reduces hemorrhage distal to the level of the occlusion, and in patients with profound hemorrhagic shock secondary to intra-abdominopelvic hemorrhage, it may prevent cardiovascular collapse during laparotomy [11–14].

Some data suggests that zone 1 aortic occlusion, particularly via REBOA, may also help in achieving return of spontaneous circulation (ROSC) after circulatory arrest. In patients who have suffered cardiac arrest, zone 1 aortic occlusion increases both coronary perfusion pressure and end-tidal CO_2 ($ETCO_2$), two measures that are independent predictors of ROSC [16,17]. Further, in one study of six swine receiving cardiopulmonary resuscitation (CPR) after prolonged ventricular fibrillation-induced cardiac arrest, zone 1 aortic occlusion significantly increased coronary perfusion pressure and $ETCO_2$, and three of the animals subsequently had ROSC [18]. However, less favorable results have been reported with REBOA in animal models of infradiaphragmatic NCTH [19].

Thoracic aortic occlusion also has several potentially adverse pathophysiologic effects. Complete zone 1 aortic occlusion induces supraphysiologic proximal aortic and aortic branch pressures and increases left ventricular (LV) afterload, wall tension, and subendocardial oxygen demand [15]. It also causes mesenteric, hepatic, renal, spinal cord (because of reduced intercostal, lumbar, and internal iliac arterial collateral flow to the anterior spinal artery), and lower extremity ischemia; therefore, prolonged inflation in aortic zone 1 may produce mesenteric infarction, acute kidney and spinal cord injury, and may potentially lead to limb loss [15]. In an ovine hemorrhagic shock model, all six sheep who had a zone 1 aortic occlusion time of 60 min died as compared with only one of six who had an occlusion time of 30 min [20]. Further, all animals with 60 min of zone 1 REBOA had renal histologic evidence of acute tubular necrosis [20]. Prolonged proximal aortic occlusion also induces a systemic inflammatory response that likely leads to an increased incidence of acute lung injury and acute respiratory distress syndrome (ARDS) [21]. In a swine hemorrhagic shock

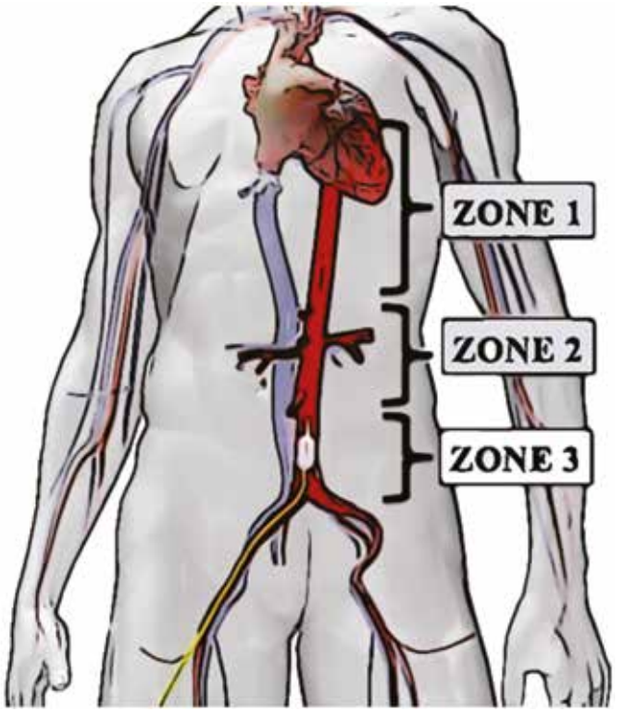

Figure 1 Aortic occlusion zones 1, 2, and 3.

model, when compared with 30 min of zone 1 REBOA, animals with 60 min and 90 min of zone 1 occlusion had significantly higher concentrations of systemic interleukin-6. There was also a trend toward a greater incidence of ARDS in these groups [21].

EDT

To prevent cardiovascular collapse during laparotomy, EDT with cross-clamping of the descending thoracic aorta was first advocated by Ledgerwood et al. in 1976 for hypotensive trauma patients with tense abdominal distention [9]. EDT consists of a left anterolateral or clamshell (i.e. bilateral anterior) thoracotomy performed in the Emergency Department (ED) [22,23]. In contrast, the term "resuscitative thoracotomy" (RT) refers to a thoracotomy performed in the operating room or intensive care unit (ICU) for delayed physiologic decompensation [22]. Importantly, in addition to cross-clamping the aorta, EDT is also indicated to release pericardial tamponade, temporarily control cardiac, mediastinal, pulmonary, or pulmonary hilar hemorrhage, evacuate air emboli, and perform open cardiac massage and defibrillation [22]. It has also been used to provide rapid, large-volume fluid resuscitation via a catheter sutured into the right atrial appendage [24,25].

In 2015, the Eastern Association for the Surgery of Trauma (EAST) published a clinical practice guideline on patient selection for EDT [26]. The authors conducted a systematic review of published EDT studies and used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework to determine whether patients who present to hospital pulseless should undergo EDT based on the mechanism of injury and signs of life [26]. Ultimately, they included 72 cohort studies published between 1974 and 2013 that enrolled 10,238 patients who underwent EDT for traumatic circulatory arrest [26]. Based on these studies, EAST provided one strong (based on moderate quality evidence) and five conditional recommendations (based on low to moderate quality evidence) regarding the use of EDT [26]. They also reported estimates of in-hospital and neurologically intact survival associated with the use of these indications across the included studies [26].

In 2018, DuBose et al. and the American Association for the Surgery of Trauma (AAST) Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) study group conducted a retrospective cohort study of the AORTA registry to determine if publication of the EAST guideline was associated with changes in EDT practice or outcomes [27]. This registry included data on 310 patients who underwent EDT across 16 American College of Surgeons (ACS)-verified level I or II or active Canadian trauma centers between November 2013 and December 2016 [27]. Most patients were injured by penetrating mechanisms (64%), had received prehospital CPR (58%), and had signs of life upon presentation (47%), including organized electrical activity, pupillary response, spontaneous movement, or appreciable pulse/BP [27]. When compared with the systematic review conducted by EAST, there was no difference in in-hospital or neurologically intact survival among patients included in the AORTA registry when EDT was conducted for any of the indications recommended by EAST (Table 1) [27]. In both this study and the EAST systematic review, the estimated survival associated with conducting EDT for patients with blunt mechanisms of injury or without signs of life was dismal (<5% for all indications) [27].

The precise safe duration of thoracic aortic cross-clamping in trauma patients is largely unknown and likely dependent on a number of factors [26–28]. Data from studies published decades ago suggest that, although thoracic aortic cross-clamp durations up to 60 min are likely safe, shorter durations are associated with a higher probability of survival [9,29]. The original EDT study by Ledgerwood et al. reported that thoracic aortic cross-clamp durations ranged from 7–60 min and averaged 27 min among trauma patients who survived after EDT before or after trauma laparotomy [9]. Millikan and Moore subsequently reported that nearly one-third of 39 patients with significant hemodynamic instability before or after trauma laparotomy survived following cross-clamping of the descending thoracic aorta for an average of 56 min or 58 min, respectively. Further, the average cross-clamp duration was 29 min among survivors versus 57 min among patients who died.

Table 1 Estimates of hospital and neurologically intact survival after EDT for select indications conditionally recommended by EAST [26,27].

	Estimate of Survival – No./Total (%)			
Indication	*In-Hospital (AORTA Registry, 2013–2016)*	*In-Hospital (EAST Systematic Review, 1974–2013)*	*Neurologically Intact (AORTA Registry, 2013–2016)*	*Neurologically Intact (EAST Systematic Review, 1974–2013)*
Penetrating extrathoracic injury with signs of life on admission	4/32 (13)	25/160 (16)	4/32 (13)	14/85 (17)
Penetrating extrathoracic injury without signs of life on admission	1/64 (2)	4/139 (3)	1/64 (2)	3/60 (5)
Blunt injury with signs of life on admission	3/68 (4)	21/454 (5)	1/68 (2)	7/298 (2)
Blunt injury without signs of life on admission	0/45 (0)	7/995 (1)	0/45 (0)	1/825 (0.1)

AORTA: Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery; EDT: emergency department thoracotomy; EAST: Eastern Association for the Surgery of Trauma.

EDT is associated with an increased risk of provider occupational injury and exposure to trauma patient blood-borne illnesses [26,30]. Studies conducted in the United States have reported that the prevalence of human immunodeficiency virus (HIV) and hepatitis C virus infection among trauma patients may approach 4.3% and 14%, respectively [30]. In a multicenter prospective cohort study conducted across 16 predominantly level 1 American trauma centers, 7.2% of 305 EDTs were complicated by occupational exposures [30]. Those providers who suffered exposures were primarily trainees (68%) who endured percutaneous (86%) (i.e. needlestick or cut with a sharp object) injuries [30]. In this study, full personal protective equipment (PPE) was utilized by only 46% of exposed providers, and utilizing more PPE items during EDT was independently associated with a lower odds of occupational exposure [30].

Survivors of EDT may suffer a number of post-procedural complications. In a retrospective cohort study conducted across two level 1 trauma centers in Houston, Texas, 32% of 298 patients who underwent an RT after traumatic arrest survived to ICU admission and 9.4% to discharge [31]. The most common complications among patients admitted to the ICU after RT included acute kidney injury (10.4%), ventilator-associated pneumonia (8.3%), ARDS (7.3%), deep surgical site infection (7.3%), and deep venous thrombosis (7.3%). For the 28 patients who survived to hospital discharge, the average number of per-patient complications was 1.9, and the mean length of ICU and hospital stay was 24 and 44 days, respectively.

REBOA

In 1954, Lieutenant Colonel Carl W. Hughes was the first to report the use of an intra-aortic balloon catheter to control infra-diaphragmatic NCTH in injured patients [32,33]. For decades after this, little was written regarding the use of intra-aortic occlusion balloons for trauma because of a limited availability of balloon catheters [33]. However, with innovations in vascular and endovascular surgery came the development of commercial, compliant aortic balloon catheters that could be inserted over stiff wires through 12 or 14 French sheaths during elective and emergent repair of abdominal aortic aneurysms [33–35]. Surgical experience gained from the Iraq and Afghanistan military conflicts led to increased interest in using REBOA in military and civilian settings as an alternative to EDT for proximal aortic control, particularly for patients with pelvic fracture-related hemorrhagic shock [33,36].

The Basic Endovascular Skills for Trauma (BEST™) course has developed a REBOA decision-making algorithm for hypotensive patients [37]. Before deciding to use REBOA in patients who do not respond, or only partially respond, to traditional resuscitation measures, trauma providers must assess for signs of thoracic aortic injury or intrathoracic pathology that may produce hemodynamic compromise (e.g. cardiac tamponade or tension pneumo- or hemopneumothorax) [33,37,38]. An extended focused assessment with sonography for trauma (eFAST) examination (or bilateral finger or tube thoracostomy in patients who have suffered cardiac arrest) may be used to rule out hemopneumothoraces while eFAST/cardiac ultrasound is used to exclude pericardial tamponade [33,37,39]. A relative contraindication to REBOA is chest X-ray findings suggestive of thoracic aortic injury (widened mediastinum, opacified aortopulmonary window, irregular aortic arch, blurred aortic contour, rightward tracheal deviation, and left apical pleural hematoma/cap) [37,40].

In 2018, the ACS Committee on Trauma and the American College of Emergency Physicians (ACEP) issued a joint statement outlining indications for REBOA [41]. They also provided guidelines for REBOA use and implementation, patient transfer and management

during and after REBOA, REBOA training and credentialing, and REBOA quality assurance, maintenance of competence, performance improvement, and patient safety. They outlined that while REBOA will be uncommon in most settings, it is currently standard practice for select patients at a small number of trauma centers where surgeons are immediately available. Further, they recommended REBOA for traumatic life-threatening infra-diaphragmatic hemorrhage in patients arriving in arrest or hemorrhagic shock who are unresponsive or transiently responsive to resuscitation. The balloon catheter was suggested to be inflated in zone 1 for control of intra-abdominal or retroperitoneal hemorrhage or those with traumatic arrest and zone 3 for control of severe pelvic, junctional, or proximal lower extremity hemorrhage. The second edition of the guideline also emphasized the need for rapid definitive hemorrhage control, advocating that complete occlusion be <30 min in zone 1 and <60 min in zone 3 [42]. The guideline also recommends that REBOA not be performed in locations where definitive hemorrhage control cannot begin within 15 min for patients with REBOA in zone 1 and/or 30 min for those with REBOA in zone 3.

The above joint statements recognized that no high-grade evidence demonstrates that REBOA improves outcomes or survival compared with standard treatments for severe hemorrhage [41,42]. A randomized controlled trial evaluating the safety, effectiveness, and cost-effectiveness of REBOA in injured patients with NCTH has not yet been completed. There have, however, been a number of observational studies that have evaluated the safety and effectiveness of REBOA. Results of these studies have been summarized across one scoping and four systematic reviews [43–47]. In the scoping review, Bekdache et al. included 105 articles that enrolled 8,741 trauma patients [43]. Most articles included patients with blunt abdominal or pelvic trauma who had REBOA inserted percutaneously in the ED by trauma and acute care surgeons. The majority of current articles reported using the 7 French catheter in zone 1 or 3. Aortic occlusion times ranged from 10–60 min, with 20 min being most commonly reported.

Results of systematic reviews of case reports/series and cohort studies on the use of REBOA are summarized in Table 2 [44–47]. These studies reported that REBOA deployment was associated with a median 53–79 mmHg increase in systolic BP, and that it may be associated with improved mortality when compared with alternate methods of proximal aortic occlusion [44–47]. In contrast, in a propensity score-matched retrospective cohort study by Joseph et al. published in 2019, the use of REBOA in severely injured trauma patients was associated with a higher risk of mortality, acute kidney injury, and lower extremity amputation when compared with no use of REBOA [48]. However, the study was unable to consider certain critical variables such as duration of aortic occlusion, physiology at the time of REBOA, size of introducer sheaths, and others that have been demonstrated to correlate with morbidity and mortality [49]. Patients who received REBOA after 60 min were also not included despite representing a critical subset of patients who come to the ED normotensive and receive REBOA after that time. A multi-institutional study demonstrated that up to 60% of patients who receive REBOA are not admitted with a systolic BP of >90 mmHg [50]. Patients who were dead-on-arrival (DOA) were also excluded, although in some high volume REBOA centers approximately half of REBOA patients were DOA or in arrest at the time of the procedure.

REBOA complications may occur among 4–5% or more of patients treated [44–47]. These most frequently include arterial access complications (e.g. pseudoaneurysm) and arterial thrombosis or thromboembolic events, which may ultimately require lower extremity amputation [44–47]. In the above scoping review, complications reportedly associated with use of REBOA in trauma patients most commonly included distal ischemic events and amputations (12%), pseudoaneurysm formation (7%), and balloon migration (0.15%) or rupture (0.07%) [43]. However, lower extremity compartment syndrome, intracranial hemorrhage, acute kidney injury, multisystem organ failure, and balloon catheter exit through an aortic injury have also been described [43].

PARTIAL AND INTERMITTENT REBOA

Two alternate methods of aortic balloon occlusion that aim to improve the balance between minimizing ongoing hemorrhage and lessening distal ischemia-reperfusion injury include partial and intermittent REBOA [51,52]. A common method of performing partial REBOA is to serially deflate the completely inflated aortic occlusion balloon by incrementally removing small volumes of saline until minimum arterial waveforms appear distal to the balloon (measured via the side-port of the REBOA insertion sheath or via a second sheath placed in the contralateral CFA) [51,52]. As compared with complete REBOA, animal studies have reported that partial or intermittent REBOA may extend the safe duration of aortic occlusion, mitigate the potentially detrimental effects of supraphysiologic proximal arterial pressures, reduce the distal ischemia-reperfusion injury, the inflammatory and metabolic insult, and infra-diaphragmatic end-organ injury, and possibly improve survival [13,51,53–59]. Animal studies have also suggested that precipitous proximal arterial BP drops are reduced with partial REBOA; further, weaning REBOA may be better tolerated after a period of partial REBOA [13,51,53–59]. To facilitate partial REBOA, a commercial partial REBOA catheter was recently developed that features a semi-compliant balloon that allows for small adjustments in balloon volume and more accurate control of distal aortic flow [60].

Table 2 Principal results of systematic reviews of the safety and effectiveness of REBOA for management of trauma patients.

Author, Year	*Search Period*	*No.*		*Trauma Pts (%)*	*Access*	*Occlusion Time*	*Safety*	*Effectiveness*
		Articles	*Pts*					
Borger van der Burg et al., 2018 [44]	1900–2017	89	1,482	59	NR	Median zone 1 = 59 min, zone 2 = 4 min, and zone 3 = 68 min	Iatrogenic injuries = 4%	REBOA associated with a mean increase of 79 mmHg (95% CI = 59–99) in systolic BP Use of REBOA instead of other methods of aortic occlusion associated with improved mortality (OR = 0.25; 95% CI = 0.11–0.56)
Manzano-Nunez et al., 2018 [45]	Database inception–2018	13	424	100	Percutaneous = 73% and cut down = 27%	NR	Incidence of complications = 5% (95% CI = 3–9%) Lower limb amputation required in 2% of patients Incidence of groin access complications was 0%, 5%, and 16% when REBOA was inserted by ED physicians, trauma surgeons, and anesthesiologists or radiologists, respectively The incidence of complications was 2% in studies where REBOA was inserted percutaneously versus 5% when both both percutaneous and surgical cutdown techniques were reported, and 11% when only surgical cutdown was used	NR

Author, Year	Search Period	No. Articles	No. Pts	Trauma Pts (%)	Access	Occlusion Time	Safety	Effectiveness
Gamberini et al., 2017 [46]	Database inception–2016	61	1,355	100	NR	Mean occlusion time ranged from 20–65 min	There may be a significant correlation between total occlusion time, serum lactate, and shock index Distal ischemia/thromboembolic events (0.7%), intracranial hemorrhage (0.07%), access pseudoaneurysm (0.2%), renal failure (0.9%), balloon migration (e.g. into zone 2) (0.2%), infection (0.3%), retroperitoneal hematoma (0.07%), insertion failure (0.07%), balloon rupture (0.07%) Risk factors for complications include increased BMI, thrombocytopenia, emergency procedures, large introducer size, and use of antiplatelet drugs	NR
Morrison et al., 2016 [47]	1946–2015	41	857	15/41 studies	Percutaneous=77% when prophylactic arterial access was obtained in anticipation of major hemorrhage and only 56% when patients were in hemorrhagic shock	Median zone 1 = 63 min (IQR = 33–88) Median zone 3 = 45 min (IQR = 30–105)	Overall rate of morbidity within the reporting literature = 4%, arterial injury = 3%, amputation = 1%, and nonfatal embolic events = 0.8% There were no reports of lower extremity paralysis	REBOA associated with a mean increase of 53 mmHg (95% CI = 44–61) in systolic BP Cohort studies reported variable associations between REBOA and mortality

BMI: body mass index; BP: blood pressure; CI: confidence interval; ED: Emergency Department; IQR: interquartile range; NR: not reported; OR: odds ratio; Pts: patients; REBOA: resuscitative endovascular balloon occlusion of the aorta.

REVERSING AORTIC OCCLUSION AFTER EDT AND REBOA

Strategies for reversing aortic occlusion include the gradual release of the aortic cross-clamp or deflation of the balloon, volume loading, and administration of vasoconstricting agents [61]. Typically, longer periods of aortic occlusion require more gradual weaning and increased fluid resuscitation and vasopressor support [51]. For complete and partial REBOA, the suggested goal for reversing aortic occlusion is to increase the systolic arterial BP distal to the balloon by 50% from baseline every 5 min to allow distal ischemic metabolites to be washed out into the central circulation between deflations [51].

EDT VERSUS REBOA FOR MANAGEMENT OF NCTH

There are several potential advantages of REBOA over EDT for proximal aortic occlusion in patients with NCTH. REBOA is less invasive, may be associated with less aortic endothelial damage, and in skilled hands may be more rapidly performed when compared to RT [41,62]. Use of REBOA instead of EDT for proximal aortic occlusion may also be safer for trauma providers, as it avoids risk of transmission of HIV, hepatitis B and C, and other blood borne viruses that may occur during EDT [26]. REBOA also avoids opening the thoracic cavity and therefore may be expected to be associated with a lower loss of heat and incidence of severe hypothermia after injury when compared with EDT (a finding associated with an increased incidence of traumatic coagulopathy, further blood loss, and the vicious cycle of hypothermia, acidosis, and coagulopathy) [63,64]. Finally, incrementally removing small volumes of saline from the aortic occlusion balloon during the transition from complete to no REBOA may allow for a safer or more precise method of reversing aortic occlusion than gradually removing an aortic cross-clamp during EDT.

In patients who have suffered a traumatic circulatory arrest, some clinical data also exists to suggest that REBOA is associated with improved CPR and a higher probability of ROSC when compared with EDT [65,66]. In one cohort study, Teeter et al. used multiview, time-stamped videography to compare total cardiac compression time (TCCT) (the total time that closed compressions (for REBOA patients) or that closed compressions and open cardiac massage (for RT patients) were performed) and total cardiac compression fraction (TCCF) (the time compressions occurred during the entire resuscitation phase) between patients who received aortic occlusion after cardiac arrest via REBOA or RT [65]. The authors reported that TCCT and TCCF were higher in those who underwent REBOA; further, the total duration of interruptions of cardiac compressions (e.g. for procedural tasks) was shorter in patients who received REBOA before and during resuscitation with aortic occlusion [65]. Another cohort study by the same group reported that in patients with traumatic arrest, patients who underwent REBOA instead of RT had a higher $ETCO_2$ and TCCF prior to and after aortic occlusion [66]. Moreover, when compared with those who received RT, ROSC was more common in patients who received REBOA and more patients survived to operative intervention [66].

Perhaps because of the previously mentioned potential advantages, a systematic review and meta-analysis reported that use of REBOA over aortic cross-clamping during RT in patients with NCTH may be associated with improved in-hospital mortality (67). This systematic review included three cohort studies (two retrospective and one prospective) published between 2016 and 2017 enrolling 1,276 trauma patients with NCTH, including 873 (68%) who underwent REBOA and 403 (32%) who underwent RT [68–70]. When compared with those who received RT, patients who received REBOA had significantly higher systolic BPs, a higher probability of survival on admission, and more often underwent arterial embolization. Using a random-effects model, the pooled adjusted odds of in-hospital mortality was non-significantly lower among patients who underwent REBOA instead of RT. Further, in sensitivity analyses where results were pooled after excluding a study at higher risk of bias or using risk ratios or propensity score-adjusted risk ratios, the risk of in-hospital mortality was significantly lower in patients who underwent REBOA instead of RT.

Importantly, the outcomes of REBOA may be predicated on obtaining early and rapid CFA access [71–73]. In one recent cohort study conducted at an American level 1 trauma center, time to aortic occlusion in trauma patients was faster with RT than REBOA [71]. However, approximately 50% of the overall procedural time was attributed to obtaining CFA access, with no significant difference reported between percutaneous access and surgical cut-down. Therefore, proactive CFA access in injured patients who are thought to possibly need aortic occlusion may be associated with improved outcomes [72,73]. In support of this, in one cohort study of 109 injured patients who presented to one of 23 hospitals in Japan, a shorter hospital arrival to CFA access time in patients managed with REBOA was associated with improved survival [72,73]. Further, patients who achieved CFA access within 22 min of arrival had significantly shorter times to definitive hemostasis and a higher survival at 30 days.

CONCLUSION AND RECOMMENDATIONS

In patients presenting with profound hemorrhagic shock or traumatic circulatory arrest, REBOA may provide a less invasive alternative to EDT that reduces occupational risks and insensible heat losses. REBOA does not appear to be inferior to EDT for patients with traumatic arrest and may permit higher quality CPR and be associated

with a higher probability of ROSC. However, the outcomes of REBOA are likely predicated on obtaining early, rapid CFA access and avoiding access-related complications. Therefore, REBOA may afford a potentially less morbid option for proximal aortic control when performed by experienced providers.

Ethics Statement

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

Conflicts of Interest

Dr. Brenner is a Prytime Medical Inc. (the manufacturer of the ER-REBOA™ catheter) Clinical Advisory Board Member. The other authors have no conflicts of interest to declare.

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Author Contributions

MLB conceived the idea for the manuscript. DJR and MLB performed the literature search. DJR wrote the manuscript, which was critically revised by all authors. All authors reviewed and approved the final manuscript.

REFERENCES

[1] Teixeira PG, Inaba K, Hadjizacharia P, et al. Preventable or potentially preventable mortality at a mature trauma center. J Trauma. 2007;63(6):1338–46; discussion 46–7.
[2] Tien HC, Spencer F, Tremblay LN, Rizoli SB, Brenneman FD. Preventable deaths from hemorrhage at a level I Canadian trauma center. J Trauma. 2007;62(1):142–6.
[3] Holcomb JB, McMullin NR, Pearse L, et al. Causes of death in U.S. Special Operations Forces in the global war on terrorism: 2001–2004. Ann Surg. 2007;245(6): 986–91.
[4] Eastridge BJ, Mabry RL, Seguin P, et al. Death on the battlefield (2001–2011): implications for the future of combat casualty care. J Trauma Acute Care Surg. 2012;73(6 Suppl 5):S431–7.
[5] Morrison JJ, Rasmussen TE. Noncompressible torso hemorrhage: a review with contemporary definitions and management strategies. Surg Clin N Am. 2012; 92(4):843–58.
[6] Morrison JJ. Noncompressible torso hemorrhage. Crit Care Clin. 2017;33(1):37–54.
[7] Chang R, Fox EE, Greene TJ, et al. Multicenter retrospective study of noncompressible torso hemorrhage: anatomic locations of bleeding and comparison of endovascular versus open approach. J Trauma Acute Care Surg. 2017;83(1):11–8.
[8] Sankaran S, Lucas C, Walt AJ. Thoracic aortic clamping for prophylaxis against sudden cardiac arrest during laparotomy for acute massive hemoperitoneum. J Trauma. 1975;15(4):290–6.
[9] Ledgerwood AM, Kazmers M, Lucas CE. The role of thoracic aortic occlusion for massive hemoperitoneum. J Trauma. 1976;16(08):610–5.
[10] Stannard A, Eliason JL, Rasmussen TE. Resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct for hemorrhagic shock. J Trauma. 2011; 71(6):1869–72.
[11] Deakin CD, Barron DJ. Haemodynamic effects of descending aortic occlusion during cardiopulmonary resuscitation. Resuscitation. 1996;33(1):49–52.
[12] White JM, Cannon JW, Stannard A, Markov NP, Spencer JR, Rasmussen TE. Endovascular balloon occlusion of the aorta is superior to resuscitative thoracotomy with aortic clamping in a porcine model of hemorrhagic shock. Surgery. 2011;150(3):400–9.
[13] Kuckelman JP, Barron M, Moe D, et al. Extending the golden hour for Zone 1 resuscitative endovascular balloon occlusion of the aorta: improved survival and reperfusion injury with intermittent versus continuous resuscitative endovascular balloon occlusion of the aorta of the aorta in a porcine severe truncal hemorrhage model. J Trauma Acute Care Surg. 2018;85(2):318–26.
[14] Dogan EM, Beskow L, Calais F, Horer TM, Axelsson B, Nilsson KF. Resuscitative endovascular balloon occlusion of the aorta in experimental cardiopulmonary resuscitation: aortic occlusion level matters. Shock. 2019; 52(1):67–74.
[15] Qasim ZA, Sikorski RA. Physiologic considerations in trauma patients undergoing resuscitative endovascular balloon occlusion of the aorta. Anesth Analg. 2017; 125(3):891–4.
[16] Hartmann SM, Farris RW, Di Gennaro JL, Roberts JS. Systematic review and meta-analysis of end-tidal carbon dioxide values associated with return of spontaneous circulation during cardiopulmonary resuscitation. J Intensive Care Med. 2015;30(7):426–35.
[17] Link MS, Berkow LC, Kudenchuk PJ, et al. Part 7: adult advanced cardiovascular life support: 2015 American Heart Association guidelines update for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation. 2015;132(18 Suppl 2):S444–64.
[18] Tiba MH, McCracken BM, Cummings BC, et al. Use of resuscitative balloon occlusion of the aorta in a swine model of prolonged cardiac arrest. Resuscitation. 2019;140:106–12.
[19] Barnard EBG, Manning JE, Smith JE, Rall JM, Cox JM, Ross JD. A comparison of selective aortic arch perfusion and resuscitative endovascular balloon occlusion of the aorta for the management of hemorrhage-induced traumatic cardiac arrest: a translational model in large swine. PLoS medicine. 2017;14(7):e1002349.
[20] Reva VA, Matsumura Y, Horer T, et al. Resuscitative endovascular balloon occlusion of the aorta: what is the optimum

occlusion time in an ovine model of hemorrhagic shock? Eur J Trauma Emerg Surg. 2018;44(4):511–8.
[21] Morrison JJ, Ross JD, Markov NP, Scott DJ, Spencer JR, Rasmussen TE. The inflammatory sequelae of aortic balloon occlusion in hemorrhagic shock. J Surg Res. 2014;191(2):423–31.
[22] Mattox KL, Moore EE, Feliciano DV, Eds. Trauma. 7th ed. China: McGraw Hill Companies Inc.; 2013.
[23] Simms ER, Flaris AN, Franchino X, Thomas MS, Caillot JL, Voiglio EJ. Bilateral anterior thoracotomy (clamshell incision) is the ideal emergency thoracotomy incision: an anatomic study. World J Surg. 2013;37(6):1277–85.
[24] Samelson SL, Robin AP, Merlotti GJ, Lange DA, Barrett JA. A new method of rapid fluid resuscitation during thoracotomy performed in the emergency room. Surg Gynecol Obstet. 1987;165(2):175–6.
[25] Renz BM, Stout MJ. Rapid right atrial cannulation for fluid infusion during resuscitative emergency department thoracotomy. Am Surg. 1994;60(12):946–9.
[26] Seamon MJ, Haut ER, Van Arendonk K, et al. An evidence-based approach to patient selection for emergency department thoracotomy: a practice management guideline from the Eastern Association for the Surgery of Trauma. J Trauma Acute Care Surg. 2015;79(1):159–73.
[27] DuBose J, Fabian T, Bee T, et al. Contemporary utilization of resuscitative thoracotomy: results from the AAST aortic occlusion for resuscitation in trauma and acute care surgery (AORTA) multicenter registry. Shock. 2018;50(4):414–20.
[28] Nevins EJ, Bird NTE, Malik HZ, et al. A systematic review of 3251 emergency department thoracotomies: is it time for a national database? Eur J Trauma Emerg Surg. 2019;45(2):231–43.
[29] Millikan JS, Moore EE. Outcome of resuscitative thoracotomy and descending aortic occlusion performed in the operating room. J Trauma. 1984;24(5):387–92.
[30] Nunn A, Prakash P, Inaba K, et al. Occupational exposure during emergency department thoracotomy: a prospective, multi-institution study. J Trauma Acute Care Surg. 2018;85(1):78–84.
[31] Fitch JL, Dieffenbaugher S, McNutt M, et al. Are we out of the woods yet? The aftermath of resuscitative thoracotomy. J Surg Res. 2020;245:593–9.
[32] Hughes CW. Use of an intra-aortic balloon catheter tamponade for controlling intra-abdominal hemorrhage in man. Surgery. 1954;36(1):65–8.
[33] Osborn LA, Brenner ML, Prater SJ, Moore LJ. Resuscitative endovascular balloon occlusion of the aorta: current evidence. Open Access Emerg Med. 2019;11:29–38.
[34] Malina M, Veith F, Ivancev K, Sonesson B. Balloon occlusion of the aorta during endovascular repair of ruptured abdominal aortic aneurysm. J Endovasc Ther. 2005;12(5):556–9.
[35] Berland TL, Veith FJ, Cayne NS, Mehta M, Mayer D, Lachat M. Technique of supraceliac balloon control of the aorta during endovascular repair of ruptured abdominal aortic aneurysms. J Vasc Surg. 2013;57(1): 272–5.
[36] Rasmussen TE, Dubose JJ, Asensio JA, et al. Tourniquets, vascular shunts, and endovascular technologies: esoteric or essential? A report from the 2011 AAST Military Liaison Panel. J Trauma Acute Care Surg. 2012; 73(1):282–5.
[37] Brenner M, Hoehn M, Pasley J, Dubose J, Stein D, Scalea T. Basic endovascular skills for trauma course: bridging the gap between endovascular techniques and the acute care surgeon. J Trauma Acute Care Surg. 2014;77(2): 286–91.
[38] Roberts DJ, Leigh-Smith S, Faris PD, et al. Clinical presentation of patients with tension pneumothorax: a systematic review. Ann Surg. 2015;261(6):1068–78.
[39] Roberts DJ, Niven DJ, James MT, Ball CG, Kirkpatrick AW. Thoracic ultrasonography versus chest radiography for detection of pneumothoraces: challenges in deriving and interpreting summary diagnostic accuracy estimates. Crit Care. 2014;18(2):416.
[40] Gutierrez A, Inaba K, Siboni S, et al. The utility of chest X-ray as a screening tool for blunt thoracic aortic injury. Injury. 2016;47(1):32–6.
[41] Brenner M, Bulger EM, Perina DG, et al. Joint statement from the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP) regarding the clinical use of resuscitative endovascular balloon occlusion of the aorta (REBOA). Trauma Surg Acute Care Open. 2018; 3(1):e000154.
[42] Bulger EM, Perina D, Qasim Z, et al. The clinical use of resuscitative endovascular balloon occlusion of the aorta (REBOA) in civilian trauma systems in the United States, 2019: a joint statement from the American College of Surgeons Committee on Trauma, the American College of Emergency Physicians, the National Association of EMS Physicians, and the National Association of EMTs. Trauma Surg Acute Care Open. 2019;20;4(1):e000376.
[43] Bekdache O, Paradis T, Shen YBH, et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA): indications: advantages and challenges of implementation in traumatic non-compressible torso hemorrhage. Trauma Surg Acute Care Open. 2019;4(1):e000262.
[44] Borger van der Burg BLS, van Dongen T, Morrison JJ, et al. A systematic review and meta-analysis of the use of resuscitative endovascular balloon occlusion of the aorta in the management of major exsanguination. Eur J Trauma Emerg Surg. 2018;44(4):535–50.
[45] Manzano-Nunez R, Orlas CP, Herrera-Escobar JP, et al. A meta-analysis of the incidence of complications associated with groin access after the use of resuscitative endovascular balloon occlusion of the aorta in trauma patients. J Trauma Acute Care Surg. 2018;85(3):626–34.
[46] Gamberini E, Coccolini F, Tamagnini B, et al. Resuscitative endovascular balloon occlusion of the aorta in trauma: a systematic review of the literature. World J Emerg Surg. 2017;12:42.
[47] Morrison JJ, Galgon RE, Jansen JO, Cannon JW, Rasmussen TE, Eliason JL. A systematic review of the use of resuscitative endovascular balloon occlusion of the aorta in the management of hemorrhagic shock. J Trauma Acute Care Surg. 2016;80(2):324–34.
[48] Joseph B, Zeeshan M, Sakran JV, et al. Nationwide analysis of resuscitative endovascular balloon occlusion of the aorta in civilian trauma. JAMA Surg. 2019;154(6): 500–8.
[49] DuBose RJ, Morrison J, Brenner M, et al. AORTA Registry 7F vs 11–12 F access. J Endovasc Resusc Trauma Manag. 2019;3(1):15–21.

[50] Brenner M, Inaba K, Aiolfi A, et al. Resuscitative endovascular balloon occlusion of the aorta and resuscitative thoracotomy in select patients with hemorrhagic shock: early results from the American Association for the Surgery of Trauma's Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery Registry. J Am Coll Surg. 2018;226(5):730–40.

[51] Johnson MA, Neff LP, Williams TK, DuBose JJ. Partial resuscitative balloon occlusion of the aorta (P-REBOA): Clinical technique and rationale. J Trauma Acute Care Surg. 2016;81(5 Suppl 2 Proceedings of the 2015 Military Health System Research Symposium): S133–7.

[52] DuBose JJ. How I do it: partial resuscitative endovascular balloon occlusion of the aorta (P-REBOA). J Trauma Acute Acute Care Surg. 2017;83(1):197–9.

[53] Russo RM, Neff LP, Lamb CM, et al. Partial resuscitative endovascular balloon occlusion of the aorta in swine model of hemorrhagic shock. J Am Coll Surg. 2016; 223(2):359–68.

[54] Russo RM, Williams TK, Grayson JK, et al. Extending the golden hour: partial resuscitative endovascular balloon occlusion of the aorta in a highly lethal swine liver injury model. J Trauma Acute Care Surg. 2016;80(3):372–8; discussion 8–80.

[55] Sadeghi M, Horer TM, Forsman D, et al. Blood pressure targeting by partial REBOA is possible in severe hemorrhagic shock in pigs and produces less circulatory, metabolic and inflammatory sequelae than total REBOA. Injury. 2018;49(12):2132–41.

[56] Reva VA, Matsumura Y, Samokhvalov IM, et al. Defining degree of aortic occlusion for partial-REBOA: a computed tomography study on large animals. Injury. 2018;49(6):1058–63.

[57] Kauvar DS, Schechtman DW, Thomas SB, et al. Effect of partial and complete aortic balloon occlusion on survival and shock in a swine model of uncontrolled splenic hemorrhage with delayed resuscitation. J Trauma Acute Care Surg. 2019;87(5):1026–34.

[58] Johnson MA, Hoareau GL, Beyer CA, et al. Not ready for prime time: intermittent versus partial resuscitative endovascular balloon occlusion of the aorta for prolonged hemorrhage control in a highly lethal porcine injury model. J Trauma Acute Care Surg. 2020;88(2):298–304.

[59] Kuckelman J, Derickson M, Barron M, et al. Efficacy of intermittent versus standard resuscitative endovascular balloon occlusion of the aorta in a lethal solid organ injury model. J Trauma Acute Care Surg. 2019;87(1): 9–17.

[60] Russo RM, Franklin CJ, Davidson AJ, et al. A new, pressure-regulated balloon catheter for partial resuscitative endovascular balloon occlusion of the aorta (REBOA). J Trauma Acute Care Surg. 2020;89(2S Suppl 2):S45–S49.

[61] Zammert M, Gelman S. The pathophysiology of aortic cross-clamping. Best Pract Res Clin Anaesthesiol. 2016;30(3):257–69.

[62] Gelman S. The pathophysiology of aortic cross-clamping and unclamping. Anesthesiology. 1995;82(4):1026–60.

[63] Kashuk JL, Moore EE, Millikan JS, Moore JB. Major abdominal vascular trauma—a unified approach. J Trauma. 1982;22(8):672–9.

[64] Roberts DJ, Ball CG, Feliciano DV, et al. History of the innovation of damage control for management of trauma patients: 1902–2016. Ann Surg. 2017;265(5): 1034–44.

[65] Teeter W, Romagnoli A, Wasicek P, et al. Resuscitative endovascular balloon occlusion of the aorta improves cardiac compression fraction versus resuscitative thoracotomy in patients in traumatic arrest. Ann Emerg Med. 2018;72(4):354–60.

[66] Teeter WA, Bradley MJ, Romagnoli A, et al. Treatment effect or effective treatment? Cardiac compression fraction and end-tidal carbon dioxide are higher in patients resuscitative endovascular balloon occlusion of the aorta compared with resuscitative thoracotomy and open-chest cardiac massage. Am Surg. 2018;84(10):1691–5.

[67] Manzano Nunez R, Naranjo MP, Foianini E, et al. A meta-analysis of resuscitative endovascular balloon occlusion of the aorta (REBOA) or open aortic cross-clamping by resuscitative thoracotomy in non-compressible torso hemorrhage patients. World J Emerg Surg. 2017;12:30.

[68] Aso S, Matsui H, Fushimi K, Yasunaga H. Resuscitative endovascular balloon occlusion of the aorta or resuscitative thoracotomy with aortic clamping for noncompressible torso hemorrhage: a retrospective nationwide study. J Trauma Acute Care Surg. 2017;82(5):910–4.

[69] DuBose JJ, Scalea TM, Brenner M, et al. The AAST prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA). J Trauma Acute Care Surg. 2016;81(3):409–19.

[70] Abe T, Uchida M, Nagata I, Saitoh D, Tamiya N. Resuscitative endovascular balloon occlusion of the aorta versus aortic cross clamping among patients with critical trauma: a nationwide cohort study in Japan. Crit Care. 2016;20(1):400.

[71] Romagnoli A, Teeter W, Pasley J, et al. Time to aortic occlusion: It's all about access. J Trauma Acute Care Surg. 2017;83(6):1161–4.

[72] Matsumura Y, Matsumoto J, Kondo H, et al. Early arterial access for resuscitative endovascular balloon occlusion of the aorta is related to survival outcome in trauma. J Trauma Acute Care Surg. 2018;85(3):507–11.

[73] Matsumura Y, Matsumoto J, Kondo H, et al. Early arterial access for REBOA is related to survival outcome in trauma. J Trauma Acute Care Surg. 2018;85(3):507–11.

Tips and Techniques

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Open Balloon Tamponade and Hepatic Angiography for Hemorrhage Control of Transhepatic Gunshot Wounds in a Hybrid Trauma Operating Room Environment

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The management of high-grade liver trauma is challenging and mortality rates are high. Balloon tamponade is a valuable tool for control of transhepatic penetrating injuries. We report three cases of hybrid management of penetrating liver trauma with balloon tamponade and hepatic angiography in a hybrid operating room environment. The combination of balloon tamponade with hepatic angioembolization provides an enhanced approach for the management of these injuries.

Keywords: *Penetrating Liver Trauma; Balloon Tamponade; Hybrid Techniques; Endovascular Intervention*

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The optimal management of liver trauma continues to evolve. The development of endovascular adjuncts has afforded an increasing range of hemorrhage control capabilities that can be utilized in primary or supportive roles in appropriate patients. Even among patients requiring initial emergent damage-control laparotomy with open control of the liver hemorrhage, angiography and angioembolization can be effectively employed in a hybrid intra-operative fashion or postoperatively in order to improve the outcome and reduce mortality [1,2].

Despite the ready availability of open and endovascular capabilities, however, gunshot wounds (GSWs) to the liver can represent a particularly problematic form of hepatic injury. In particular, the optimal management of bleeding GSW tracts that traverse deep through the central aspect of the liver remain a clinical challenge. Although fortunately uncommon, these deep bleeding tracts require dexterous clinical thinking and tailored approaches to optimize the outcome.

For a select pattern of GSW tracts through the central liver, balloon tamponade may prove a useful tool for initial hemorrhage control in the context of damage control. A quite effective improvised tamponade balloon to accomplish this can be fashioned from a simple red rubber or Foley catheter inserted into a Penrose drain that is closed with a tie on each end, as initially described by Poggetti and Moore [3]. A pictorial representation is shown in Figure 1. After the infusion end of the catheter is brought out through the abdominal wall, the end with the Penrose drain is passed through the liver injury and saline (or contrast dye) is instilled into the Penrose drain, inflating it until an effective diameter to achieve tamponade of bleeding from the hepatic wound tract is reached. The external portion of the infusion catheter is then clamped to prevent fluid escape and to maintain tamponade. Care should be taken to avoid accidental dislodgement of the clamp. If possible, at least 2–4 cm of the balloon should be protruding from each end of the tract to prevent underfilling of the balloon, kinking, or dislodgement. The created tamponade balloon is kept in place for 24–48 hours to allow time for hemostasis while minimizing the risk of intra-abdominal sepsis. It is subsequently removed intra-operatively at the time of re-exploration with or without endovascular embolization.

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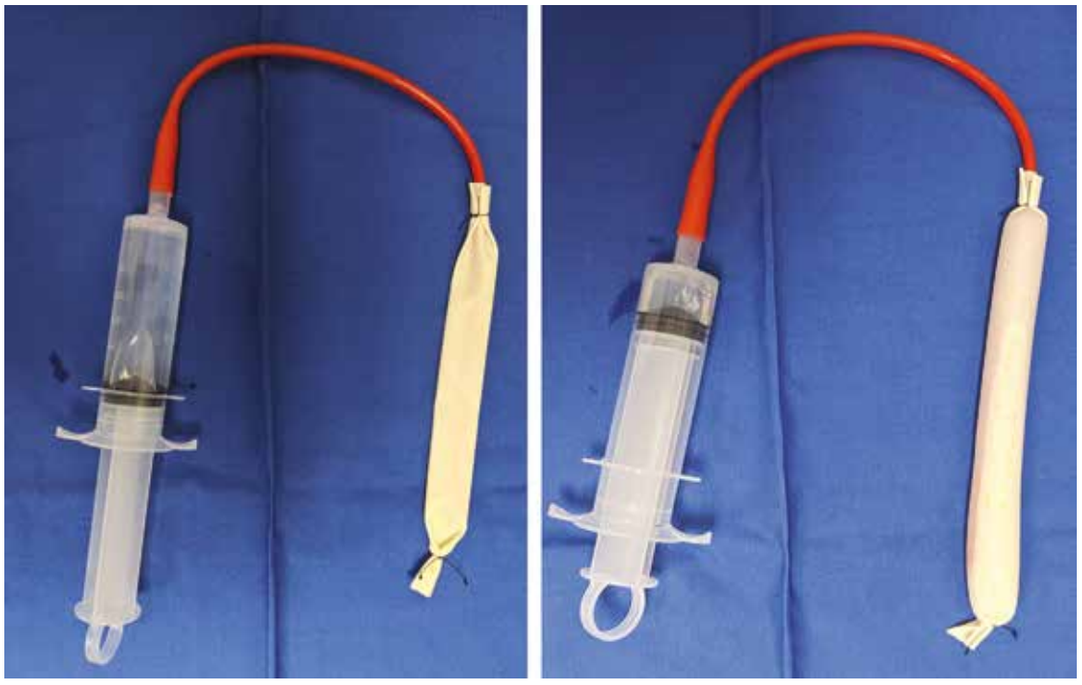

Figure 1 Demonstration of the Poggetti balloon pre- (left) and post-inflation (right).

Our present report demonstrates a successful case series of collaborative employment of the open damage-control Poggetti balloon followed by angiography or angioembolization for bleeding deep-hepatic GSW tracts. All procedures were conducted in a hybrid operating room (OR) environment specifically designed for trauma care by a cohesive team of trauma surgeons and dual-trained endovascular trauma specialists.

Case 1

A 37-year-old woman presented to the trauma resuscitation unit (TRU) having sustained one GSW to her right axilla. She had a systolic blood pressure of 70 mmHg, a heart rate of 115 beats per minute (bpm), and had severe tenderness and guarding throughout her abdomen. A foreign body series demonstrated a bullet in the right mid-abdomen (Figure 2). Decreased breath sounds were identified in the right chest and a large-bore chest tube was placed. A Focused Assessment with Sonography in Trauma (FAST) exam demonstrated free fluid in the right upper quadrant. After blood-product resuscitation, she was taken emergently to the hybrid OR for an exploratory laparotomy and hepatic angiography. A through-and-through injury through the right lobe of the liver, a right diaphragm injury, and a right renal hilar injury were identified. A diaphragm repair and nephrectomy were performed. Control of the liver injury was obtained with balloon tamponade by placing a red rubber catheter through a Penrose drain tied off at each end, passing it through the bullet tract and inflating it with saline (Figure 3). There was some arterial bleeding from around the balloon. The balloon was then deflated and hepatic angiography was performed. This showed

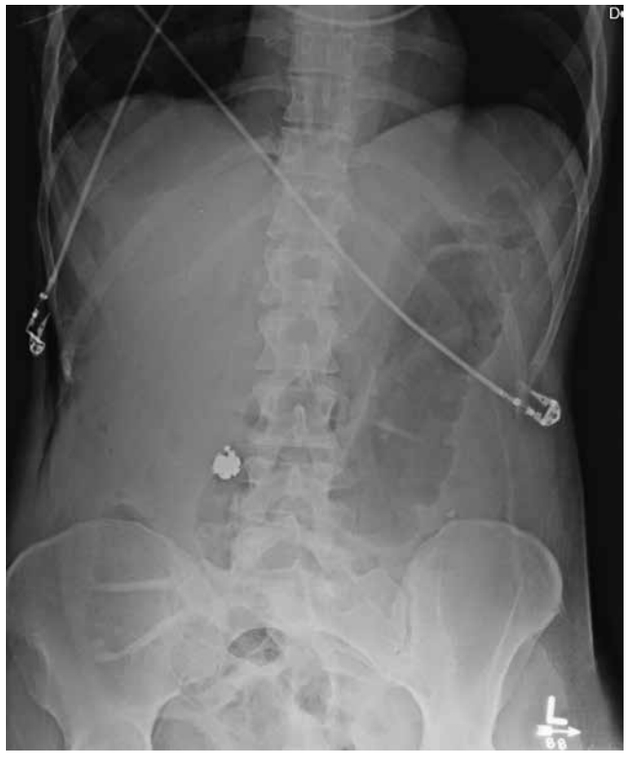

Figure 2 Foreign body series demonstrating the retained bullet in the right mid-abdomen.

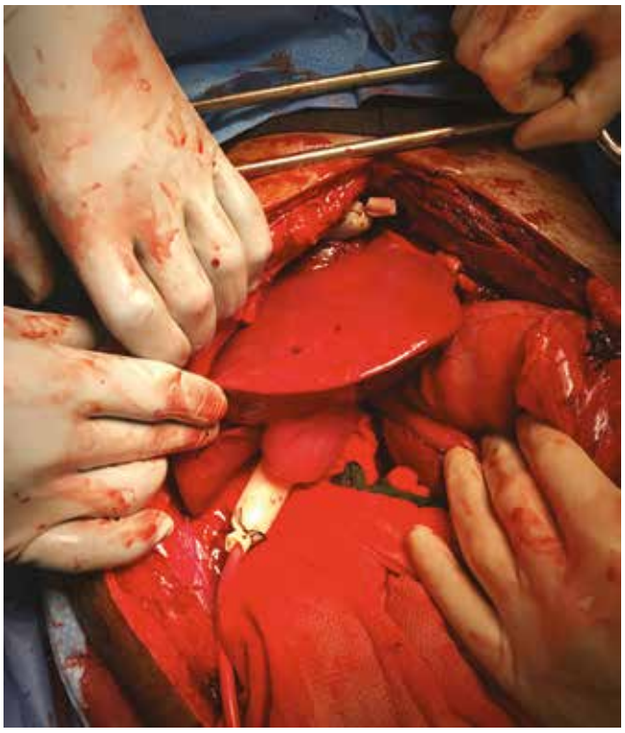

Figure 3 Intra-operative picture demonstrating balloon tamponade through the bullet tract.

active extravasation from a branch of the right hepatic artery. This was coil embolized (Figure 4). After reinflation of the balloon, complete hemostasis was apparent. Several packs were placed above and below the liver and a temporary closure of the abdomen was fashioned. An immediate postoperative computed tomography (CT) scan of her abdomen did not demonstrate evidence of ongoing bleeding from the liver injury (Figure 5). Then, 72 hours later, she was taken back to the OR, during which the balloon was deflated and the packs were removed. There was no evidence of ongoing bleeding. An omental plug into the bullet tract was performed and the fascia was closed. Her postoperative course was complicated by a hepatic abscess that was managed with antibiotics and percutaneous drainage. She otherwise had an uneventful recovery and was discharged home.

Case 2

A 22-year-old man presented to the TRU with two GSWs – one to the right of the sternum and another to the right posterior thoracolumbar region. He had thready pulses, was diaphoretic, and had a systolic blood pressure of 60 mmHg. Decreased breath sounds on the right necessitated placement of a chest tube. Large-bore access was obtained and he was given blood product resuscitation. A FAST exam was positive in the right upper quadrant. The chest tube drained 1,500 ml and he was taken emergently to the OR. A right anterolateral thoracotomy identified several lung lacerations which were managed with tractotomy and wedge resection. An exploratory laparotomy identified a diaphragm injury and a through-and-through injury to the midportion of the right lobe of the liver. Packing followed by the Pringle maneuver did not control the hemorrhage, which was presumed to be coming from hepatic venous branches. Balloon tamponade, as described previously, was created in the bullet tract. This controlled the hemorrhage. The liver was packed above and below the injury, temporary closure was performed of the chest and abdomen, and the patient was transported to the intensive care unit for resuscitation. Two days later he was taken to the hybrid OR, at which point the balloon was deflated and a hepatic arteriogram was performed. There was no evidence of bleeding. The balloon and packs were removed, two drains were placed above and below the bullet tracts, and the chest and abdominal fascia were closed. The patient had an uneventful recovery and was discharged home 1 week after presentation.

Case 3

A 28-year-old man presented to the TRU having sustained a single GSW to the right upper quadrant. He had a blood pressure of 150/78, a heart rate of 110 bpm, and was complaining of severe abdominal pain. His abdomen was distended and firm. An abdominal x-ray showed a retained bullet in the right upper quadrant at the level of the eleventh intercostal space (Figure 6). He was taken to the OR for an exploratory laparotomy. A trans-lobar GSW was identified through the right hepatic lobe that was actively bleeding. The Pringle maneuver was performed but the bleeding persisted. Balloon tamponade was then applied to the bullet tract which effectively controlled the bleeding. The liver was packed, the abdomen was temporarily closed, and the patient was taken for a postoperative CT scan of the abdomen and pelvis (Figure 7). There was no evidence of ongoing bleeding from the liver. Then, 36 hours later, the patient was taken to the hybrid OR and an on-table hepatic angiogram was performed after deflation of the balloon (Figure 8). There was no further evidence bleeding. An omental plug was placed into the bullet tract, two drains were placed above and below the injury, and the fascia was closed. The patient had an uneventful recovery and was discharged home several days later.

DISCUSSION

The use of endovascular techniques in traumatic injury have undergone significant transformations over the past several decades. Endovascular diagnostic and therapeutic adjuncts are now employed across a broad spectrum of vascular injuries and other hemorrhagic sources. Increasingly, endovascular approaches for the management of non-compressible torso hemorrhage are being

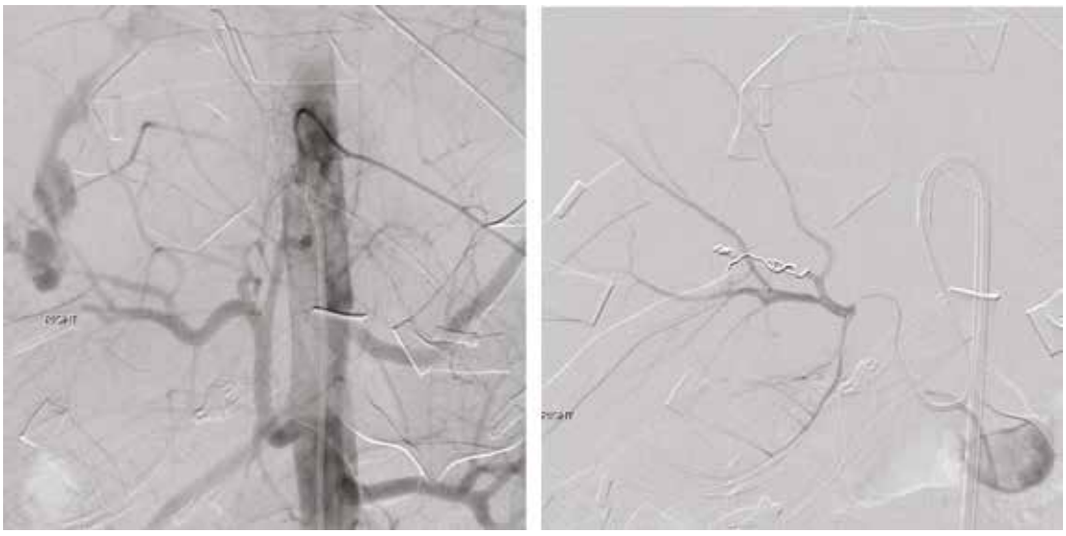

Figure 4 Aberrant right hepatic arterial takeoff from the superior mesenteric artery with active extravasation from a branch (left). Postembolization arteriogram demonstrates control of bleeding (right).

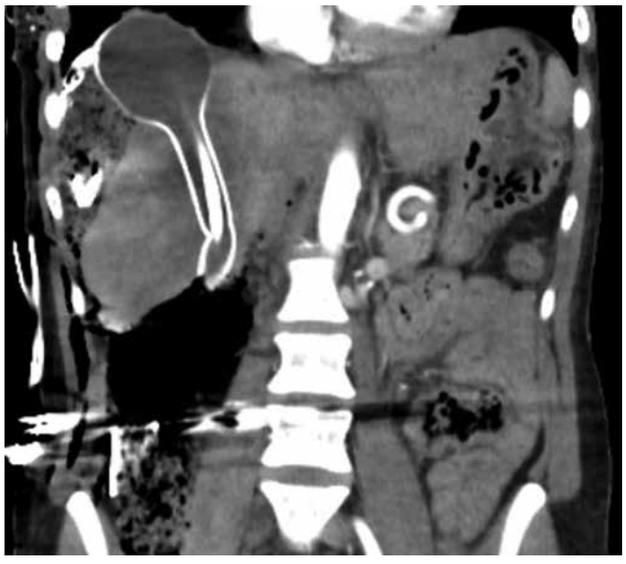

Figure 5 Coronal view CT demonstrating placement of the balloon catheter.

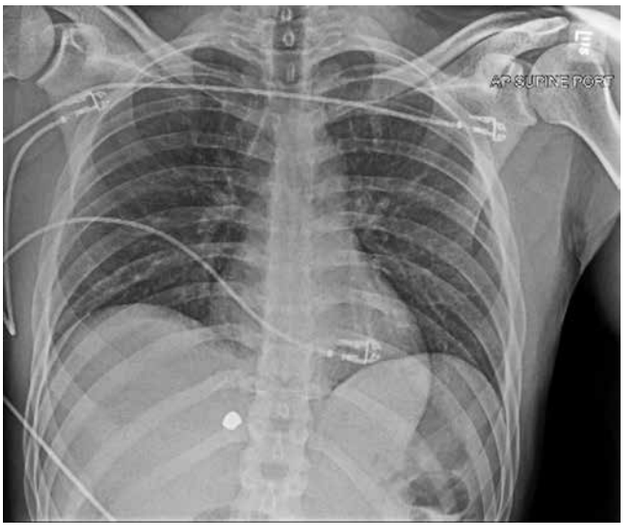

Figure 6 Foreign body series demonstrating the retained bullet in the right upper quadrant.

adopted in conjunction with open techniques or as a substitute for open surgery [4,5]. Several investigations have shown that these approaches can lead to a reduction in mortality and complication rates for specific injuries [6].

Despite these advancements, some specific injuries remain significant clinical challenges. Among them, major penetrating liver injury continues to be associated with high morbidity and mortality. Data suggest that among grade IV and V hepatic injuries, mortality rates can be as high as 80% [7], primarily due to initial hemorrhage and major complications specific to liver injury. Among these, bile leak, hepatic necrosis, and abscess formation complicate management in 80–100% of cases [5]. While better outcomes in the contemporary era have been observed in stable patients appropriate for nonoperative management [8], emergent operative intervention remains a requirement for patients presenting with indications for surgery such as refractory hypotension and peritonitis.

Operative management of liver injury varies based on the location and type of injury as well as the physiology of the patient. Simple injuries can be managed with finger fracture, direct suture ligation, and hemostatic agents, whereas more complex injuries may require packing, the Pringle maneuver, and/or resectional debridement. These

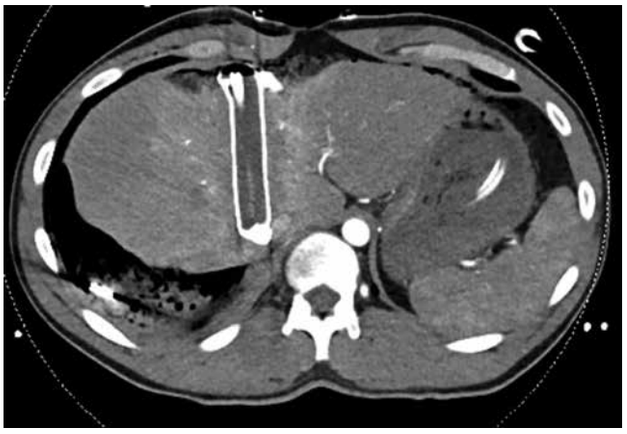

Figure 7 CT scan of the abdomen demonstrating adequate control of bleeding with balloon tamponade.

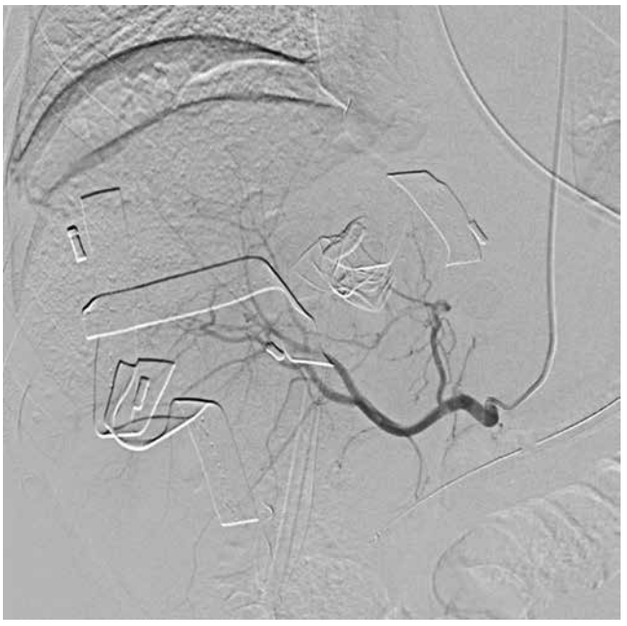

Figure 8 Hepatic arteriogram after balloon deflation demonstrating no arterial extravasation.

interventions are successful in most cases [9]. Major retrohepatic venous injuries or retrohepatic caval injuries are often considered a more problematic category of liver trauma and may be best temporized with packing, as last-ditch efforts such as total vascular exclusion and the Schrock shunt are associated with mortality rates of 90% or higher [7].

Balloon tamponade as a method for the management of liver injury was first described in Denver in 1992 by Poggetti and Moore [3]. This approach was described for the treatment of trans-hepatic GSWs that are difficult to control due to their extension deep into the liver parenchyma. The Poggetti balloon controls hemorrhage by tamponade of low-pressure portal and hepatic venous bleeding that can then thrombose over time. The classic description utilized a 12F red rubber catheter inflated inside a 30 cm Penrose drain which was tied off at each end. To this day, balloon tamponade continues to be a valuable tool in the management of central, penetrating liver trauma [10,11].

Following Poggetti balloon utilization and resuscitation, hepatic arteriography and potential embolization may serve as useful adjuncts to both identify and more selectively control unresolved sources of arterial hemorrhage from within the hepatic GSW tract. Depending upon patient condition and the operative scenario, these procedures can be undertaken at the index operation or at the time of balloon deflation at re-exploration. At our institution, this decision is made on a case-by-case basis. Although not without its complications [2,12,13], hepatic angioembolization (HAE) at the time of damage control laparotomy is a valuable adjunct to arrest bleeding from areas of the liver that are difficult to control surgically [12]. Some low-velocity penetrating liver injuries can even potentially be managed with HAE alone [14,15], although reported success rates with this adjunct are higher for injuries due to blunt trauma [16].

Traditionally, endovascular procedures for the management of liver trauma were performed by interventional radiologists in a separate procedural suite located in another wing, or even building, of the hospital. However, the need for the rapid control of bleeding in conjunction with endovascular adjuncts for non-compressible torso hemorrhage has led to the development of hybrid OR suites that have advanced open and endovascular capabilities [17]. These hybrid ORs allow for ongoing resuscitation by trauma anesthesiologists while a dedicated team of surgeons use open and endovascular techniques to gain expedient and definitive hemorrhage control. At our institution, an endovascular trauma service (ETS) staffed by dual-trained trauma and vascular surgeons is available 24/7 for this purpose [18]. The decision to transfer a patient to the hybrid OR is made jointly by the trauma and ETS attending. The availability of the hybrid OR allows for flexibility in intra-operative decision-making regarding the use of endovascular adjuncts.

This is the first series to date describing a combined approach of balloon tamponade with hepatic arteriography for penetrating liver injuries. In our series, all patients underwent angiogram in a hybrid OR at the time of re-exploration and Poggetti balloon deflation. One patient required selective angioembolization for subsequent arterial bleeding. The combination of location and expertise afforded by this hybrid approach provides optimal versatility in intervention strategies and complements the technique of balloon tamponade for penetrating liver trauma.

Ethics Statement

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

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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REFERENCES

[1] Matsumoto S, Cantrell E, Jung K, Smith A, Coimbra R. Influence of postoperative hepatic angiography on mortality after laparotomy in Grade IV/V hepatic injuries. J Trauma Acute Care Surg. 2018;85(2): 290–7.
[2] Green CS, Bulger EM, Kwan SW. Outcomes and complications of angioembolization for hepatic trauma: a systematic review of the literature. J Trauma Acute Care Surg. 2016;80(3):529–37.
[3] Poggetti RS, Moore EE. Balloon tamponade for bilobar transfixing hepatic gunshot wounds. J Trauma. 1992; 33(5):694–7.
[4] Faulconer ER, Branco BC, Loja MN, et al. Use of open and endovascular surgical techniques to manage vascular injuries in the trauma setting: a review of the American Association for the Surgery of Trauma PROspective Observational Vascular Injury Trial registry. J Trauma Acute Care Surg. 2018;84(3):411–7.
[5] Mohr AM, Lavery RF, Barone A, et al. Angiographic embolization for liver injuries: low mortality, high morbidity. J Trauma. 2003;55(6):1077–82.
[6] Branco BC, DuBose JJ, Zhan LX, et al. Trends and outcomes of endovascular therapy in the management of civilian vascular injuries. J Vasc Surg. 2014;60(5):1297–307.e1.
[7] Cogbill TH, Moore EE, Jurkovich GJ, Feliciano DV, Morris JA, Mucha P. Severe hepatic trauma: a multi-center experience with 1,335 liver injuries. J Trauma. 1988; 28(10):1433–8.
[8] Schellenberg M, Benjamin E, Piccinini A, Inaba K, Demetriades D. Gunshot wounds to the liver: no longer a mandatory operation. J Trauma Acute Care Surg. 2019;87(2):350–5.
[9] Trunkey DD. Hepatic trauma: contemporary management. Surg Clin North Am. 2004;84(2):437–50.
[10] Ball CG, Wyrzykowski AD, Nicholas JM, Rozycki GS, Feliciano DV. A decade's experience with balloon catheter tamponade for the emergency control of hemorrhage. J Trauma. 2011;70(2):330–3.
[11] Kodadek LM, Efron DT, Haut ER. Intrahepatic balloon tamponade for penetrating liver injury: rarely needed but highly effective. World J Surg. 2019;43(2): 486–9.
[12] Misselbeck TS, Teicher EJ, Cipolle MD, et al. Hepatic angioembolization in trauma patients: indications and complications. J Trauma. 2009;67(4):769–73.
[13] Dabbs DN, Stein DM, Scalea TM. Major hepatic necrosis: a common complication after angioembolization for treatment of high-grade liver injuries. J Trauma. 2009; 66(3):621–9.
[14] Demetriades D, Rabinowitz B, Sofianos C. Non-operative management of penetrating liver injuries: a prospective study. BJS Br J Surg. 1986;73(9):736–7.
[15] MacGoey P, Navarro A, Beckingham IJ, Cameron IC, Brooks AJ. Selective non-operative management of penetrating liver injuries at a UK tertiary referral centre. Ann R Coll Surg Engl. 2014;96(6):423–6.
[16] Stassen NA, Bhullar I, Cheng JD, et al. Nonoperative management of blunt hepatic injury: an Eastern Association for the Surgery of Trauma practice management guideline. J Trauma Acute Care Surg. 2012;73(5):S288–93.
[17] Kirkpatrick AW, Vis C, Dubé M, et al. The evolution of a purpose designed hybrid trauma operating room from the trauma service perspective: the RAPTOR (resuscitation with angiography percutaneous treatments and operative resuscitations). Injury. 2014; 45(9):1413–21.
[18] Morrison JJ, Madurska MJ, Romagnoli A, et al. A surgical endovascular trauma service increases case volume and decreases time to hemostasis: Ann Surg. 2019; 270(4):612–9.

Tips and Techniques

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Venous Chimney Procedure: A Novel Technical Solution to Prevent Iatrogenic Budd–Chiari Syndrome Following Retrohepatic Vena Cava Injury

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Retro hepatic IVC injuries (RHVCI) are extremely rare and lethal. The open surgical technique of treating these injuries is a master skill which is not available for most surgeons taking care of these patients. The endovascular trauma management (EVTM) application dictates a new approach in some cases based on applying arterial treatment concepts to the venous trauma cases.

We hereby describe a novel technique in which the known chimney technique, often used to treat juxta renal abdominal aortic aneurysm, was used to prevent iatrogenic Budd Chiary which might have been caused by hepatic veins drainage occlusion by a Stent Graft (SG) that was inserted to treat RHVCI.

Care should be taken to prevent secondary cardiac injury by long SG.

Keywords: *Penetrating Injury; Retrohepatic Vena Cava; Hepatic Veins; Endovascular Treatment; Stenting*

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INTRODUCTION

Traumatic inferior vena cava (IVC) lesions account for approximately 25% of abdominal vascular injuries. These injuries are among the most challenging and lethal lesions sustained by trauma patients, with an overall mortality rate of up to 92%. As many as 50% of casualties die before reaching medical care, and for those who reach trauma centers, the mortality is between 20% and 57% [1].

Retrohepatic vena cava (RHVC) injuries (RHVCI) are sporadic, and therefore both the treating trauma surgeon and the vascular surgeon often lack the necessary experience to deal with such complicated injuries. The mortality rates secondary to these injuries are incredibly high. Improving the outcome of these injuries remains a significant challenge to modern trauma care [2,3].

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The treatment of RHVCI confronts the treating surgeon with major obstacles due to the anatomic location of the RHVC at the posterior aspect of the liver and the abundancy of bridging veins between the RHVC and the liver. These anatomic obstacles create a significant technical challenge in gaining proximal and distal control, in proximity to the injured RHVC, frequently both abdominal and thoracic exposure.

The average trauma surgeon, as well as the vascular surgeon, lack the ability to deal with complex injuries due to their decreasing experience with open surgery, especially for vascular surgeons who are mainly familiar with endovascular techniques [4].

The advancements in endovascular techniques have introduced new treatment alternatives. Exploration of a retro-hepatic hematoma, which might be the single thing that prevents free venous bleeding, should be avoided. Venous balloon occlusion might be used as a bridging maneuver, for proximal and distal control, during hybrid repair. Our unique case highlights the option of total endovascular treatment of this extremely challenging venous injury.

CASE DESCRIPTION

A previously healthy 22-year-old male was shot in his right upper abdomen. On scene, the patient was found to be slightly tachycardic, with a heart rate of 112 bpm, and had diminished breathing sounds over the right lung. The rest of his physical examination was unremarkable.

Upon arrival at the trauma bay, a chest tube was inserted to the right pleural space draining 600 ml of dark venous blood. On physical examination, an entrance wound was noted below the right rib cage on the midclavicular line and the exit wound was found at the T10 vertebral level. Neurologic examination revealed that the patient was paraplegic. A chest computerized tomography (CT) scan revealed small residual pneumohemothorax. An abdominal CT scan demonstrated grade 5 liver injury with a surrounding large hematoma, retrohepatic vena cava (RHVC) tear, and left hepatic vein laceration (Figure 1).

Due to hemodynamic instability, an emergency laparotomy was conducted. Although the liver was tightly packed, following evacuation of 1.5 l of blood from the peritoneal cavity and extensive blood products transfusion, the patient's hemodynamic status did not improve. In order to treat the RHVCI, a 12F sheath (Medtronic Sentrant™, USA) was inserted percutaneously to the right common femoral vein, through which a compliant balloon (Medtronic Reliant™, USA) was inserted and inflated at the RHVC level using C-arm fluoroscopic guidance (Figure 2).

The balloon inflation stabilized the patient's blood pressure and an attempt of liver packing removal was performed. An expansion of the RHVC hematoma to the diaphragm level necessitated liver repacking. A 34 × 100 mm^3 thoracic aortic stent graft (SG; Medtronic Valiant™, USA), which was the only available on shelf SG, was inserted into the RHVC, covering the RHVCI up to the level of the right atrium orifice. In order to prevent iatrogenic Budd–Chiari syndrome, secondary to the occlusion of the hepatic veins drainage to the RHVC by the SG, a covered stent (CS; Gore, Viabahn 9 × 100 mm) was inserted transhepatically, parallel to the SG, like a chimney, draining the right hepatic vein to the right atrium (Figures 3 and 4).

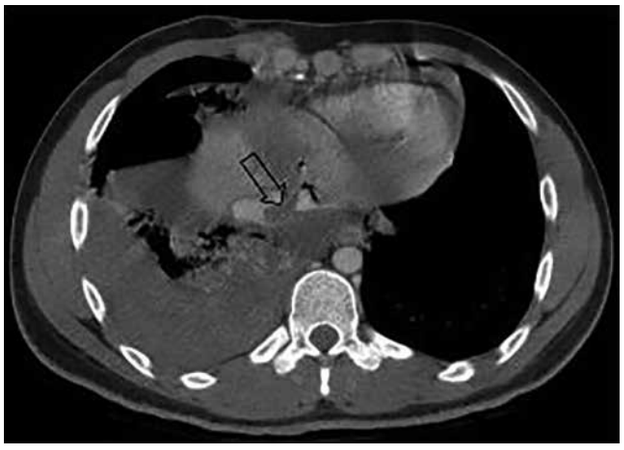

Figure 1 CT demonstrating hepatic rupture. The arrow points to the intra-hepatic IVC tear and thrombus.

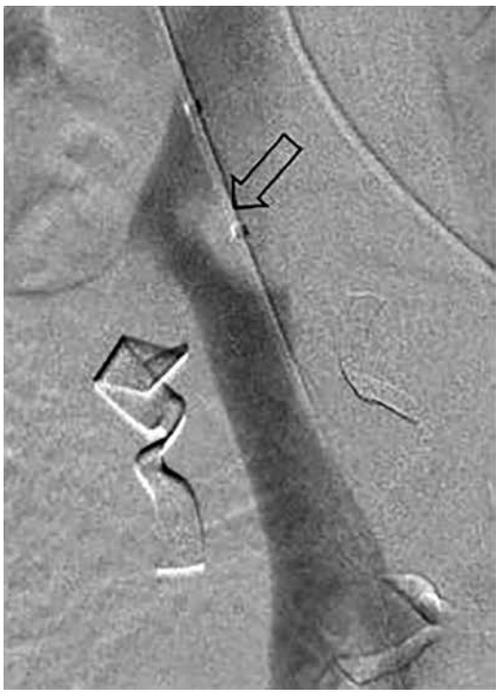

Figure 2 Digital subtraction angiography image demonstrating intra-hepatic IVC thrombus and balloon deflated marking.

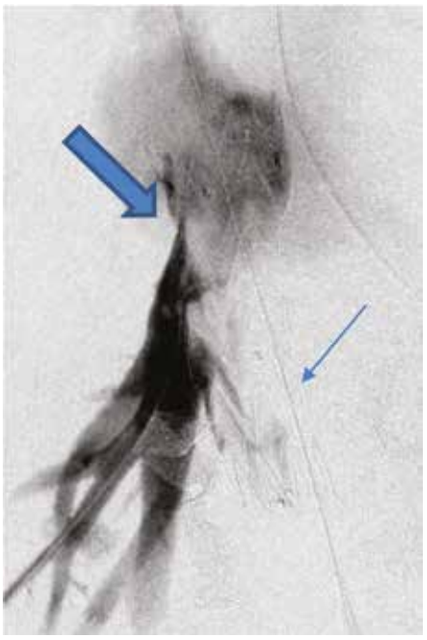

Figure 3 Post-IVC SG implantation digital subtraction angiography via intra-hepatic IV injection. The thin arrow is pointing at the SG and the wide arrow is pointing at the expected obstructed hepatic veins confluence.

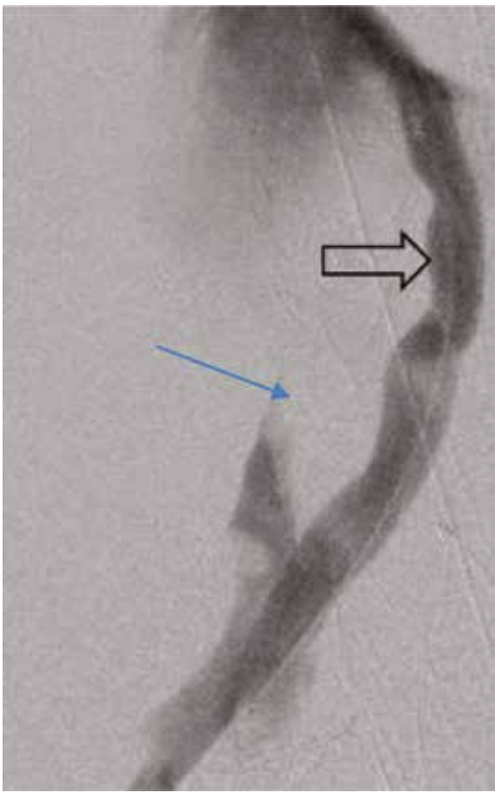

Figure 4 Chimney technique. The thin arrow is pointing at the SG in the RHVC, and the wide arrow is pointing at the Viabahn CS draining the hepatic veins.

The abdomen was temporarily closed, utilizing the vacuum packing technique. A second look laparotomy was done 48 h after the initial operation, during which the liver packing was removed, and the abdomen was closed.

On the first postoperative day, the patient underwent abdominal CT due to deteriorating hemoglobin counts. The CT revealed that the chimney stents were shown to be functioning properly (Figure 5) and bleeding from the left hepatic artery branches was diagnosed. These branches were angiographically embolized and the bleeding ceased.

Asystole, on the second post-operative day, and symptomatic bradycardia, secondary to complete Atrioventricular (AV) block, were attributed to mechanical irritation of the AV node by the stents, which was confirmed by trans esophageal echo.

The patient was transferred to a cardiac surgery ward, in a level 1 trauma center, where he underwent an urgent operation in order to deal with the chimney stent protrusion into the right atrium. This protrusion also caused an aortic root to the right atrium fistula. The stents were gently shortened, up to just below the inferior vena cava orifice at the right atrium, and the hole in the aortic root was primarily repaired. The patient was transferred to a rehabilitation facility 32 days after the primary trauma.

DISCUSSION

Traumatic IVC injuries are among the most challenging and lethal injuries sustained by trauma patients [1]. This is even truer with regard to RHVCI which is associated with even higher mortality rates due to the combination of liver injury and RHVCI [2,3].

Packing is considered as the preferred treatment option. Ligation and/or lateral venography are considered as "second line" maneuvers. The unique location of the RHVCI often necessitates thoraco-abdominal exposure in order to gain proper proximal and distal control over the bleeding vessel and over the abundant bridging veins connecting the liver and the RHVC [4].

Burch's thorough description of the sophisticated techniques and the disappointing experience with the atriocaval shunt concluded that improvement of the treatment techniques should be looked for in the future [5]. The use of an atriocaval shunt is a very challenging maneuver, usually reserved for the most difficult cases for which the preliminary assumption is that it should be used in earlier treatment stages in order to be effective. It is accepted among surgeons dealing with these injuries that the number of published studies regarding the atriocaval shunt technique is larger than the number of survivors [4,6].

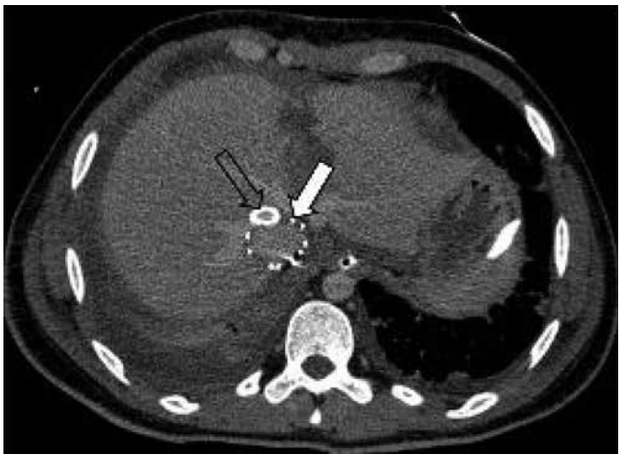

Figure 5 Post-procedure abdominal CT. The white arrow is pointing at the RHVC SG, and the transparent arrow is pointing at Viabahn CS. Both stents are working properly.

Worldwide, most patients with RHVCI are treated in local hospitals lacking hepatobiliary surgeons skilled in dealing with complicated trauma cases. Attempts to explore the RHVC, mobilize the liver, and completely occlude the liver vascularization might be fatal in unexperienced hands.

Rosenthal's description of his small animal study with a new type of shunt, combined with an occluding balloon inserted into the RHVC during the operation, suggested a new approach for treatment. The same concept of excluding the bleeding area by using CS gained popularity several years later [7].

The evolution of endovascular trauma management has recently gained popularity among the vascular and trauma surgery communities, either as a primary definitive treatment modality or as part of a hybrid approach combining endovascular and open treatment tools. Once the only technique used to manage venous injuries, surgical treatment is increasingly being replaced by the endovascular procedure as part of the EVTM concept [8,9].

Endovascular means can be used as an adjunct to the open surgical treatment, using balloon occlusion proximal and distal to the bleeding site, in order to facilitate the exposure [10]. On the other hand, it can be used for definitive treatment using CS to exclude the bleeding area. Total endovascular solution for RHVCI, mainly when done percutaneously, significantly reduces morbidity and mortality.

CS usage for RHVCI carries an inherited problem: an occlusion of the hepatic veins drainage to the RHVC causes secondary Budd–Chiari syndrome. A creative approach should be used to confront this problem, either by creating a splenorenal shunt, an operation rarely done during the current era, or by endovascular means. In-situ laser fenestration of the CS, which might be the preferred treatment option, can be used in selected centers of excellence, with a lot of experience with this technique, mainly in elective cases. However, since this treatment option is not available in our institution and in most of the real world centers, other options, like the one we have used, have to be considered. Using parallel SG in a chimney fashion is a fast and friendly solution [11].

The complications of stent protrusion through the right atrium and secondary AV irritation, as well as the aorto–right atrium fistula, were secondary to stent misplacement. To avoid such complications, adjustable size CS, like the aortic BeGraft (Bentley InnoMed GmbH) whose diameter can be adjusted by balloon inflation, should be used.

CONCLUSION

Our novel concept of venous chimney procedure for RHVCI, to prevent iatrogenic Budd–Chiari syndrome, highlights the advantages of adopting endovascular arterial treatment concepts to treat extremely complicated venous injuries such as RHVCI. It is obvious that further studies should be conducted in order to assess the short-term as well as the long-term patency of such covered stents in the venous system, and in order to assess the accessory medical treatment that should be given, either with anti-aggregation or anti-coagulation agents, in order to preserve the stent's patency.

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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REFERENCES

[1] Buckman RF, Pathak AS, Badellino MM, et al. Injuries of the inferior vena cava. Surg Clin North Am. 2001; 81:1431–47.
[2] Hampton M, Bew D, Edu S, Nicol A, Naidoo N, Navsaria P. An urban trauma centre experience with abdominal vena cava injuries. S Afr J Surg. 2016; 54(1):36–41.
[3] Degiannis E, Velmahos GC, Levy RD, Souter I, Benn CA, Saadia R. Penetrating injuries of the abdominal inferior vena cava. Ann R Coll Surg Engl. 1996;78(6):485–9.

[4] Perkins ZB, Death HD, Aylwin C, Brohi K, Walsh M, Tai NR. Epidemiology and outcome of vascular trauma at a British Major Trauma Centre. Eur J Vasc Endovasc Surg. 2012;44(2):203–9.
[5] Burch JM, Feliciano DV, Mattox KL. The atriocaval shunt. Facts and fiction. Ann Surg. 1988;207(5):555–68.
[6] Wiencek RG Jr, Wilson RF. Inferior vena cava injuries – the challenge continues. Am Surg. 1988;54(7):423–8.
[7] Rosenthal D, Wellons ED, Shuler FW, Levitt AB, Henderson VJ. Retrohepatic vena cava and hepatic vein injuries: a simplified experimental methods of treatment by balloon shunt. J Trauma. 2004;56(2):450–2.
[8] Branco BC, Boutrous ML, DuBose JJ et al. Outcome comparison between open and endovascular management of axillo-subclavian arterial injuries. J Vasc Surg. 2016; 63(3):702–9.
[9] Heldenberg E, Daskal Y, DuBose JJ, Sheizaf G, Aizer Z, Kessel B. Severe venous injury in acute trauma setup – is there a role for endovascular treatment? J Endovasc Resusc Trauma Manag. 2018;2(3):111–16.
[10] Galili O, Hebron D, DuBose J, et al. Use of endovascular balloons may simplify Proximal and distal control in complicated vascular trauma. J Endovasc Resusc Trauma Manag. 2017;1(1):39–41.
[11] Tolenaar LJ, Van Keulen WJ, Trimarchi S, Muhs EB, Moll LF, Van Herwaarden AJ. The chimney graft, a systematic review. Ann Surg. 2012;26(7):1030–8.

Tips and Techniques

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Development of a Custom Extracorporeal Circuit for Endovascular Resuscitation Research

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Our aim was to demonstrate the utility and applicability of in vitro extracorporeal circuits in endovascular resuscitation research. The method for building an inexpensive in vitro extracorporeal circuit for endovascular resuscitation research is described. In this study, aortic cannulas and pump combinations were evaluated in the in vitro extracorporeal circuit. Then one aortic cannula and pump set up was evaluated in a post-mortem swine model. Flow data was collected and compared among groups. The peristaltic pump generated the highest flow as compared with the other pump combinations at any given catheter size. The peristaltic pump combined with the 10 Fr cannula produced the highest flow overall at 2,304 ml/min. This same combination produced a peak flow of 886 ml/min at the aortic root in the swine model. The flow generated in the swine model was less than half of that generated in the in vitro model. However, all flow was channeled through one outflow tract in the in vitro model whereas the swine aorta has several branches of outflow. As such, a 50% reduction in flow or greater is anticipated at the level of the aortic root. An in vitro extracorporeal circuit for endovascular research can be built for less than US$10,000, with most of the materials being reusable, and can be used to generate representative data that may be anticipated in a swine model.

Keywords: *Extracorporeal Circuit; Endovascular Resuscitation; Endovascular Research*

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INTRODUCTION

Traumatic injury constitutes the leading cause of loss of life in patients between 16 and 40 years of age [1]. Prompt resuscitation of patients presenting in extremis with deranged physiology is critical to survival [2]. Conventional resuscitation measures include fluid administration, surgery, and the use of drugs such as vasopressors. Extracorporeal circuits have been used in organ support for many years, but this has largely been limited to refractory organ failure and is rarely used during acute resuscitation.

This paradigm is changing with the advent of endovascular resuscitation where catheter-based therapies are used to manipulate physiology, usually as a bridge to definitive intervention. An early example of this is resuscitative endovascular balloon occlusion of the aorta (REBOA) [3]. While compelling, the experience of REBOA in patients in cardiac arrest has been poor and has prompted the exploration of therapies such as selective aortic arch perfusion and emergency preservation and resuscitation [4,5].

Common to these therapies is the need for an extracorporeal circuit to deliver a perfusate. This has generally involved the adaption of commercially available circuits like those found in cardiopulmonary bypass or extracorporeal membrane oxygenation [4,6]. The expense of these products can be prohibitive for labs. Furthermore, these materials are not meant to be reused and are not easily customizable.

Research in this nascent area is critical to progressing our understanding of these adjuncts. The aim of this study is to describe the laboratory fabrication of a practical and customizable extracorporeal circuit for endovascular resuscitation research.

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METHODS

Building the Circuit

A United Biologics™ (Santa Ana, CA) silicone aorta model was used to build the circuit. All materials used

Table 1 A list of materials necessary to build a circuit and their associated costs.

Item	*Cost (US$)*
Silicone aorta model	5,100
10 feet of tubing	10
Connectors and stopcocks	600
1,000 zip ties	15
Zip tie gun	50
Pulsatile pump	3,500
Reservoir	110
Total	**9,385**

are listed in Table 1. A series of tubing, connectors, and stopcocks (Figure 1) make up the circuit. Zip ties were critical to maintain the integrity of the circuit at connecting points as high flows delivered by the pumps could cause a breakdown at these relative weak points. Pumps were included to drive flow in the circuit. A reservoir was also incorporated to hold excess fluid in the circuit and to allow for easy addition of fluid into the system. Fluid was made up of 20% glycerol in water to replicate the density and viscosity of blood and added to the system via the reservoir [7]. Aortic cannulas of varying sizes were included in the circuit after the pump and connected the circuit to the aorta model. An in-line flow probe was included in the circuit to measure the flow the pump generated through the aortic cannula.

To replicate low level perfusion in the system, a United Biologics™ FlowTek125 pulsatile pump was added to the circuit to deliver a low level mean arterial pressure (MAP). The complete circuit with labeled components is depicted in Figure 2.

Model Development

Aortic cannula size and pump configuration were both varied. Aortic cannula sizes included 6, 8, and 10 Fr, each 80 cm in length. Harvard Apparatus (Holliston, MA) centrifugal and peristaltic pumps were used. Centrifugal pumps use rotational kinetic energy to propel fluid forward whereas peristaltic pumps use roller heads. Pump configurations included a single centrifugal pump, two centrifugal pumps in series as well as in parallel, and a peristaltic pump. Given the circuit set up, all of these configurations could be incorporated into the system with relative ease.

For each run, the pulsatile pump was set to a pulse of 80 and flow of 10%. External compression with a clamp was applied to the aorta model 5 cm distal to the aortic cannula tip to mimic the presence of an occluding balloon, which prevents distal perfusion and maintains maximum pressure in the aortic arch. Centrifugal pump flow was set to maximum in each case. Peristaltic pump flow was set to the maximum flow tolerated by the system. The peristaltic pump setting for each catheter is represented in Table 2. Each run began with a short 5–10 s baseline to establish that the initial measured MAP was within the 10–20 mmHg range followed by a 5-min run. Flow was measured proximal to the aortic cannula tip.

In Vivo Study

The circuit with the peristaltic pump and the 10 Fr aortic cannula was selected, as it demonstrated the highest flow rate in the in vitro study, to examine the reliability of the circuit when used in vivo. This was done in a single post-mortem swine model, and, as such, did not require formal approval. The animal required femoral arterial access for placement of the aortic cannula intravascularly. The cannula's associated balloon was inflated in zone 1 (the thoracic aorta) corresponding with the region of occlusion in the in vitro model. The animal's chest was opened to place a flow probe around the aortic root. A run was completed using blood that had been exsanguinated from the animal shortly beforehand.

Data Collection and Analysis

All flow data were captured continuously using the PowerLab system (AD Instruments, Colorado Springs, CO). For in vitro model development, flow data was averaged every 20 s for a total of 15 data points per 5-min run. For the post-mortem swine model, flow data was averaged every 3 s for a total of 15 data points as the run was 45 s long. All data were exported to Microsoft Excel (Redmond, WA) for storage and analysis. Data were analyzed and graphed using GraphPad version 8 (San Diego, CA).

RESULTS

Using an aortic model and a "home-made" circuit, flow generated from a variety of pumps and catheters in different combinations were evaluated. Figure 3 summarizes these findings. The peristaltic pump was able to generate more flow than the centrifugal pump at any given catheter size. The peristaltic pump combined with the 10 Fr cannula produced the highest flow at 2,304 ml/min.

To test the applicability of the model to the in vivo model, the circuit using the peristaltic pump and the 10 Fr aortic cannula was selected. Figure 4 demonstrates the flow generated in the aortic root; the flow peaked initially at 886 ml/min but then deteriorated to as low as 698 ml/min and was 700–800 ml/min for the remainder of the run.

DISCUSSION

An in vitro vascular model for extracorporeal research was successfully and relatively inexpensively built as reflected in Table 1. The bulk of these costs comes from durable equipment that can be reused for a long time. Moreover, they afford researchers the ability to develop

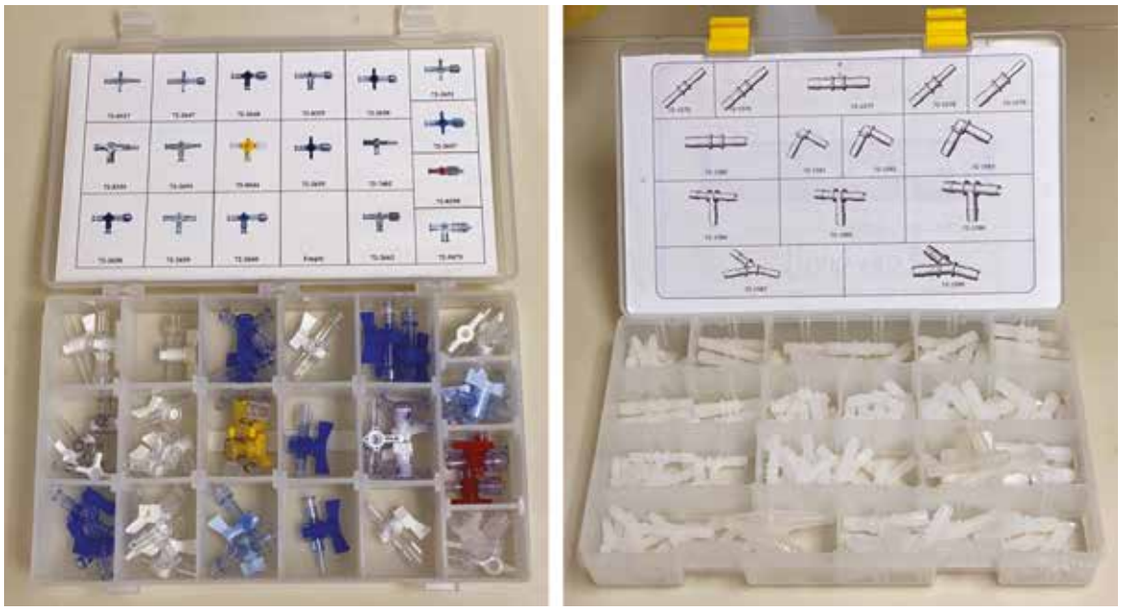

Figure 1 The kits from which connectors and stopcocks were used to build the circuit.

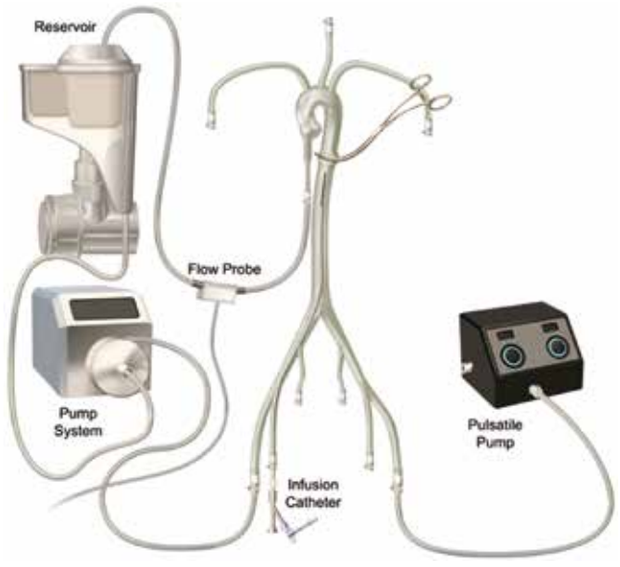

Figure 2 The in vitro vascular circuit.

Table 2 Peristaltic pump flow corresponding with each catheter.

Catheter Size (Fr)	*Peristaltic Pump Flow (rpm)*
6	120
8	170
10	215

methodology, gather preliminary data, and troubleshoot problems in endovascular research prior to moving to an animal model, which introduces many high costs.

The in vitro model was successfully used to evaluate the flow capacity of different catheters and pumps. It is not surprising that higher flow rates were generated using larger catheters with any given pump or pump combination. However, the model provided important information as to what flow could be generated with a given circuit.

In the swine model, flow rates at the aortic root did not exceed 900 ml/min. Initially this may appear to be a flaw with the model. However, given that the model had only one outflow through which all the fluid was traveling as opposed to the animal model that has branches off of the aortic arch, a 50% reduction or more in flow at the aortic root is anticipated. In addition, the swine model has an initial peak of flow that then decreases in contrast to the in vitro model where that does not occur in an appreciable way. This too makes sense as the in vitro model is a circuit where fluid always moves forward, whereas the animal model does not have the same luxury likely resulting in some back pressure and reduced flow. Although these differences are limitations of the model, they do also suggest that measurements made in the in vitro model may be translatable to the animal model for research purposes.

Another limitation of the in vitro model was the inability to maximize pump flow when using the peristaltic pump secondary to circuit failure. This required the use of the maximum pump flow that the circuit could handle rather than the true maximum pump flow.

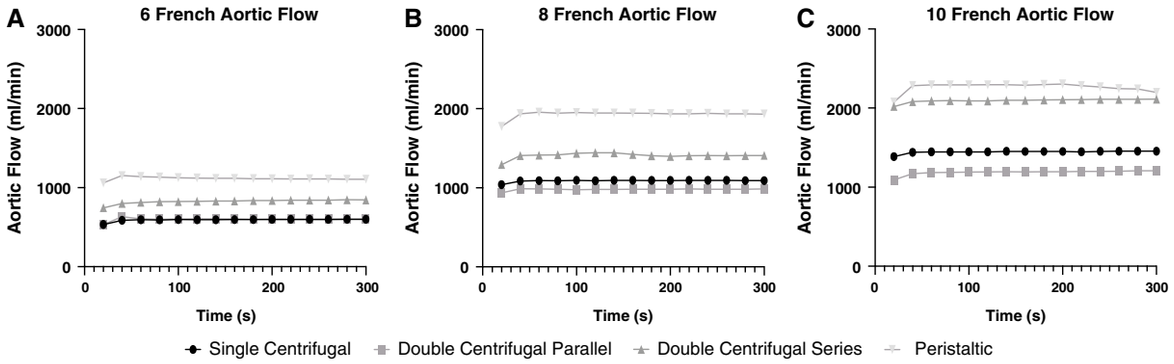

Figure 3 Flows generated through each aortic cannula by each pump combination. (**a**) 6 Fr catheter. (**b**) 8 Fr catheter. (**c**) 10 Fr catheter.

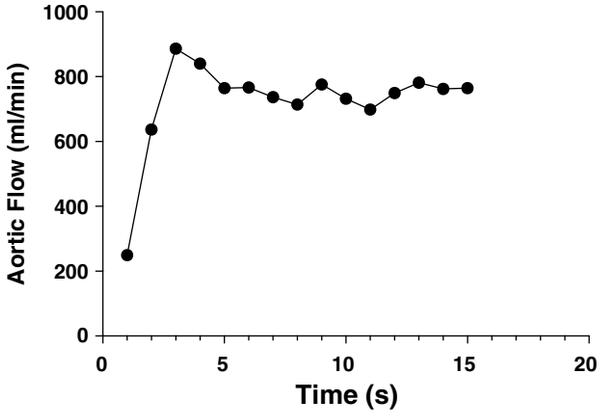

Figure 4 Aortic root flow generated in the swine model using a 10 Fr catheter and the peristaltic pump.

This is probably a consequence of the tubing and connector quality as they are not medical grade. However, this does again demonstrate the importance of using zip ties when building circuits, particularly if high pressures or flows will be run through the circuit. More importantly, we would maintain that the expense justifies the use of circuits such as this as a lot of information can be derived using this inexpensive system.

CONCLUSIONS

We believe that this cost-effective in vitro model will be of great value to many laboratories exploring endovascular resuscitation and catheter-based therapies. It will help remove some of the financial burden and enable more investigators to further research in this field.

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.

REFERENCES

[1] Jenkins DH, Cioffi WG, Cocanour CS, et al. Position statement of the Coalition for National Trauma Research on the National Academies of Sciences, Engineering and Medicine report, a national trauma care system: integrating military and civilian trauma systems to achieve zero preventable deaths after injury. J Trauma Acute Care Surg. 2016;81(5):816–8.
[2] Morrison JJ. Noncompressible Torso Hemorrhage. Crit Care Clin. 2017;33(1):37–54.
[3] Brenner M, Teeter W, Hoehn M, et al. Use of resuscitative endovascular balloon occlusion of the aorta for proximal aortic control in patients with severe hemorrhage and arrest. JAMA Surg. 2018;153(2):130–5.
[4] Barnard EBG, Manning JE, Smith JE, Rall JM, Cox JM, Ross JD. A comparison of selective aortic arch perfusion and resuscitative endovascular balloon occlusion of the aorta for the management of hemorrhage-induced

traumatic cardiac arrest: a translational model in large swine. PLoS Med. 2017;14(7):e1002349.

[5] Chen Y-S, Lin J-W, Yu H-Y, et al. Cardiopulmonary resuscitation with assisted extracorporeal life-support versus conventional cardiopulmonary resuscitation in adults with in-hospital cardiac arrest: an observational study and propensity analysis. Lancet. 2008;372(9638): 554–61.

[6] Wu X, Drabek T, Tisherman SA, et al. Emergency preservation and resuscitation with profound hypothermia, oxygen, and glucose allows reliable neurological recovery after 3 h of cardiac arrest from rapid exsanguination in dogs. J Cereb Blood Flow Metab. 2008;28(2): 302–11.

[7] Bosart LW, Snoddy AO. New glycerol tables. Ind Eng Chem. 1927;19(4):506–10.

Case Report

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Non-Occlusive Mesenteric Ischemia After Resuscitative Endovascular Balloon Occlusion of the Aorta for Out-of-Hospital Cardiac Arrest due to Massive Gastrointestinal Bleeding

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Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been used as a method of controlling intra-abdominal bleeding in case of hemorrhagic shock and an adjunct to improve traditional advanced cardiac life support in non-traumatic cardiac arrest. Partial REBOA is proposed as an alternative method to regulate low-volume continuous blood flow across the area of occlusion with the aim of minimizing the risk of ischemia-reperfusion injury. An 82-year-old male suffered an out-of-hospital cardiac arrest due to massive gastric bleeding. He was initially resuscitated with partial REBOA but died of non-occlusive mesenteric ischemia (NOMI) or rebleeding. REBOA was performed during his cardiac arrest and deflated after the return of spontaneous circulation. We aimed for a proximal arterial pressure of 70–80 mmHg and a distal arterial pressure of 20–30 mmHg. The total time of REBOA was 25 min of complete occlusion and 88 min of partial occlusion. The possible causes of NOMI were age of the patient, the low flow state with prolonged cardiopulmonary resuscitation, the lower proximal-to-distal gradient of the partial REBOA, and the longer duration of total occlusion. Further studies may be required to determine the optimal distal pressure during partial REBOA to limit the burden of mesenteric ischemia.

Keywords: *Gastrointestinal Bleeding; Non-occlusive Mesenteric Ischemia; Out-of-Hospital Cardiac Arrest; Resuscitative Endovascular Balloon Occlusion of the Aorta*

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BACKGROUND

Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been used to gain proximal aortic control and to decrease the distal hemorrhage until definitive hemorrhage control is achieved [1]. REBOA has also recently been used as an adjunct to improve traditional advanced cardiac life support in non-traumatic cardiac arrest (NTCA) [2,3]. Partial REBOA is proposed as an alternative method to regulate the continuous low-volume blood flow across the area of occlusion with the aim of minimizing the risk of ischemia-reperfusion injury [4,5]. We present a case of a patient who suffered an out-of-hospital cardiac arrest due to massive gastric ulcer bleeding and underwent partial REBOA but died of non-occlusive mesenteric ischemia (NOMI), or rebleeding.

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CASE REPORT

An 82-year-old male was found lying at home, unresponsive, and having passed a large amount of melena. He had been taking non-steroidal anti-inflammatory drugs for about two weeks because of a lumbar body

fracture. He had a history of distal aortic arch aneurysm followed with non-surgical treatment and idiopathic pulmonary fibrosis. The emergency medical service (EMS) was called immediately. On the arrival of the EMS 20 min later, he was unresponsive and tachycardic without a radial pulse. Fluid resuscitation was initiated by paramedics. On the way to the hospital, after 11 min and about 1 min before arrival at the hospital, the patient went into pulseless electrical activity. Cardiopulmonary resuscitation (CPR) was immediately initiated by the paramedics. On arrival at the emergency department, he was in asystole. Advanced cardiac life support was performed (Figure 1). We suspected that the cardiac arrest was due to hemorrhagic shock from gastrointestinal (GI) bleeding because he had suffered massive melena. We speculated that if the GI bleeding could be stabilized with REBOA there would be a better chance of achieving definitive control of the bleeding and patient resuscitation. Endotracheal intubation was performed immediately and transfusion with type-O packed red blood cells (PRBCs) was commenced 5 min after arrival at the hospital. The right common femoral artery was punctured and a 7-French sheath was introduced. A Rescue Balloon-ER® (Tokai Medical Products, Aichi, Japan) was inserted over the metal guidewire and placed in the supradiaphragmatic descending thoracic aorta. It was fully inflated with 25 mL of normal saline. After 2 min of occlusion of the aorta and 13 min of cardiac arrest, return of spontaneous circulation (ROSC) was achieved. The patient was administrated 3 mg of adrenaline during the 13 min of CPR. Initial laboratory results were as follows: hemoglobin, 5.3 g/dL; pH, 6.817; lactate, 168 mg/dL; and potassium, 5.5 mEq/L. His proximal arterial pressure was monitored with a left radial arterial line, while his distal arterial pressure was monitored with a 5-French sheath in the left femoral artery.

Five minutes after initial ROSC, the patient went into ventricular fibrillation (VF) and CPR with defibrillation was performed. After 2 min of VF, ROSC was achieved for the second time. The patient's systolic blood pressure (SBP), monitored by proximal arterial pressure, reached 100 mmHg. After 10 min of REBOA at complete inflation, the balloon was completely deflated in a stepwise fashion over a period of 4 min to terminate aortic occlusion. However, his SBP gradually decreased to 55 mmHg 10 min after complete deflation. The balloon was therefore partially re-inflated with 10 mL of normal saline and manual pressure pumping of the transfusion was performed. We aimed for a proximal arterial pressure of 70–80 mmHg and a distal arterial pressure of 20–30 mmHg. Although his SBP gradually increased to 80 mmHg, VF occurred again after 12 min of partial REBOA. CPR was performed, and the balloon was again inflated completely. After 2 min of the second episode of VF, ROSC was achieved for the third time. The REBOA was converted to partial inflation with 10 mL of normal saline 15 min after the second complete REBOA. At this point, the laboratory results were as follows: hemoglobin, 6.6 g/dL; pH, 6.666; lactate, 190 mg/dL; and potassium, 5.3 mEq/L. A truncal contrast-enhanced computed tomography (CT) scan was performed 77 min after arrival at the hospital. However, although gastroduodenal hemorrhage was observed, the bleeding source could not be identified. Since we observed a gastric hematoma without active extravasation of contrast, we concluded that active extravasation could not be detected via abdominal angiography. We decided to perform esophagogastroduodenoscopy (EGD) instead. EGD was performed in the intensive care unit (ICU) 96 min after arrival at our hospital. Multiple gastric A1-stage ulcers were detected in the antrum and angular notch of the lesser curvature (Figure 2*a*). Cauterization of an ulcer with visible vessels was performed with a Coagulasper Hemostatic Grasper. At 132 min after arrival at our hospital, the REBOA balloon was completely deflated. The patient's Glasgow coma scale score was E3VTM4 at this point. The laboratory results were as follows: hemoglobin, 7.9 g/dL; pH, 7.058; lactate, 194 mg/dL; and potassium, 4.6 mEq/L. The total time of REBOA was 25 min of complete occlusion and 88 min of partial occlusion. The transfusion administered between arrival at hospital and the CT was 8 units of PRBCs and 2 units of fresh frozen plasma. The transfusion administered between CT and complete deflation of the balloon was 2 units of PRBCs, 8 units of fresh frozen plasma, and 10 units of platelets.

Twelve hours after complete deflation of REBOA, the patient's consciousness level was E4VTM6. He was extubated and the REBOA was removed. At this point, the laboratory results were as follows: hemoglobin, 15.4 g/dL; pH, 7.421; and lactate, 66 mg/dL. His SBP subsequently decreased to 53 mmHg and a massive amount of dark blood came out through the nasogastric tube. Three hours after extubation, his respiration became agonal. He was reintubated and a transfusion was restarted. Although EGD was performed in the ICU again, no active hemorrhage was detected. After EGD, an abdominal contrast-enhanced CT scan was performed to detect the source of the bleeding. The CT scan showed a decreased contrast enhancement in the ileum and colon, presence of air in the colonic wall and the superior mesenteric vein, and enhancement in the superior mesenteric artery (Figure 2*b*). No aortoiliac injury or limb ischemia occurred. We concluded that NOMI, or rebleeding, was the cause of the second bout of hemodynamic instability. Further treatment was withheld at his family's request. Then, 14 hours after the second intubation, the patient died.

Ethical Approval and Informed Consent

Ethical approval to report these cases was given by Fukui Prefectural Hospital. Written informed consent was obtained from the patient's family.

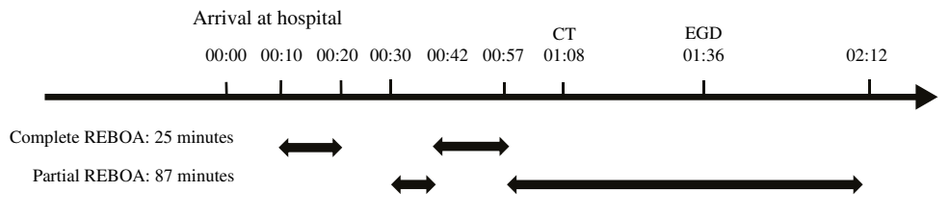

Figure 1 The clinical course of this patient. The horizon axis represents the elapsed time after arrival at hospital. REBOA: resuscitative endovascular balloon occlusion of the aorta; CT: computed tomography; EGD: esophagogastroduodenoscopy.

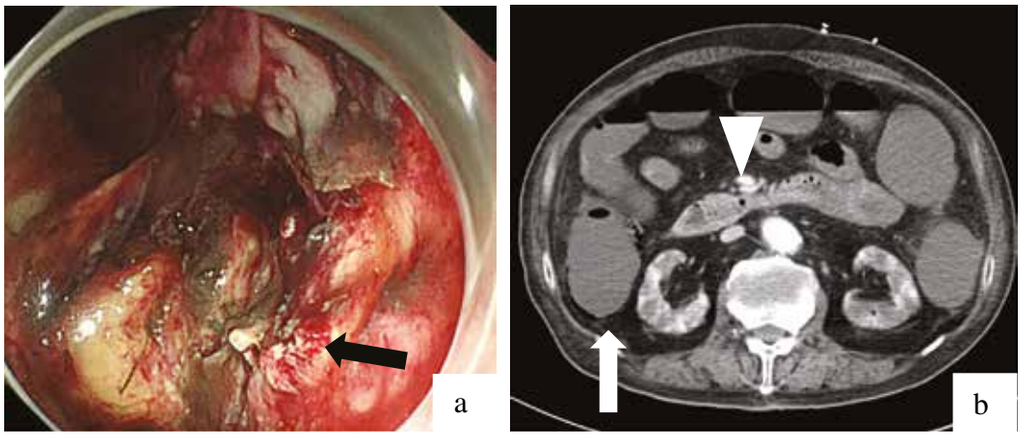

Figure 2 Diagnostic imaging of this patient. (**a**) First esophagogastroduodenoscopy. The black arrow indicates gastric A1-stage ulcers with visible vessels in the angular notch of the lesser curvature. (**b**) The abdominal contrast-enhanced computed tomography scan after reintubation. The white arrow indicates decreased contrast enhancement in the colon and air in the colonic wall. The white arrowhead indicates contrast enhancement in the superior mesenteric artery.

DISCUSSION

This case involved the use of partial REBOA during NTCA caused by a massive hemorrhage from gastric ulcers with initially successful resuscitation followed by fatal NOMI. Although there have been some reports on the use of REBOA in hemorrhagic shock caused by GI bleeding [1], there is currently no evidence of the use of REBOA to control massive GI bleeding in patients who are unresponsive to resuscitation or in cardiac arrest. Traditional transfusion without REBOA with permissive hypotension and definitive EGD to control the hemorrhage might not have been a better option because the patient in our case had two episodes of VF, regardless of the combination of REBOA and transfusion. Further research into the use of REBOA as a bridge is required.

Experimental studies have demonstrated that the occlusion of blood flow to the distal aorta in animal models of NTCA improved the hemodynamics of the heart and brain and increased rates of ROSC and short-term survival [6–8]. The clinical literature involving human subjects with NTCA is limited to several case reports and case series [2,9]. This case demonstrated that REBOA is a feasible method to use during CPR for NTCA, to increase coronary and cerebral perfusion, and to achieve ROSC.

Partial REBOA is an alternative technique that may minimize the negative physiological consequences related to the profound distal ischemia caused by complete aortic occlusion. Clinical reports describing the use of partial REBOA have been limited to several case reports and case series. Overall, positive outcomes were reported [4,5]. The patient in our case developed NOMI within 19 hours but did not develop lower extremity ischemia. We targeted a left femoral arterial pressure of 20–30 mmHg, about 25–30% of proximal pressure, as an indicator of distal flow. We speculated that if we aimed for a distal pressure of around 40 mmHg in this case, in which the patient would experience NTCA caused by severe hemorrhagic shock, there would be a lower chance of a proximal pressure of 80 mmHg. In our study, the partial REBOA with a 30% proximal-to-distal gradient was lower than the 50–70% that Russo et al. had, and had a greater chance of visceral ischemia [10]. Another possible cause of NOMI was the longer duration

of total occlusion than that in a previous study (median: 58 min) [5]. In addition, a previous report indicated that a longer duration of complete occlusion was associated with fasciotomy of the lower extremities [11]. In our case, the patient was also suffering from a vascular disease. This might have predisposed him to having a NOMI with reduced flow. In our case, NOMI could be secondary to the age of the patient and low flow state with prolonged CPR. Although the partial REBOA in our study had the lower proximal-to-distal gradient and the longer duration of total occlusion than those in the previous reports, it was unclear whether the REBOA was the direct cause of NOMI [5,10]. Further research into the available and reliable parameters for monitoring the mesenteric or bowel blood flow is required. In our case, the patient experienced rebleeding after extubation. Although no active gastroduodenal bleeding was detected on the second EGD, it was difficult to determine whether the patient died from NOMI or rebleeding.

The current management of acute upper GI bleeding begins with procedural intervention with endoscopy [12]. Early surgical treatment without endoscopy has been considered for patients with recurrent massive upper GI hemorrhage following initial endoscopy [13]. In our case, surgical intervention was not performed as the primary method of treating GI bleeding. Although our patient suffered three resuscitation attempts due to ongoing bleeding, operative intervention was not performed due to the age of the patient and multiple comorbidities, including a distal aortic arch aneurysm with non-surgical treatment and idiopathic pulmonary fibrosis. Based on the unsuccessful outcome with EGD, we speculated that exploratory laparotomy immediately after the third ROSC may have decreased the risk of NOMI and the REBOA time.

CONCLUSION

We achieved ROSC with REBOA during NTCA caused by massive GI bleeding. The outcome was eventually unsuccessful because of rebleeding or the development of NOMI. The possible causes of NOMI were age of the patient, the low flow state with prolonged cardiopulmonary resuscitation, the lower proximal-to-distal gradient of partial REBOA, and the longer duration of total occlusion.

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 made substantive contributions to the study and manuscript writing.

REFERENCES

[1] Hoehn MR, Hansraj NZ, Pasley AM, et al. Resuscitative endovascular balloon occlusion of the aorta for non-traumatic intra-abdominal hemorrhage. Eur J Trauma Emerg Surg. 2019;45(4):713–8.
[2] Aslanger E, Golcuk E, Oflaz H, et al. Intraaortic balloon occlusion during refractory cardiac arrest. A case report. Resuscitation. 2009;80(2):281–3.
[3] Daley J, Morrison JJ, Sather J, Hile L. The role of resuscitative endovascular balloon occlusion of the aorta (REBOA) as an adjunct to ACLS in non-traumatic cardiac arrest. Am J Emerg Med. 2017;35(5):731–6.
[4] Davidson AJ, Russo RM, DuBose JJ, Roberts J, Jurkovich GJ, Galante JM. Potential benefit of early operative utilization of low profile, partial resuscitative endovascular balloon occlusion of the aorta (P-REBOA) in major traumatic hemorrhage. Trauma Surg Acute Care Open. 2016;1(1):e000028.
[5] Matsumura Y, Matsumoto J, Kondo H, et al. Fewer REBOA complications with smaller devices and partial occlusion: evidence from a multicentre registry in Japan. Emerg Med J. 2017;34(12):793–9.
[6] Sesma J, Labandeira J, Sara MJ, Espila J, Arteche A, Saez MJ. Effect of intra-aortic occlusion balloon in external thoracic compressions during CPR in pigs. Am J Emerg Med. 2002;20(5):453–62.
[7] Gedeborg R, Rubertsson S, Wiklund L. Improved haemodynamics and restoration of spontaneous circulation with constant aortic occlusion during experimental cardiopulmonary resuscitation. Resuscitation. 1999;40(3):171–80.
[8] Rubertsson S, Bircher NG, Alexander H. Effects of intra-aortic balloon occlusion on hemodynamics during, and survival after cardiopulmonary resuscitation in dogs. Crit Care Med. 1997;25(6):1003–9.
[9] Deakin CD, Barron DJ. Haemodynamic effects of descending aortic occlusion during cardiopulmonary resuscitation. Resuscitation. 1996;33(1):49–52.
[10] Russo RM, Williams TK, Grayson JK, et al. Extending the golden hour: partial resuscitative endovascular balloon occlusion of the aorta (P-REBOA) in a highly lethal liver injury model. J Trauma Acute Care Surg. 2016;80(3):372–80.

[11] Wasicek PJ, Teeter WA, Yang S, et al. Life over limb: Lower extremity ischemia in the setting of resuscitative endovascular balloon occlusion of the aorta (REBOA). Am Surg. 2018;84(6):971–7.
[12] Bardou M, Benhaberou-Brun D, Le Ray I, Barkun AN. Diagnosis and management of nonvariceal upper gastrointestinal bleeding. Nat Rev Gastroenterol Hepatol. 2012;9(2):97–104.
[13] Choy TY, Simoens C, Thill V, Mboti F, Vandaele S, Mendes da Costa P. Results of surgical treatment of uncontrollable upper gastrointestinal hemorrhage using endoscopy. Hepatogastroenterology. 2011;58(105):89–95.

Reflection on Clinical Practice

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Interventional Vascular Surgery Guidance during the COVID-19 Pandemic

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Background: The ongoing outbreak of the COVID-19 pandemic is considered a major public concern and has resulted in a huge burden on health care. We hereby provide a brief review for vascular surgeons regarding COVID-19 clinical issues, pathogenesis, diagnosis, and treatment approaches.
Methods: We review the international society's guidance on managing vascular interventions during the COVID-19 outbreak.
Results: This work provides summarized descriptions of how to manage and deal with vascular surgery cases at time of COVID-19 outbreak, including measures at outpatient clinic, emergency room, and operations.
Conclusions: Although vascular surgeons are not considered to be the front line in combating the COVID-19 pandemic, certain measures, detailed in this work, can be adopted in their practice during this period to control and lessen the spread of the disease.

Keywords: *COVID-19; Surgery During Pandemic; COVID-19 and Vascular Practice*

Received: 13 April 2020

INTRODUCTION

The ongoing outbreak of COVID-19, coronavirus disease 2019, is considered a major public concern. It was first identified in December 2019 in Wuhan, China, and has spread to most countries of the world. The World Health Organization (WHO) declared it a pandemic on the 11 March 2020 and called on countries to take urgent actions to control its spread [1]. The information in this review is updated to June 2020. Briefly, Coronaviruses are enveloped, positive single-stranded large RNA viruses that infect humans but also a wide range of animals [2]. The COVID-19 virus shares 96% of its whole-genome with a bat coronavirus causing the accusation that bats were the origin of the virus [4]. Disease transmission mainly occurs via human respiratory droplets and direct contact from symptomatic or even asymptomatic carriers with a mean incubation period of 5 days [5,6]. At present, there are no specific antiviral drugs or vaccines against the COVID-19 infection for potential therapy in humans and the current treatment is mainly supportive. The elderly, the immunocompromised, those with ischemic heart disease or diabetes, men, people with high Body Mass Index (BMI), hypertension and smokers appear to be at a greater risk of severe complications when infected and these demographics are highly pertinent to vascular patients. Although vascular surgeons are not considered as the frontline in combating the pandemic of COVID-19, certain measures can be adopted in their practice during this period to control and lessen the spread of the disease. These measurements are based on rapid guidelines adopted by international societies and summarized in this article.

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METHODS

A general review of current guidelines of major vascular and surgical societies was carried out and updated to April 2020. Pubmed and surgical society web sites where used for data search.

Figure 1 Priorities listed by importance [16].

Summary of Vascular Surgery Measures and discussion

The advice given by the Vascular Society of Great Britain and Ireland is that, where possible, only urgent outpatients should be seen, and virtual clinics should be considered [12]. The American College of Surgeons recommends that all non-urgent in-person clinic/office visits should be canceled or postponed, unless needed to triage active symptoms or manage wound care. It is recommended that elective urgent inpatient diagnostic and surgical procedures are shifted to outpatient settings when feasible [13]. The Vascular Society of Great Britain and Ireland also suggests that surgeons in training will have key roles to play in this crisis but the underlying principles of appropriate supervision, working practices, rest, and pastoral care remain [12].

Clinical interpretation of the guidelines (Figure 1)

Maintenance of emergency surgery capabilities is achieved as follows:

1. Maintaining Emergency surgery provision, including major trauma (MT), must be achieved for the surgery workforce.
2. Initially, this will be delivered by individual specialty rotas. These will include rotas where some members of the team do not come into work and act as a healthy reserve.
3. If the workforce is reduced and it may be necessary to move to a generic surgeon rota, based around competencies and would manage the initial triage, some of the surgery, and the post-operative management.
4. It is likely that the workforce will break down into torso/cavity surgeons (vascular, general, urology) and extremity surgeons (orthopedics, plastics). Virtual support from specialists would be required for the generic surgeon. Some of the operations will still require a specialist surgeon when available.
5. It is suggested that each site would have a torso surgeon and an extremity surgeon with middle grades present. The shift pattern would be 24 h or 12 h depending on numbers of surgeons and tempo.
6. The MT pathway has been identified as a national priority. Surgeons may be required to take over running of the MT service, including trauma team leader (TTL) role, depending on local arrangements.
7. Regional solutions may be required if smaller surgical units collapse. The existing MT networks are likely to be the best vehicle to achieve this [18].

Due to the pressure on emergency departments, non-respiratory emergencies may be triaged to an alternate pathway which may need support from surgeons (Non-COVID Emergency Department). This could be incorporated into providing TTL cover for MT centers/trauma units, depending on existing local arrangements [16].

Fulfillment of alternate surgical roles is achieved as follows:

1. If all other priorities have been met and the surgical workforce has been maintained, it may be possible for some surgeons to take on non-surgical roles.
2. These could include running level 2/3 units or non-clinical roles in command and control. Individuals

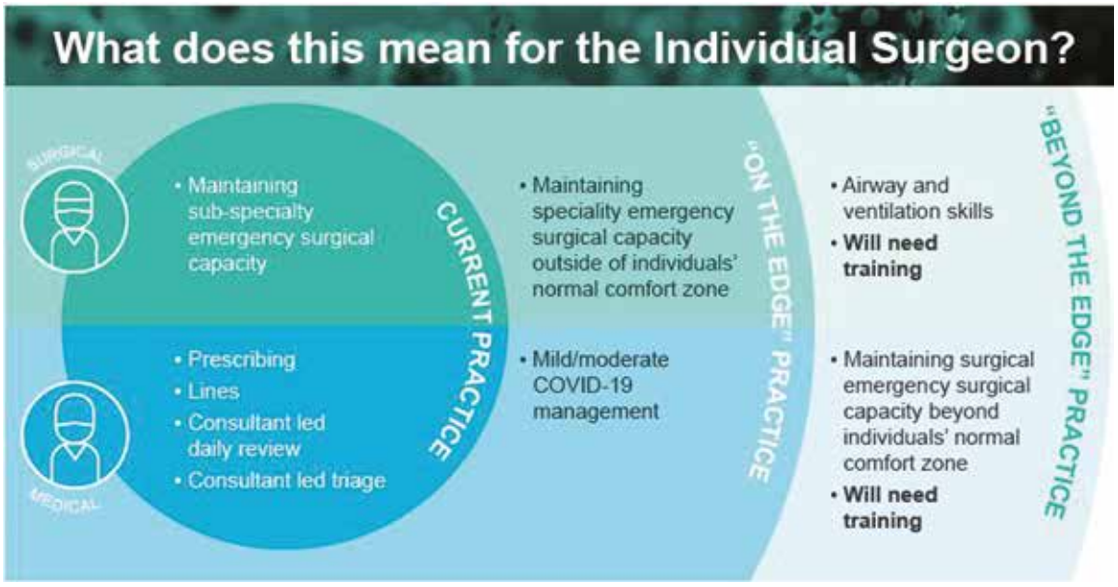

Figure 2 What does this mean for the individual surgeon [16]?

will need training/mentoring/support in these roles outside their normal practice [18].

To explain what this means for each individual surgeon, there are 3 zones of practice as follows:

(A) Current practice. Medical – prescribing, lines, consultant led daily review, and consultant led triage. Surgical – maintaining sub-specialty emergency surgical capacity.
(B) "On the edge" practice. Medical – mild/moderate COVID-19 management. Surgical – maintaining specialty emergency surgical capacity outside of individuals' normal comfort zone.
(C) "Beyond the edge" practice. Medical – airway and ventilation skills will need training. Surgical – Maintaining emergency capacity beyond individuals' normal comfort zones. (Figure 2) [16].

The American College of Surgeons provide the "By the Well-Being Index" for health care administrators to reduce stress and pressure upon Health Care Workers (HCWs). Applying some or all of them will substantially increase the overall well-being of staff; living accommodation should be offered for intensive care unit (ICU)/Emergency Room (ER) physicians who live with a vulnerable family member, so that they do not have to go home (e.g. on-campus, hotel). Meal credits should be provided (e.g. Uber eats, delivery) for those working extra shifts or unanticipated overtime. Dictation and transcription services should be made available to all in the ICU/hospital/ER. HCWs with known health conditions, which place them at an elevated risk for complications should they contract COVID-19, should be redeployed to other settings. Workers should be required to take breaks to recharge and adequate time off between shifts should be encouraged. All required online modules and non-essential tasks should be halted. Taxi and ride-sharing fare reimbursement should be provided to all employees directly engaged in COVID-19 efforts [13].

Institutional and specific area of treatment guidelines

In Ain Shams University, Egypt, the number of trainees per shift has been reduced by half, the number of intern doctors has also been reduced by half, the number of operations has been reduced, and non-emergent or urgent cases have been postponed. The decision to intervene or postpone is made by the head of each surgical department at weekly scientific meetings. All educational platforms and lectures have cancelled and replaced by meetings over the internet. Triage areas in ERs have been established to isolate feverish and suspected cases to avoid mixing with non-suspected cases. All HCWs in ERs use PPE in the form of gowns, masks, and an eye shield, while HCWs in operation rooms only wear masks in between operations. We also advise staying home and self-monitoring for those who have come into contact with suspected cases, until COVID-19 results are collected. Positive COVID-19 of HCWs are isolated at a quarantine-hospital outside Cairo. This belongs to Ain Shams University Hospitals, which has ICU beds and mechanical ventilators. The Center for Disease Control and Prevention provides a suggested method for using PPE (Figures 3 and 4) [17].

On-Call Arrangements

The Vascular Society of Great Britain and Ireland advises that a second on-call consultant is available to help with

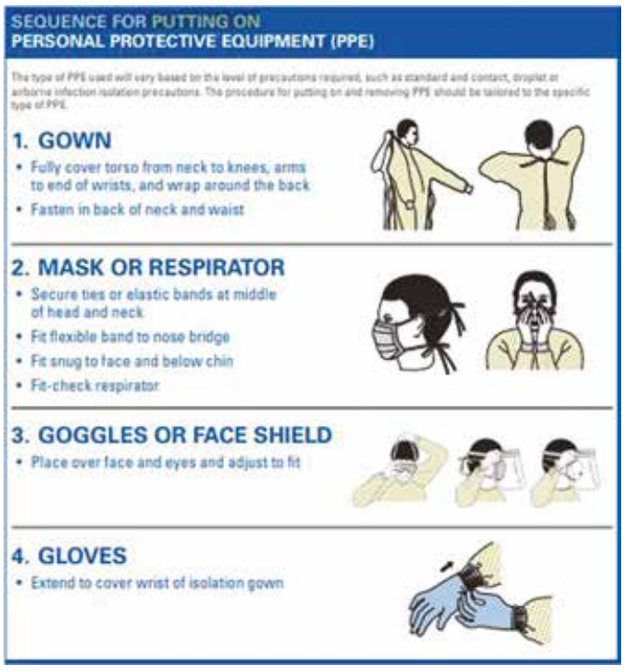

Figure 3 Putting on PPE [17].

the emergency workload (and also if self-isolation becomes common) [12]. A vascular consultant surgeon should be on call and available to see all referrals. Trusts should consider having another vascular surgeon on call for performing surgery [12].

Elective Surgery

The Vascular Society of Great Britain and Ireland advises that elective arterial surgery and venous surgery should be deferred. Asymptomatic carotid surgery and surgery for claudication should be deferred [12].

Aortic Surgery

The Vascular Society of Great Britain and Ireland advises that the size threshold for AAA surgery needs to weigh up the risk of rupture in the next few months against the risk from intervention and resource limitation [12]. It advises that ruptured aneurysms should ideally be treated by endovascular aortic repair (EVAR) whenever possible to reduce dependence on the High Dependency Unit and reduce the length of stay. Open surgery should only be considered when EVAR is inappropriate or unavailable and in cases where there is a good chance of success. ITU capacity will need to be considered prior to intervention [12].

The American College of Surgeons has recently published COVID-19 guidelines for the triage of vascular surgery patients including aortic diseases (Table 1) [13].

Acute Ischemia/Critical Leg Ischemia ± Foot Infection

The Vascular Society of Great Britain and Ireland advises that there may be situations where primary amputation may be more appropriate than complex revascularizations, multiple debridements, and potential prolonged hospital stay [12].

A pathway for guidance has been developed by a collaborative group of expert clinicians in Foot in Diabetes UK (FDUK) to support all lower-limb clinicians during the COVID-19 situation in line with current best practice. It includes the assessment of the following conditions:
(1) Non limb-threatening problems: leg or foot pain that is not due to severe infection or ischemia, superficial leg/foot ulcers that show evidence of healing, asymptomatic peripheral arterial disease or intermittent claudication only, foot pulses non-palpable or monophasic on Doppler (asymptomatic), mild foot or leg infections with shallow ulcers and local erythema <2 cm from the edge with no signs of tracking or sepsis, and acute Charcot feet without infection (to be completely rested/offloaded). All the previous cases should be treated, monitored, or advised by an appropriately skilled lower limb clinician or general practitioner, using local infection wound care and pain management guidelines or protocols where available.

If previous conditions deteriorate and develop key indications of limb-threating infection or sepsis or critical limb ischemia, consultation and intervention is required [20].
(2) Limb-threatening infection or sepsis: deteriorating/tracking infection, especially with ulcer depth to bone or critical limb ischemia, spreading cellulitis in the foot or leg (e.g. redness, swelling, pus, heat, pain, black discoloration) without sepsis, or with sepsis indicated by pulse rate <50 beats per minute (BPM) or >90 BPM, respiration rate <11 or >20 breaths per minute, flu-like symptoms, and being confused/unresponsive/drowsy (these features could also be caused by COVID-19 infection). All previous cases require consultation and intervention [18].
(3) Critical limb ischemia: foot pulses not palpable/absent, Doppler signals monophasic/absent, indications of Buerger's disease (foot goes pale on elevation and goes red when hung down), ankle systolic blood pressure <50 mmHg, and toe systolic blood pressure <30 mmHg. In addition to these are any of the following: ischemic rest pain in toes/feet for more than 2 weeks, new gangrene or necrosis, acute limb ischemia, and sudden onset cold, pale, pulseless, painful limb, especially if also developing paresthesia or paralysis. All previous conditions require consultation and intervention [18].

Consultation and intervention are in the form of urgent discussions with high-risk foot podiatry, hospital vascular, diabetes foot, infectious disease, or orthopedic

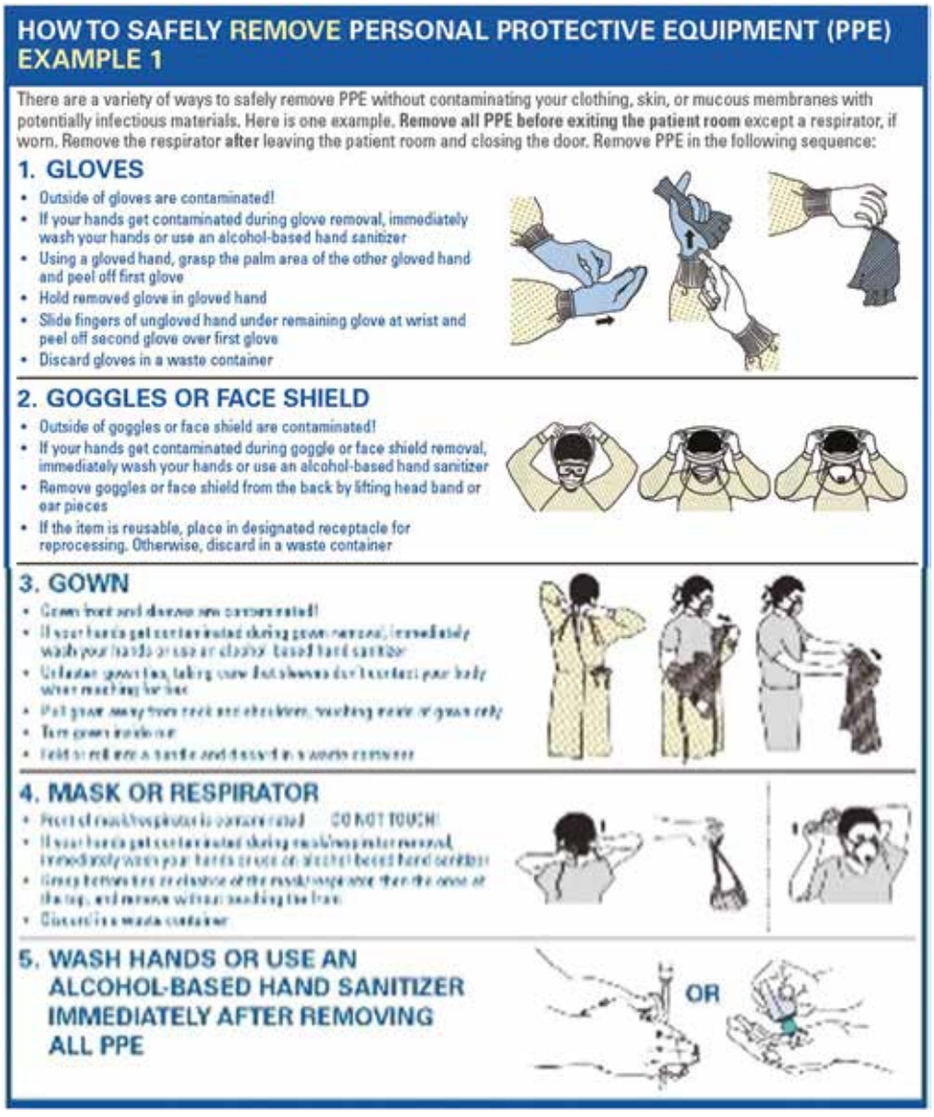

Figure 4 Removal of PPE [17].

Table 1 American College of Surgeons' COVID-19 guidelines for triage of vascular surgery patients and aortic diseases [21].

Category	*Condition*	*Tier Class*
AAA	Ruptured or symptomatic TAAA or AAA	3. Do not postpone
	Aneurysm associated with infection or prosthetic graft infection	3. Do not postpone
	AAA > 6.5 cm	2b. Postpone if possible
	TAAA > 6.5 cm	2b. Postpone if possible
	AAA < 6.5 cm	1. Postpone
Aortic dissection	Acute aortic dissection with rupture or malperfusion	3. Do not postpone
Aortic emergency NOS	AEF with septic/hemorrhagic shock, or signs of impending rupture	3. Do not postpone

AAA, abdominal aortic aneurysm; TAAA, Thoracic aortic aneurysm; AEF, Aorto-enteric fistula; NOS, not otherwise specified

multi-disciplinary teams. The vascular team or the on-call vascular/surgical registrar must be contacted immediately for discussions. If the clinical situation appears acute and life- or limb-threatening, intervention may be needed. The team must be informed of the COVID-19 infection status, if known [18].

The American College of Surgeons recently published COVID-19 guidelines for triage of vascular

Table 2 American College of Surgeons' COVID-19 guidelines for triage of vascular surgery patients including peripheral vascular diseases [21].

Category	*Condition*	*Tier Class*
Aneurysm peripheral	Peripheral aneurysm, symptomatic	3. Do not postpone
	Peripheral aneurysm, asymptomatic	2a. Consider postponing
	Pseudoaneurysm repair: not a candidate for thrombin injection or compression, rapidly expanding, complex	3. Do not postpone
	Symptomatic non-aortic intra-abdominal aneurysm	3. Do not postpone
	Asymptomatic non-aortic intra-abdominal aneurysm	2a. Consider postponing
Bypass graft complications	Infected arterial prosthesis without overt sepsis hemorrhagic shock, or impending rupture	3. Do not postpone
	Revascularization for high grade re-stenosis of previous intervention	2b. Postpone if possible
	Asymptomatic bypass graft/stent restenosis	1. Postpone
Peripheral vascular disease	Acute limb ischemia	3. Do not postpone
	Limb ischemia: progressive tissue loss, acute limb ischemia, wet gangrene, ascending cellulitis	3. Do not postpone
	Fasciotomy for compartment syndrome	3. Do not postpone
	Peripheral vascular disease: chronic limb-threatening ischemia, rest pain, or tissue loss	2b. Postpone if possible
	Peripheral angiograms and endovascular therapy for claudication	1. Postpone
	Surgical procedures for claudication	1. Postpone
Wounds/Gangrene/Amputation	Amputations for infection/necrosis (TMA, BKA, AKA)	3. Do not postpone
	Lower extremity disease with non-salvageable limb (amputation)	3. Do not postpone
	Deep debridement of surgical wound infection or necrosis	2b. Postpone if possible
	Wounds requiring skin grafts	2b. Postpone if possible
	Amputations for infection/necrosis (toes)	2b. Postpone if possible

TMA, Trans-metatarsal amputation; BKA, Below knee amputation; AKA, Above knee amputation

surgery patients including peripheral vascular diseases (Table 2) [21].

Diabetic Foot and Podiatric

Podiatric care is associated with fewer diabetes-related amputations, ER visits, hospitalizations, lower length-of-stay, and lower costs. However, podiatrists must mobilize and adopt the new paradigm of shifts away from hospital care to community-based care. Implementing the proposed Pandemic Diabetic Foot Triage System in-home visits, higher acuity office visits, telemedicine, and remote patient monitoring can help podiatrists manage patients while reducing the COVID-19 risk. The goal of podiatrists during the pandemic is to reduce the burden on the health care system by keeping diabetic foot and wound patients safe, functional, and at home [21]. Podiatrists have adapted quickly to the new pandemic system of care and made changes so as to provide services in new and unique ways. They strongly recommend implementing a triage system for lower-extremity wounds and diabetic foot problems, which will drive the site and urgency of podiatric care (Figure 5) [19].

Carotid Surgery

The Vascular Society of Great Britain and Ireland advises that crescendo Transient Ischemic Attacks (TIAs) would normally need urgent surgery. If there are severe resource limitations, aggressive pursuit of the

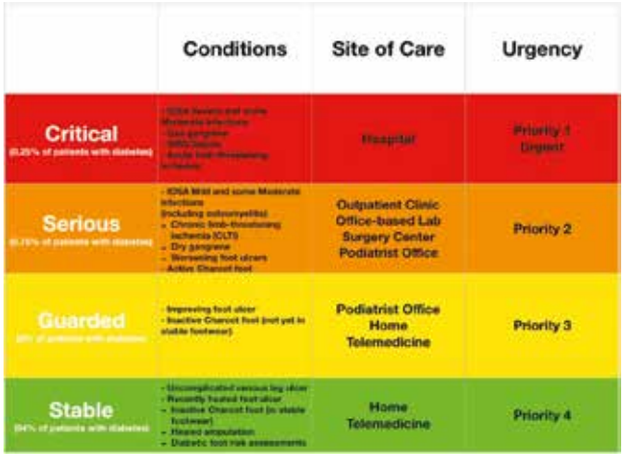

Figure 5 *Priority and urgency for podiatric conditions.*

best medical therapy would be more appropriate for recently symptomatic carotid disease [12].

The American College of Surgeons' COVID-19 guidelines for triage of vascular surgery patients advise not to postpone symptomatic carotid stenosis, while it advises to postpone asymptomatic ones [21].

Venous Surgery

The Vascular Society of Great Britain and Ireland advises that elective arterial surgery and venous surgery should be deferred [12].

The American College of Surgeons' COVID-19 guidelines for triage of vascular surgery patients advise the postponement of asymptomatic patients with May–Turner syndrome, patients with varicose veins, and Inferior Vena Cava (IVC) filter removal. It advises consideration of the postponement for massive symptomatic ilio-femoral deep venous thrombosis (DVT) in low risk patients, procedures for ulcerations secondary to venous disease, and IVC filter placement [21]. It also advises proceeding with intervention in cases of acute ilio-femoral DVT with phlegmasia [21].

For trauma, it advises proceeding with intervention in cases of traumatic injury with hemorrhage and/or ischemia or surgery/embolization for uncontrolled bleeding in unstable patients. Otherwise it advises postponement if possible in cases of surgery/embolization for bleeding in stable patients [21].

For mesenteric vascular disease, it advises proceeding with intervention and no postponement for symptomatic acute mesenteric occlusive disease. However, it advises considering postponement for cases of chronic mesenteric ischemia [21].

For thoracic outlet syndrome (TOS), it advises postponement for cases of neurogenic and mild venous TOS and postponement, if possible, for cases of arterial thoracic outlet syndrome with thrombosis or symptomatic venous TOS with acute occlusion and marked swelling [21].

Renal Dialysis

Rapid National Institute for Health and Care Excellence (NICE) recommendations for dialysis service delivery include the following:

(1) Communicating with patients: communicate with patients and support their mental wellbeing to help alleviate any anxiety and fear. Tell patients to alert their dialysis unit if they are unwell. Minimize face-to-face contact by offering telephone or video consultations, cutting non-essential face-to-face follow-up, using home-delivery services for medicines, and using local services for blood tests [20].
(2) Patients not known to have COVID-19: encourage patients to use their own transport and to travel alone to the dialysis unit when possible. Minimize time in the waiting area by careful scheduling, encouraging patients not to arrive early, and texting patients when the unit is ready to see them [20].
(3) Patients known or suspected to have COVID-19: follow the national guidance on infection prevention and control.
(4) Patient transport to and from dialysis units: ensure that outpatient transport services get patients to their dialysis as scheduled to avoid their condition deteriorating. Work with transport providers to have arrangements in place to ensure continuity in patient care. Collaborate with the transport provider to minimize cross-infection between patients with known COVID-19 and those suspected of having COVID-19 [20].
(5) Before patients enter the unit for dialysis: screen and triage patients before they enter the dialysis unit (for example, at the reception waiting area). If people are suspected of having COVID-19, where possible, carry out rapid turnaround testing before dialysis to establish COVID-19 status. Dialysis may be needed before the test results are available [20].
(6) Home dialysis provision: Continue and maintain current home dialysis provision (home hemodialysis and peritoneal dialysis) and maintain adequate supplies and staffing support. Test for COVID-19 in patients, carers, and assistants (paid and unpaid) in the community using any form of home dialysis if they develop symptoms. Test paid assistants carrying out assisted automated peritoneal dialysis [20].

From another point of view, the American College of Surgeons advise proceeding with intervention and not postponing cases of thrombosed or nonfunctional dialysis access, infected dialysis access, fistula revision for ulceration, renal failure with need for dialysis access, and tunneled dialysis catheter. They advise postponing,

if possible, cases of fistula revision for malfunction, vascular access steal syndrome and fistulagram for vascular access malfunction. They advise considering postponement for cases of Arterio-venous (AV) fistula and graft placement for dialysis (End Stage Renal Disease (ESRD), chronic kidney disease stage 4, chronic kidney disease stage 5 only) [21].

We suggest that vascular access operations are lifeline operations; they should be continued especially when they are based on "single-day operations" with no need for admission. Patients diagnosed with venous hypertension low-grade steal syndrome should be managed conservatively. Patients diagnosed with chronic kidney disease and who have not started dialysis yet should be postponed.

Surgical Measures at Ain Shams University Hospital

(1) Specialized hospital treatment for all patients as if infected with COVID-19 until proven otherwise and requests for laboratory testing before intervention except in emergent cases.
(2) The general hospital (limited resources) provides a surgical service for non-COVID-19 patients aimed at the clinical picture (no fever, cough, leucopenia), while suspected clinical or confirmed cases are transferred to Obour hospital (university quarantine hospital) outside of Cairo which provides surgical and medical care.
(3) There are a limited number of operation lists and limited times of operations. The vascular surgery operation list has been reduced from five to three times per week.
(4) Surgical intervention is limited to urgent and emergent cases based on a weekly meeting consultation by the head of department and other consultants.
(5) Cleaning of the operation room is intensively carried out under direct supervision of the operation room manager and head nurse.
(6) Regular cleaning and disinfection of surfaces by sodium-hypochlorite disinfectant is carried out and hand alcohol-based disinfectants are available everywhere.
(7) Well-spaced feet signs have been put in elevators, with no face-to-face communication in close and limited spaces.
(8) Patients have no time to wait in the induction room; they arrive from the ward and immediately enter the operation room. The recovery room has separate sectors for isolation and only half the number of rooms are on demand so there are fewer patients in the recovery room.
(9) Admissions are served for non COVID-19 suspected emergent or urgent cases only, and visits by patient's relatives are limited. There are enough spaces between patients, with good ventilation.
(10) HCWs use personal protective equipment (PPE) in the emergency triage area, such as gowns, surgical masks, and eye shields, while they use only masks in the operation rooms and ward. Alcohol-based antiseptic solutions are available everywhere.

CONCLUSIONS

Although vascular surgeons are not considered to be the front line in combating the pandemic of COVID-19, certain measures can be adopted in their practice during this period to control and lessen the spread of the disease.

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 author declares that they have no conflicts of interest.

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REFERENCES

[1] World Health Organization. Situation reports. https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020. Accessed 22 March 2020.
[2] Tyrrell DA, Bynoe ML. Cultivation of viruses from a high proportion of patients with colds. Lancet. 1966;1:76–7.
[3] GISAID Global Initiative on Sharing All Influenza Data. Phylogeny of SARS-like betacoronaviruses including novel coronavirus (nCoV). https://nextstrain.org/groups/blab/sars-like-cov. Accessed 26 February 2020.
[4] Zhou P, Yang XL, Wang XG, et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature. 2020; *In Press*. doi: 10.1038/s41586-020-2012-7.
[5] Rothe C, Schunk M, Sothmann P, et al. Transmission of 2019-nCoV infection from an asymptomatic contact in Germany. N Engl J Med. 2020;382:970–1
[6] Guan W, Ni Z, Yu H, et al. Clinical characteristics of 2019 novel coronavirus infection in China. N Engl J Med. In Press. doi: 10.1056/NEJMoa2002032.
[7] Holshue ML, DeBolt C, Lindquist S, et al. First case of 2019 novel coronavirus in the United States. N Engl J Med 2020;382:929–36.

[8] Lu R, Zhao X, Li J, et al. Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. Lancet. 2020. *In Press*. doi: 10.1016/S0140-6736(20)30251-8.
[9] Kampf G, Todt D, Pfaender S, Steinmann E. Persistence of coronaviruses on inanimate surfaces and its inactivation with biocidal agents. J Hosp Infect. 2020;104:246–51.
[10] Huang C, Wang Y, Li X, Ren L, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet. 2020;395(10223):497–506.
[11] H. Lu. Drug treatment options for the 2019-new coronavirus (2019-nCoV). Biosci Trends. 2020;14(1):69-71.
[12] Vascular Society of Great Britain and Ireland. COVID-19 virus and vascular surgery. https://www.vascularsociety.org.uk/professionals/news/113/covid19_virus_and_vascular_surgery. Accessed 20 March 2020.
[13] American College of Surgeons. COVID-19: recommendations for management of elective surgical procedures. https://www.facs.org/about-acs/covid-19/information-for-surgeons/elective-surgery. Accessed 13 March 2020.
[14] Liang ZC, Wang W, Murphy D, Po Hui JH. Novel Coronavirus and orthopaedic surgery: early experiences from Singapore. J Bone Joint Surg Am. 2020. *In Press*. doi: 10.2106/JBJS.20.00236.
[15] Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES and EAES Recommendations regarding surgical response to COVID-19 crisis. https://www.sages.org/recommendations-surgical-response-covid-19/. Accessed 19 March 2020.
[16] Royal College of Surgeons. Guidance for surgeons working during the COVID-19 pandemic https://www.rcseng.ac.uk/coronavirus/joint-guidance-for-surgeons-v1/. Accessed 20 March 2020.
[17] Centers for Disease Control and Prevention. PPE sequence. https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf. Accessed May 2018.
[18] Foot in Diabetes UK. COVID-19 situation v1.3 lower limb amputation prevention guidance. https://www.wounds-uk.com/resources/details/lower-limb-amputation-prevention-guidance. Accessed 23 March 2020.
[19] Rogers LC, Lavery LA, Joseph WS, Armstrong DG. All feet on deck—the role of podiatry during the COVID-19 pandemic: preventing hospitalizations in an overburdened healthcare system, reducing amputation and death in people with diabetes. J Am Podiatr Med Assoc. In Press. doi:10.7547/20-05.
[20] NICE guideline [NG160]. COVID-19 rapid guideline: dialysis service delivery. https://www.nice.org.uk/guidance/ng160. Accessed at March 2020.
[21] American College of Surgeons. COVID-19 guidelines for triage of vascular surgery patients. https://www.facs.org/covid-19/clinical-guidance/elective-case/vascular-surgery. Accessed 24 March 2020.

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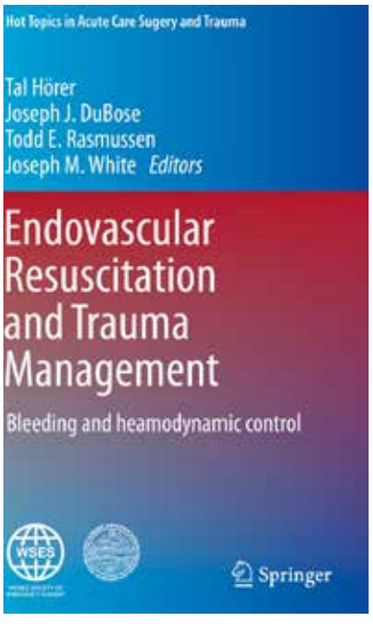

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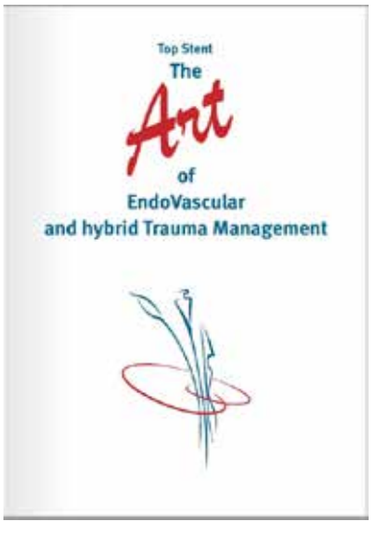

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