



Journal of Endovascular Resuscitation and Trauma Management

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Issue Highlights

Resuscitative Thoracotomy and Aortic Cross-Clamp and Resuscitative Endovascular Balloon Occlusion of the Aorta

Present Strategy for REBOA Management After Catheter Placement: A Current Suggestion From the Japanese Society of DIRECT

Partial Resuscitative Endovascular Balloon Occlusion of the Aorta and Intermittent Resuscitative Endovascular Balloon Occlusion of the Aorta

Proactive Use of Whole-Body Computed Tomography and Resuscitative Endovascular Balloon Occlusion of the Aorta in Hemodynamically Unstable Trauma Patients

and more...



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

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

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

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

The Journal will publish 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.

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



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Author Guidelines

GUIDELINES FOR SUBMISSION

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

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

The submission process requires three discreet documents:

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

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

Cover Letter

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

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

Title Page

This should consist of the following:

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

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

Main Body

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

Main Heading **BOLD, FULL CAPITALS**

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

Sub-sub-heading *Italicized, sentence case*

Abstract

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

Background

Methods

Results

Conclusions

Keywords

Three to six appropriate keywords should be included.

Types of Article

Original Articles

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

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

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

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

Editorials

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

Narrative Review Articles

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

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

Systematic Reviews and Meta-Analyses

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

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

Tips and Techniques

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

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

Images of Interest

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

Case Reports

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

Conference Proceedings

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

Letters to the Editor

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

Residents Corner

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

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

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

References

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

An example article:

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

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

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

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

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

Figure/Tables

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

Figure captions should be styled as follows.

Figure 1 Title of figure.

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

(b) Second sub-item.

Table captions are styled similarly.

Supplementary Digital Content

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

SUPPORT FOR LANGUAGE AND ARTICLE CONTENT

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

ETHICAL AND LEGAL CONSIDERATIONS

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

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

Authors' Responsibilities

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

All published material will include the following Ethics Statement:

Ethics Statement

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

Detailed Ethical Guidelines

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

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

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

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

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

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

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

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

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

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

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

Editors' Responsibilities

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

Reviewers' Responsibilities

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

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

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

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

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

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

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Patient Anonymity and Informed Consent

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

Protection of Human Subjects & Animals in Research

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

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

Ethical Approval and Informed Consent

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

Or in the negative

Ethical Approval and Informed Consent

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

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

General Statement

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

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

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

Join the Endovascular Resuscitation Platform

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

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

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

The Membership fee is 50 USD biannually.

Vision and Mission:

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

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

Structure:

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

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

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

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

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

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

Declaration of the EVTM Society

Tal Hörer, Boris Kessel, Joe Dubose, Megan Brenner and Yosuke Matsumura

Senior Editorial Board of the JEVTM

The EndoVascular Resuscitation and Trauma Management (EVTM) Society, and the entire world, watches as the Russian–Ukraine military conflict unfolds. The Russian Federation, one of the most powerful countries widely recognized for its economics, culture, and science, has decided to resolve problems with military force. The consequences of this huge humanitarian catastrophe will last for many years to come. Millions of refugees, women, and children have, or will be, unnecessarily killed or injured. We will never turn our backs on the basic human rights of health, medicine, and ethics. All of us are now firm in our commitment to be physicians without borders, to be “people of peace” and to spread our voice everywhere.

Our society includes hundreds of very professional specialists in various medical disciplines who treat trauma patients across the planet.

As physicians, our society condemns any harmful military acts against civilians, and we call for an immediate cessation of aggression and the use of force.

As people who signed the Hippocratic Oath, we stand by the medical teams and are ready to support casualties of war in any possible way.

Erratum: Correction to Contents List for JEVTM Issue 5(3)

During the publication process, an error was introduced in the contents list of the last issue. The authors of the fifth paper in JEVTM issue 5(3) should be

Endovascular Instead of Open Surgical Repair of Axillosubclavian Artery Injuries: An Evolving Paradigm Shift

Shreya Jalali, Derek J Roberts, Megan L Brenner, Joseph J DuBose, Laura J Moore and Adam H Power

All online versions of the issue have been corrected.

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Crossing the Rubicon: REBOA and Endovascular Hemorrhage Control in 2022

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Resuscitative endovascular balloon occlusion of the aorta (REBOA) continues to prove its value as a tool to temporize refractory hemorrhagic shock secondary to non-compressible truncal hemorrhage, as first described by Lieutenant Colonel Carl W. Hughes in 1954 during the Korean War [1]. Early descriptions of the use of balloon aortic occlusion were case reports and series looking at mixed trauma and non-trauma settings. A systematic review of these reports by Morrison et al. [2] did not show a clear reduction in hemorrhage-related mortality. The debate on balloon aortic occlusion continued with studies in support of the use of REBOA [3–7] and studies expressing concern for the safety and efficacy of REBOA due to an association with increased mortality and access-site related complications [8–10]. The subsequent initiation of endovascular and REBOA catheter-specific courses in the past decade has led to a greater implementation and widespread adoption of the use of these devices and multiple collaborative efforts including the AAST Aorta Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry, the international ABO Trauma Registry, ER-REBOA Catheter study and UK REBOA Trial. Since then, analyses from the AORTA Registry show that REBOA is indeed a viable alternative to open aortic occlusion [11], can assist with management in severe pelvic fractures [12] and may even offer a survival benefit in select patient populations [13,14].

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The authors in this edition of JEVTM have done an excellent job investigating and surveying the impact of the use of REBOA across a broad range of indications and patient populations, as well as examining new technologies, approaches and algorithms for endovascular hemorrhage control. The breadth of topics covered in the papers for this edition give a thorough review of REBOA and its current best practices, explaining indications for REBOA in the trauma setting but also beyond trauma, methods for proper deployment of the catheter, cutting-edge techniques to reduce ischemia-reperfusion injury, and future direction for the use of balloon aortic occlusion.

The indications for the use of REBOA have been well-described in trauma patients [15], and the indications and contraindications are reviewed in detail by Ishida et al. They address and provide great discussion on current controversial topics such as the use of REBOA in chest trauma, intracranial hemorrhage, pediatric trauma, and the prehospital setting. The authors in this paper also make a thoughtful, critical point to remind us that REBOA itself is not the ultimate step in the treatment of uncontrollable hemorrhage but the bridge to definitive hemorrhage control. They correctly state that REBOA is “not a magical device” and transport to the operating theater or angiography suite should not be delayed. The review by Seno et al. then provides an excellent global overview of the procedural steps, techniques, and tips and tricks for successful arterial access and REBOA placement and deployment.

The use of REBOA has been implemented in multiple non-trauma clinical settings such as ruptured abdominal aortic aneurysms, obstetric hemorrhage, upper gastrointestinal bleeding, and elective pelvic tumor resections. Shinozuka et al. state that patients with non-traumatic sub-diaphragmatic hemorrhage usually demonstrate a single bleeding site and are rarely accompanied by coagulopathy making these patients good candidates for controlled, even partial or intermittent, aortic occlusion. When properly deployed and monitored, REBOA can be an extremely useful tool to help control or prevent expected massive hemorrhage. Matsumura and Shinozuka’s paper

continues to describe in more detail the endovascular strategies in achieving hemostasis in obstetrics and point out the additional advantage of the use of zone 3 REBOA with its potential risk reduction of operative injury to the ureter or bladder in a damage control operation. Given the high risk of maternal death from hemorrhage due to placental abnormalities and post-partum hemorrhage in settings with less robust capabilities, REBOA may be an ideal adjunct in the most austere setting to decrease these preventable deaths. A second paper by this same author highlights the high level of care and respect that we must have for the utilization of these devices, and an understanding of the associated complication profile as well as techniques to minimize or mitigate these adverse events. Sugiyama et al. then provide a thorough review of the numerous common and uncommon complications associated with REBOA, including access-site complications, iliac and aortic injury, malpositioning of the balloon, intracranial hemorrhage, and limb ischemia or compartment syndromes. In addition to outlining these issues, they provide helpful advice on recognizing and managing these complications.

In a pair of nicely written papers, Nagashima et al. discuss two critical issues in endovascular trauma management. In the first, they outline the indications, techniques, pros and cons of endovascular aortic occlusion versus thoracotomy and aortic cross-clamping, and a rational approach to making these time-critical decisions. In the second, they cover the under-appreciated but foundational aspects of obtaining safe and rapid early femoral arterial access to facilitate rapid REBOA placement and deployment if and when it becomes needed. This is an area that is often glossed over in discussions and courses on REBOA, but it represents one of the greatest “Achilles heels” of this technology in terms of both effective rapid deployment and the risk of major or even limb-threatening complications. We hope that these complications become less frequent and less severe as we gain increased familiarity and expertise in femoral access and in early recognition of developing complications, and as we move to smaller sheaths and devices such as the newly US Food and Drug Administration approved 4-French REBOA catheter.

One of the most interesting and surely most controversial papers in this edition is the piece by Miyauchi et al. discussing the use of REBOA as a bridge to performing whole body computed tomography (WBCT). While the traditional teaching and paradigm of REBOA has been that it should be used as a temporizing therapy to bridge the unstable patient to either the operating room or the angiography/interventional radiology suite, we agree with these authors that there are select patients who may be best served by immediate WBCT after REBOA deployment. This would include the patient with instability from a source that remains unclear or unidentified after the initial evaluation, the patient with a high suspicion for traumatic brain injury that may require urgent operative

intervention, the geriatric patient with coagulopathy, or the polytrauma patient with multiple compartment injuries but unclear order of prioritization or need for operative hemorrhage control. In order for this approach to be successful there must be a highly streamlined and well-rehearsed system in place that includes rapid movement to and performance of the WBCT, immediate imaging review and interpretation, continuous close monitoring with the ability to provide ongoing resuscitation, and the capability to abort and move expeditiously to the operating room or angiography suite if the patient becomes unstable. We would also draw a distinction between this approach in a patient with a zone 1 REBOA, where even a short increase in occlusion time carries major morbidity, versus a zone 3 REBOA, where longer occlusion times are better tolerated.

Finally, Hitomi et al. provide a brief but very well written review of the emerging concepts of partial and intermittent REBOA. We believe this area is one of the most exciting and promising for addressing the main limiter of more widespread adoption and utilization of REBOA, the resultant physiologic insult and ischemia-reperfusion injury that results from complete aortic occlusion. For the patient already in hemorrhagic shock, a zone 1 occlusion time of more than 30 min carries a high mortality, and a time of more than 60 min is almost universally fatal. The techniques of intermittent balloon inflation/deflation or partial controlled balloon deflation both aim to strike a balance between providing some perfusion distal to the area of occlusion but minimizing ongoing or recurrent hemorrhage below the balloon. Although there is a reasonable body of well-done large animal translational research for both of these approaches, data in human patients remains scant and anecdotal. It is also important to note that the standard REBOA catheters that have been used over the past decade were not designed to allow for fine or titratable control of flow with partial deflation, and it was not until very recently that we have had second generation devices that were designed to facilitate partial REBOA. We look forward to further accumulation of data and experience as more of these devices and techniques are utilized in human patients in both trauma and non-trauma settings. We also congratulate Dr. Hörer and the JEVTM as it enters its fifth year of publication and look forward to more exciting, novel, and groundbreaking work in future editions.

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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Trends in Aortic Occlusion and How to Minimize the Risk of Complications in REBOA

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Resuscitative endovascular balloon occlusion of the aorta (REBOA) increases proximal aortic pressure in order to maintain central organ perfusion pressure, and simultaneously regulates distal arterial flow by endovascular aortic occlusion, which is applied during subdiaphragmatic hemorrhage. This article briefly introduces the history of REBOA and discusses its potential effectiveness and harmfulness. The article also mentions the technical aspects of REBOA, and reconsiders the term “REBOA” and “resuscitation.” The risks of aortic occlusion and ischemia-reperfusion injury have not been fully elucidated. It is hoped that REBOA can be used appropriately as a powerful option for the resuscitation of hemorrhagic patients and save the lives of as many patients as possible. The Society of Diagnostic and Interventional Radiology in Emergency, Critical Care, and Trauma will publish continuous medical education articles on REBOA.

Keywords: *Resuscitative Endovascular Balloon Occlusion of the Aorta; REBOA; Complication*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a resuscitative maneuver using a balloon catheter through the femoral artery. It increases the proximal aortic pressure in order to maintain central organ perfusion pressure, and simultaneously regulates distal arterial flow by endovascular aortic occlusion. REBOA has been applied to subdiaphragmatic hemorrhage. It enables less invasive aortic occlusion in contrast to resuscitative thoracotomy with an aortic cross-clamp (RTACC) [1,2].

Ethical Approval and Informed Consent

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

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HISTORY OF REBOA

The history of aortic balloon occlusion dates back to the Korean War in the 1950s [3], and the devices have been commercially available in Japan since the 1990s. The device has been recognized as “Intra-aortic balloon occlusion (IABO)” [4], which has been used during resuscitation in severe hemorrhagic shock in torso trauma or postpartum hemorrhage, as a proximal control during surgery, and for prophylactic purposes in high-risk cesarean sections. The aortic occlusion device is not recognized globally, and there has not been a standard indication for use; rather it depends on the institutional or operator’s policy.

The term “resuscitative endovascular balloon occlusion of the aorta (REBOA)” was first published in the *Journal of Trauma* in 2011 [5]. Since then, the global trend of aortic balloon occlusion devices has drastically changed. The Block Balloon™ (Senko Medical Instrument, Tokyo, Japan) has been on the market, and it is compatible with a 10 Fr sheath [6]. Since this catheter was not available outside Japan, the Coda® Balloon Catheter (Cook Incorporated, Bloomington, IN, USA) or Reliant™ Stent Graft Balloon Catheter (Medtronic, Minneapolis, MN, USA) were used in some European countries and in the United States. The Rescue Balloon® (Tokai Medical Products, Aichi, Japan) [7], a small profile 7 Fr sheath compatible catheter, was launched in

Japan in 2013 and became available internationally. The ER-REBOA™ Catheter (Prytime Medical, Boerne TX, USA) [8] was approved and launched in the United States, after which it rapidly spread globally. The REBOA Balloon Kit™ (REBOA Medical AS, Norway) [9] and the COBRA-OS™ (FrontLine Medical Technologies, ON, Canada) [10] followed, and the development of new technology and device competition is still ongoing.

EFFECTIVE OR HARMFUL?

REBOA appears to be effective in the resuscitation of severe hemorrhagic shock patients, and many have experienced cases in which they felt it was lifesaving [11,12]. In cases of splenic injury without chest trauma, REBOA may be a better alternative to RTACC for resuscitation, instead of rushing for splenectomy. It also helps to prevent sudden hemodynamic collapse at the time of laparotomy. In post-partum hemorrhage, it may function as a proximal control tool to create a dry operative field, to decrease the intraoperative blood loss and transfusion [13–16].

However, improper use of REBOA is harmful and can easily lead to complications and life-threatening situations. In addition, database analysis has reported that there is no solid evidence that the use of REBOA contributed to improved survival outcomes, but rather that it was harmful [17–19]. In a super-aging society like Japan, REBOA is often placed in high-risk elderly patients with vascular stenosis, calcification, and tortuosity. If the procedure and management after placement is not understood, complications will occur [20]. Understanding physiological and anatomical adaptations are not sufficient to unlock the potential value of REBOA. It is essential to establish a consistent medical care system that includes resuscitation, hemostasis, and intensive care for patients with hemorrhagic shock.

The balloon is usually positioned in zone 1 or zone 3 according to the hemodynamics and assumed injury sites. Zone 1 extends from the origin of the left subclavian artery to the celiac trunk, zone 2 extends from the celiac trunk to the lowest renal artery, and zone 3 exists from the lowest renal artery to the aortic bifurcation [5,21]. Hemodynamics and injury sites are uncertain in trauma cases. Considering the hemodynamics (urgency of cardiac arrest), chest trauma (especially aortic injury), and arterial access, we should consider choosing REBOA or RTACC correctly, or converting RTACC to REBOA [22]. On the other hand, there are some non-traumatic cases for which REBOA is indicated. Zone 3 REBOA contributes to resuscitation in the patients with post-partum hemorrhage [14]. The elective use of REBOA also decreases blood loss and transfusion during cesarean delivery in the placenta accrete [16]. REBOA can be used in abdominal aortic aneurysm and gastrointestinal bleeding [23,24]. In both traumatic and non-traumatic cases, REBOA is used as a bridge to definitive hemostasis, for proximal control, or for prophylactic purposes.

TIPS AND PITFALLS IN TECHNICAL PROCEDURES OF REBOA

The procedure of REBOA is relatively simple, but REBOA providers need to master the knowledge and skills needed to minimize the risk of complications [20]. The REBOA operator needs to choose several procedural options: arterial access (blind, ultrasound-guided, cut-down), imaging modality during the procedure (ultrasound, X-ray, fluoroscopy), positioning of the balloon (external landmark, vertebral body with fluoroscopy), and location (resuscitation room, angiography suite, operation room). There are several balloon-volume adjustment methods: blind injection until tactile feedback, pre-determined volume, and titration based on the femoral arterial pulse pressure. Each adjustment method differs in terms of accuracy, reproducibility, safety, and feasibility. The operator should always prepare plans B or C in the case of any difficulty.

THE TERM “REBOA”

Now, let us return to the consideration of the term “REBOA”. Is this device really “resuscitative”? Does this device merely occlude the aorta? To answer these questions, we need to reconsider the meaning of “resuscitation”.

“Resuscitation” during a cardiac arrest comprises chest compressions, adrenaline administration, defibrillation, and airway management [25,26]. “Resuscitation” for trauma assumes a broader situation and is a process of achieving physiological stability in the primary survey. Aortic balloon occlusion may work effectively in the process of “resuscitation”. Aortic occlusion to avoid cardiac arrest in hemodynamic instability is truly “resuscitative”. Such “resuscitative” REBOA has been compared to resuscitative thoracotomy and aortic cross-clamp [2,11].

There are many ways to use an aortic balloon occlusion catheter. In addition to resuscitative use, intraoperative proximal control in slightly more stable patients and prophylactic use in elective cases are other indications for aortic balloon occlusion. Even after responding to the fluid or transfusion, the aortic occlusion catheter provides safe intrahospital transport to the operating room as a partial occlusion or deflation.

In this way, the REBOA catheter has more potential in a non-resuscitative situation. In addition, REBOA does not contribute to resuscitation during a hemorrhagic shock. It is just a bridge to definitive hemostasis. Proper and safe use of aortic balloon occlusion, including proximal control [27] and prophylactic use [15], should always be carried out in front-line clinical practice without being overwhelmed by the term “resuscitative” in “REBOA”.

CONCLUSION

The risks of aortic occlusion and ischemia-reperfusion injury have not been fully elucidated. REBOA should

only be used when really needed. In many situations, resuscitation and hemostasis without the use of REBOA is the best choice. It may not be available, depending on the patient's anatomy and the procedure environment. We strongly hope that REBOA can be used appropriately as a powerful option for resuscitation of hemorrhagic patients and can save the lives of as many patients as possible. The Society of Diagnostic and Interventional Radiology in Emergency, Critical Care, and Trauma will publish continuous medical education articles on REBOA.

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

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). The other authors declare that they have no conflicts of interest.

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Indication of Resuscitative Endovascular Balloon Occlusion of the Aorta in Trauma Patients

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In trauma bays, resuscitation as a bridge to definitive hemorrhage control to avoid cardiac arrest is challenging. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a resuscitation procedure for refractory hemorrhagic shock. The REBOA procedure itself is simple compared to other endovascular procedures, such as angioembolization or stent graft placement. However, adequate REBOA implementation requires a complete understanding of its potential risks and simulation training. We should be aware that REBOA is not a hemostatic device, but a bridge to definitive hemorrhage control; furthermore, it is not a magical device that can improve the critical situation in trauma resuscitation. For appropriate use, we herein describe the indication of REBOA in trauma resuscitation based on existing evidence.

Keywords: *Resuscitative Endovascular Balloon Occlusion of the Aorta; REBOA; Trauma; Hemorrhagic Shock; Indication*

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INTRODUCTION

In trauma bays, resuscitation as a bridge to definitive hemorrhage control to avoid cardiac arrest is challenging. Resuscitative thoracotomy with an aortic cross-clamp (RTACC) is a resuscitation procedure in patients with life-threatening refractory hemorrhagic shock. However, RTACC itself is highly invasive, and sequelae such as bleeding from the chest wall, hypothermia, and empyema are known complications. As an alternative method, intra-aortic balloon occlusion catheters have been used since the latter half of the 1990s. In 2011, resuscitative endovascular balloon occlusion of the aorta (REBOA) was reported [1], and since then, it has been widely used worldwide.

However, the effectiveness of REBOA, such as its impact on life prognosis, is controversial [2,3]. A possible reason for this is that REBOA has not been appropriately implemented. In the absence of high-quality evidence regarding REBOA implementation, we herein describe the indications for REBOA in trauma resuscitation based on existing evidence.

Ethical Approval and Informed Consent

This is a review article and does not contain any original human or animal data, therefore ethical approval was not required and consent to participate was also not required.

THE ROLE OF REBOA

The Purpose of REBOA

In addition to its resuscitative use, REBOA is used as an intraoperative proximal control in massive bleeding cases. Furthermore, the degree of balloon occlusion can be adjusted depending on the blood pressure, which is known as partial REBOA. Moreover, it is possible to switch to REBOA from other aortic occlusion procedures,

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such as RTACC or manual compression of the aorta during laparotomy. REBOA is less invasive than RTACC and may have a similar physiological effect.

REBOA as a Bridge to Definitive Hemorrhage Control

REBOA is not a magical device that can improve the critical situation in trauma resuscitation. REBOA is not a hemostatic device, but a bridge to definitive hemorrhage control. Therefore, one should not be relieved with an apparent increase in blood pressure during aortic occlusion. Definitive hemorrhage control must not be delayed. The association of REBOA with life prognosis is not constant in observational studies using large databases [2,3]. Inappropriate use of REBOA can easily lead to complications and may lead to life-threatening situations. Therefore, it is essential to conduct REBOA with a strong risk awareness.

REBOA CATHETER PLACEMENT

Aortic Zones Related to REBOA

When performing REBOA, a balloon catheter is placed in the aorta after passing through the blood vessel via the femoral artery. The descending thoracic aorta is divided into three zones. Zone 1 extends from the origin of the left subclavian artery to the celiac artery. Zone 2 extends from the celiac artery to the lowest renal artery. Zone 3 extends from the lowest renal artery to the aortic bifurcation (Figure 1) [1].

When there is impending cardiac arrest due to refractory hemorrhagic shock or the bleeding source cannot be detected, a REBOA catheter is placed in zone 1 first. Subsequently, partial REBOA (pREBOA) or repositioning to zone 3 is considered depending on the response to resuscitation and the assumed bleeding source.

How to Confirm REBOA Placement

Due to downstream migration or blood vessels with excessive tortuosity, the REBOA catheter may become dislocated proximally or distally from the target zones 1 and 3. On the other hand, resuscitation may be delayed by using portable X-rays many times in a non-fluoroscopic environment. Therefore, after confirming the guidewire's position using ultrasound or X-rays, repetitive imaging can be omitted before balloon inflation. After balloon inflation, it is necessary to confirm the balloon catheter position using portable radiography or fluoroscopy.

Training

The REBOA procedure itself is simple compared to other endovascular procedures, such as angioembolization or stent graft placement. Therefore, it should be performed by emergency physicians and surgeons who are at the frontline of trauma care. However, adequate REBOA implementation requires a complete understanding of its potential risks and simulation training. In addition, REBOA is not usually carried out frequently. For this reason, it is not easy to learn about REBOA in a clinical setting. Inexperienced people need repeated training to establish their knowledge [4].

THE CLINICAL INDICATIONS OF REBOA

Physiological Indications

In the absence of high-quality evidence regarding REBOA implementation, there is some expert consensus that REBOA is now widely used in acute subdiaphragmatic hemorrhage [5]. Physiological indications for REBOA include refractory hemorrhagic shock, systolic blood pressure below 90 mmHg despite fluid resuscitation or transfusion, and advanced trauma life

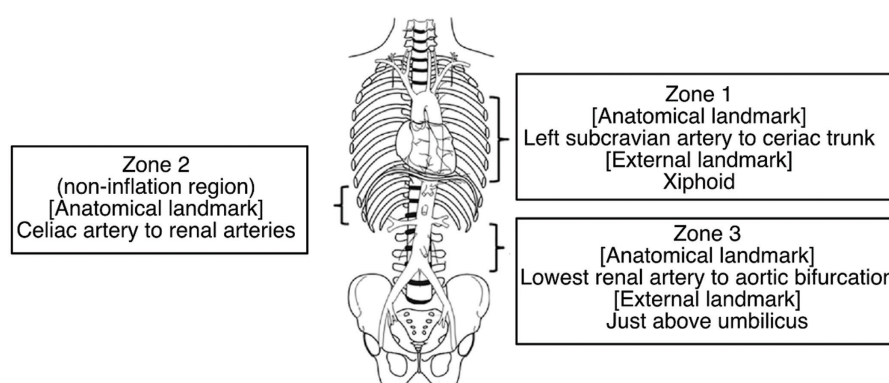


Figure 1 Aortic zones related to REBOA and the anatomical and external landmark. The approximate aortic diameter in zone 1 and zone 3 is 20 mm, and 10 mm in younger males. In older people, the catheter may not follow well in the aorta due to the excessive arteriosclerotic tortuosity of blood vessels. Thus, the external measurement method may cause a significant measurement deviation compared to X-rays.

Table 1 Advanced Trauma Life Support classification (ATLS) of hemorrhagic shock.

	<i>Class I</i>	<i>Class II</i>	<i>Class III</i>	<i>Class IV</i>
Approximate blood loss (mL) in 70 kg patient	<750	750–1,500	1,500–2,000	>2,000
Blood loss (% total blood volume)	<15	15–30	30–40	>40
Pulse rate, per minute	<100	100–120	120–140	>140
Blood pressure, systolic	Normal	Normal	Decreased	Decreased
Pulse pressure, mmHg	Normal or increased	Decreased	Decreased	Decreased
Respiratory rate, per minute	14–20	21–29	30–35	>35
Urine output, mL/h	Normal >30	Oliguria 20–30	Oliguria 5–19	Auria Negligible
Mental status	Slightly anxious	Mildly anxious	Anxious, confused	Confused, lethargic
Base deficit (mmol/L)	≤2.0	2.1–6.0	6.1–10.0	>10.0
Type of intravenous fluid	Crystalloid	Crystalloid	Crystalloid Blood (type specific)	Crystalloid Blood (massive transfusion protocol activation)

support (ATLS) class IV (Table 1) [6]. ATLS class III is not an indication.

Evidence regarding the bleeding volume and blood transfusion volume for REBOA implementation remains insufficient. Arterial access is an essential step in REBOA; however, it may be more challenging to obtain femoral artery access because the artery may not be palpable due to the circulatory collapse and spasm in hemorrhagic shock. The frequency of complications can also increase accordingly. Therefore, when REBOA is considered, femoral arterial access should be obtained using a 4-Fr, 5-Fr sheath, or 18-gauge arterial line. Afterwards, upsizing the sheath will be suitable when the decision is made to perform REBOA.

Anatomical Indications

Table 2 shows the indications for REBOA classified by zone [7,8]. Sub-diaphragmatic trauma is mainly an anatomical indication, and distal blood flow can be controlled by balloon inflation in zone 1. In pelvic fractures or lower limb trauma, REBOA may be placed in zone 3. It should be noted that although the placement in zone 3 maintains organ blood flow, the support for hemodynamics is inferior compared to that in zone 1 [9].

Indications Considering Facilities and Transportation System

It is considered that complete aortic balloon occlusion by REBOA for more than 30 minutes in zone 1 is associated with ischemic complications and death. In principle, definitive hemostasis should be initiated within 15 minutes after aortic balloon occlusion. Thus, a trauma management system in which definitive hemostasis can be performed at the same facility after REBOA implementation is ideal [7]. On the other hand, patients should be transferred to higher-level medical institutions if definitive hemostasis is not available at their institution.

However, adequate monitoring is complex with REBOA during patient transfer. Downstream migration of balloon catheters is also a concern.

Therefore, surgery in patients transferred to another hospital after REBOA must be performed with careful consideration of the risks and benefits of REBOA. From the viewpoint of organ ischemia, zone 3 occlusions for a pelvic fracture or fatal obstetric bleeding may lead to definitive hemostasis after transfer to another hospital. However, if it is unavoidable to maintain zone 1 occlusion, lifesaving may be difficult due to subsequent intestinal ischemia and necrosis. When transferring to another hospital after zone 1 occlusion, pREBOA with massive blood transfusion to maintain organ perfusion may be lifesaving.

CONTRAINDICATIONS OF REBOA

Anatomical Contraindications

REBOA regulates sub-diaphragmatic bleeding via aortic balloon occlusion. In other words, it is impossible to control bleeding proximal to the balloon catheter, but this rather worsens the bleeding. For example, REBOA is not indicated for bleeding due to massive cervical or axillary bleeding. RTACC should be generally considered in patients with severe chest injuries, including penetrating trauma and cardiac tamponade. Moreover, REBOA is not indicated for patients with suspected aortic injury based on clinical findings or diagnostic imaging [10]. Although not all bleeding proximal to the balloon catheter is contraindicated for REBOA, it must be performed cautiously. For example, splenectomy with occlusion of the aorta in zone 1 may be a reasonable choice for patients with hemorrhagic shock with severe splenic injury and multiple rib fractures. However, it should be noted that bleeding from the intercostal arteries can exacerbate a hemothorax.

Table 2 Indications for REBOA classified by zones.

Zone 1: hemorrhagic shock
Sub-diaphragmatic trauma
Non-trauma hemorrhage
Intrinsic disease (rupture of abdominal aortic aneurysm, gastrointestinal bleeding, etc.)
Postoperative hemorrhage after abdominal surgery
Postpartum hemorrhage (atonic bleeding, placenta accreta/placenta previa, placental abruption)
Zone 2: inappropriate position
Zone 2 involves the celiac artery and superior mesenteric artery, which supplies abdominal organs. Zone 2 occlusion should be avoided because it leads to malperfusion of the abdominal organ
Zone 3: hemorrhagic shock
Pelvic fracture
Lower limb trauma
Postpartum hemorrhage

Contraindications of REBOA in Clinical Practice

In trauma resuscitation, the REBOA procedure will be performed as rapidly as possible, and is often performed using X-rays or ultrasound before a detailed evaluation of the injury. REBOA is contraindicated for a bleeding source proximal to the zones of aortic balloon occlusion. However, to maintain organ perfusion (for the brain and heart, for example), REBOA might be considered simultaneously with definitive hemostasis in patients with massive cervical bleeding with impending cardiac arrest. Some studies have reported that pREBOA can control bleeding while avoiding ischemic complications [11]. However, there is no clear consensus on the implementation of REBOA in these situations.

Moreover, there is still insufficient evidence for bleeding and transfusion volumes that require REBOA deployment. It should be noted that the implementation of REBOA may lead to complications in older people with excessive arteriosclerotic tortuosity of blood vessels, terminal conditions due to malignant tumors, and severe comorbidities. Therefore, in trauma resuscitation, the patient's risk and benefit must be evaluated based on limited time and clinical information. In such difficult situations, prompt and careful decisions to implement REBOA are required. In addition, it is essential to establish a trauma management system that includes resuscitation, hemostasis, and intensive care after REBOA to bring out the potential of REBOA as a means of resuscitation.

CURRENT CONTROVERSIAL TOPICS AND FUTURE DIRECTION ABOUT REBOA

Chest Trauma

REBOA regulates blood flow distal to zones 1 or 3 by aortic occlusion. Thus, REBOA is not indicated for bleeding control proximal to the left subclavian artery. However, there are varied degrees of chest trauma. There are some opinions that REBOA may be feasible in chest trauma, although mild lung contusion, pneumothorax,

and rib fractures may exacerbate bleeding from the chest [12,13]. Besides, there are various management strategies for REBOA, such as combined use with thoracotomy and partial REBOA [11,14]. Currently, the implementation of REBOA for chest trauma is controversial.

Intracranial Hemorrhage

In patients with head trauma, an increase in the proximal blood pressure may exacerbate intracranial hemorrhage. However, REBOA may not always be harmful to the brain. Secondary brain damage may occur due to insufficient cerebral perfusion in the presence of traumatic brain injury with hemorrhagic shock. In such cases, pREBOA may increase the proximal blood flow and maintain cerebral perfusion.

RESCUE Balloon™ (Tokai Medical Products, Aichi, Japan) and IABO Block Balloon™ (Senko Medical Instrument Mfg. Co., Ltd., Tokyo, Japan) are widely used REBOA catheters in Japan. According to these package inserts, REBOA is contraindicated in the presence of intracranial hemorrhage. However, whether intracranial hemorrhage is present before REBOA implementation cannot be evaluated in the trauma bay. In several countries, REBOA is not always contraindicated in the presence of intracranial hemorrhage [5]. Thus, the decision on whether to perform REBOA may vary depending on the management system of intracranial hemorrhage.

REBOA implementation is hesitant when intracranial hemorrhage is apparent. However, it is necessary to evaluate patients' risks and benefits from limited circumstances, time, and clinical information. In such limited situations, prompt and careful decisions to implement REBOA are required.

Pediatric Trauma

REBOA is rarely performed in children compared to adults. Retrospective observational studies using large

databases suggest that REBOA is feasible for pediatric trauma [15]; however, this is not high-quality evidence, as REBOA is rarely performed in children.

The commercially available REBOA catheters in Japan are 7 Fr (Rescue Balloon, Tokai Medical Products, Aichi, Japan), and 10 Fr (IABO Block Balloon, Senko Medical Instrument Mfg. Co., Ltd., Tokyo, Japan) for adult patients. In adult patients, a small diameter sheath (7 Fr) is associated with reduced complications of REBOA use [11]. However, it is not easy to perform REBOA in children because of the difficulty of femoral artery access and the risk of lower limb ischemia. Some studies have examined the appropriate balloon volume and catheter insertion length using computed tomography (CT) data of pediatric trauma patients [16]. However, the proper use of REBOA in children has not yet been established [17].

Future accumulation of cases and the development of smaller diameter catheters may accelerate new knowledge of REBOA in children. Considering the risk of complications, the implementation of REBOA in pediatric patients should be done with caution. In summary, resuscitative thoracotomy may be safer and more reliable under current evidence.

Prehospital Setting

REBOA can be performed in various locations in hospitals, such as emergency rooms, operating suites, angiography suites, and intensive care units [5]. There has also been an attempt to implement REBOA in a prehospital setting. However, it is not easy to evaluate the indications for REBOA in a prehospital setting.

In the United Kingdom, REBOA in zone 3 for pelvic fractures has been reported in a prehospital setting [18]. However, this was a case series with no high-quality evidence. Under limited situations, prehospital REBOA may be feasible and valuable. However, the implementation of REBOA in the prehospital setting has not yet reached a clear consensus. In Japan especially, where there are many older people, the catheter may not fit well in the aorta due to the excessive arteriosclerotic tortuosity of blood vessels. Moreover, it is difficult to distinguish the presence or absence of aortic injury in a prehospital setting without chest radiography or CT in polytrauma patients.

On the other hand, ultrasound-guided arterial access in the prehospital setting may facilitate changes in REBOA after hospital arrival. Arterial lines can be used for continuous arterial pressure monitoring, even if REBOA is not performed. Thus, arterial access before the hospital is an advantage in trauma management.

Future Direction

In developing the novel REBOA catheter, it is crucial to avoid complications and perform effective aortic occlusion. When pREBOA is performed, it is possible to avoid

an excessive increase in blood pressure and to regulate distal blood flow. From this, pREBOA is a valuable procedure for avoiding lower limb ischemia, which is a severe complication of REBOA. However, the implementation of pREBOA requires frequent adjustment of the balloon injection volume. The novel REBOA catheter, pREBOA-PRO™ (Prytime Medical, Boerne, TX, USA), is equipped with a mechanism for safely adjusting pREBOA. The pREBOA-PRO™ catheter has balloons of different diameters, regulating partial distal perfusion via dual flow channels. According to the results of animal experiments, the use of pREBOA-PRO™ may reduce ischemic complications compared to conventional catheters [19,20].

SUMMARY

REBOA is a resuscitation procedure for refractory hemorrhagic shock; however, inappropriate use of REBOA can easily lead to complications and may lead to life-threatening situations. We must fully understand the indications and contraindications for REBOA use. In addition, we must be well trained in REBOA and avoid complications.

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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 JEV™ statement of ethical standards including rules of informed consent and ethical committee approval as stated in the article.

Conflicts of Interest

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). The other authors declare that they have no conflicts of interest.

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Author Contributions

KI was responsible for drafting, editing, and submission of the manuscript. YM critically appraised the manuscript. KI, SS, MT and YM contributed to the critical revision of the manuscript for important intellectual content and provided intellectual input to the research and manuscript. All authors read and approved the manuscript.

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Indication of Resuscitative Endovascular Balloon Occlusion of the Aorta in Non-Traumatic Hemorrhage

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Many blunt trauma injuries have multiple bleeding points and are accompanied by coagulopathy. In contrast, in a non-traumatic injury, the patient often demonstrates a single bleeding site that is rarely accompanied by coagulopathy. Thus, resuscitative endovascular balloon occlusion of the aorta (REBOA) is considered more effective in non-traumatic cases than in traumatic cases. In addition, in non-traumatic cases, REBOA may be used for central blood flow control during definitive hemostasis and prevention of expected massive bleeding. In such cases, REBOA should be used carefully to avoid complications. We describe the indications for and uses of REBOA in non-traumatic cases based on existing evidence.

Keywords: Resuscitative Endovascular Balloon Occlusion of the Aorta; REBOA; Non-Trauma; Hemorrhagic Shock; Management

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INTRODUCTION

In recent years, an increasing number of studies have described the efficacy of resuscitative endovascular balloon occlusion of the aorta (REBOA) for non-traumatic hemorrhagic conditions below the diaphragm, such as the rupture of abdominal aortic aneurysm (AAA), rupture of abdominal visceral pseudoaneurysm including postoperative bleeding, gastrointestinal bleeding, and

obstetric crisis bleeding. Most injuries in Japan are blunt injuries, and many of them have multiple bleeding points that are accompanied by coagulopathy. On the other hand, in a non-traumatic state, the patient often demonstrates a single bleeding site that is less frequently accompanied by coagulopathy. Thus, REBOA is considered to be more effective in controlling bleeding in non-traumatic cases than in traumatic cases [1,2].

As with traumatic resuscitation, REBOA as a means of resuscitation in non-traumatic hemorrhagic conditions should also be used as a bridge to achieve definitive hemostasis. REBOA insertion should not delay the initiation of definitive hemostasis. In non-traumatic conditions, REBOA may be on standby to control central blood flow during hemostasis or used prophylactically to prevent expected massive bleeding. When using REBOA for these purposes, the indications for partial and intermittent occlusion should be considered aggressively to minimize ischemic time and maintain peripheral blood circulation. It is necessary to manage REBOA while closely monitoring the general condition until definitive hemostasis is completed and use it carefully to avoid complications as

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much as possible. The purpose of this review article is to understand the differences between traumatic and non-traumatic conditions and to explain the indications, procedures, and management of REBOA in each non-traumatic condition, such as ruptured abdominal aortic aneurysm (rAAA), upper gastrointestinal bleeding, and obstetric hemorrhage based on existing evidence.

Ethical Approval and Informed Consent

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

ABDOMINAL AORTIC ANEURYSM RUPTURE

Previous studies have demonstrated the efficacy of REBOA for managing infra-diaphragmatic hemorrhagic diseases such as AAA rupture and visceral artery pseudoaneurysm rupture postoperatively, necrotic pancreatitis, and other iatrogenic causes [3–7]. rAAA still shows significant mortality. Circulatory collapse is the leading cause of death in patients with rAAA, and almost half of patients die before hemostasis is achieved.

The efficacy of intra-aortic balloon occlusion for rAAA has been described as far back as 1950–1960s [8]. Progress of balloon devices [9] and modalities such as angiography suite or hybrid operative room [10] possibly contributed to increased utilization of REBOA for rAAA [11]. Recent systematic review demonstrated the use of REBOA in unstable rAAA patients undergoing emergency room may improve the survival and estimated the utilization rate of REBOA across the pooled population was 14% [12].

Utilization of REBOA for rAAA could be efficient for definitive treatment; however, the clinical practice of REBOA for rAAA in emergent situation was still challenging. In this chapter, we guided optimal utilization of REBOA for rAAA with literature reviews.

Circumstances of REBOA for rAAA

Historically, patients with catastrophic physiologies by rAAA were not thought to be candidates for an endovascular approach [13] because of the extra time in preparing for an endovascular approach. Recent progress of diagnostic modalities such as angiography suite and/or hybrid theater could enable hypotensive patients with rAAA to undergo an endovascular approach and REBOA may contribute to extend the time needed to conduct endovascular repair. The team at Cincinnati University reported a protocol of REBOA for all hypotensive patients with rAAA in a hybrid operative room and survival has improved over time [10]. As described below, the deployment of REBOA into Zone 1 is challenging and should be conducted under fluoroscopic guidance in either way by brachial/axillary artery or femoral artery.

Insertion of REBOA

Left brachial artery or axillary artery

The left brachial artery or axillary artery approach is safe because REBOA does not pass through the AAA. However, with this approach, it sometimes takes longer to insert the sheath or guide the REBOA from the left subclavian artery to the descending aorta. Technical tips to guide the REBOA to the descending aorta by adjusting the tip of the catheter and advance the guidewire to the descending aorta or pull-through method.

The placement of REBOA via the left upper extremity enables stable aortic occlusion without downstream migration, which could be dangerous during laparotomy. The upper extremity REBOA creates a dry operative field without the direct aortic clamp [8]. The adverse effect of the left upper artery approach is the possibility of arterial dissection at the origin of the left subclavian artery, which is thought to be caused by mechanical damage owing to proximal pressure elevation and elevated arterial pulse after balloon inflation.

Femoral artery

The advantage of the femoral artery approach is that it is safer and more accessible than the left upper extremity approach. REBOA via the brachial artery cannot be deployed without fluoroscopy. However, the femoral artery approach can be performed using ultrasound or a portable X-ray. Radiography confirms that the guidewire is in the aorta, and that the tip has passed the ruptured aneurysm. The guidewire may proceed to the extraluminal space (extra-aortic space) and deteriorate the ruptured aneurysm. Therefore, it is reasonable to proceed with the guidewire using fluoroscopy.

In AAA patients in particular, downstream migration is more apparent because AAA patients often have an expanded aorta with strong tortuosity. In cases of strong tortuosity, it is sometimes difficult to re-insert the stylet into the REBOA, so it will be necessary to switch from the femoral artery approach to the left upper artery approach. Using the femoral approach as the first access in the emergency room and later switching to the left brachial approach with fluoroscopy could be a practical strategy.

After REBOA Deployment

After REBOA deployment and inflation, the patient should undergo immediate definitive treatment for rAAA. Three randomized controlled trials (RCTs) have studied the optimal treatment for ruptured aneurysms, EVAR or open surgical repair [15–17]. Taking together these RCTs, the obvious difference in 30-day mortality was not noted. Especially, the populations among these RCTs, hypotensive patients who had benefit from REBOA were not included and further prospective study was warranted.

UPPER GASTROINTESTINAL BLEEDING

Previous studies have reported the use of REBOA for upper gastrointestinal bleeding (UGIB) of non-variceal hemorrhage due to conditions such as gastric ulcers, duodenal ulcers, and malignant disease [18–20]. The anatomical consideration of REBOA may be adapted to inferior gastrointestinal bleeding such as diverticulum bleeding, but these cases rarely have an extreme shock-state, and there have been no previous reports.

The origin of arterial bleeding in UGIB is branches of the celiac artery or the superior mesenteric artery (SMA), such as the gastric artery, gastroepiploic artery, or gastroduodenal artery. The balloon catheter is positioned in Zone 1. The femoral artery approach is the first choice of treatment. The most typical indication is treatment failure of endoscopic therapy. A previous case report demonstrated resuscitation after cardiac arrest following REBOA deployment [21].

Subsequent definitive treatments include endovascular therapy (angioembolization or stent graft), endoscopic therapy, or surgical hemostasis. The proximal control by REBOA is feasible and effective in any of the above. When endovascular therapy is chosen, switching from Zone 1 REBOA to selective balloon occlusion in the celiac artery or SMA is a better option to localize the ischemic areas, resulting in the reduction of ischemia-perfusion injury.

There have been no reports of REBOA use in patients with variceal UGIB. This benefit is not expected anatomically. To date, the use of REBOA in UGIB have been indicated only in cases of arterial bleeding.

OBSTETRIC HEMORRHAGE

Prophylactic Use in Elective Cesarean Delivery

Selective balloon catheters can be placed in the bilateral internal iliac arteries or common iliac arteries in elective cesarean section cases with abnormal placentae, such as placenta previa or placenta accreta. A decrease in intraoperative bleeding is expected due to bilateral selective balloon occlusion. Many publications have reported REBOA use in elective cesarean sections and their effectiveness in reducing intraoperative bleeding in recent years [22–27]. REBOA is more feasible than bilateral selective balloon occlusion, owing to its simplicity.

Postpartum Hemorrhage

Multiple criteria for the diagnosis of postpartum hemorrhage (PPH) are used worldwide. Classical PPH is defined as blood loss of more than 500 mL following vaginal birth or more than 1,000 mL following cesarean delivery. The Japanese guideline focuses on vital sign abnormalities (oliguria, peripheral malperfusion), shock index ≥ 1.5 , or coagulopathy (obstetrical disseminated intravascular

coagulation score ≥ 8 points or fibrinogen level ≥ 150 mg/dL) in obstetric critical bleeding. The guidelines refer to hemostatic procedures, uterine compression sutures, interventional radiology (angioembolization, REBOA), vaginectomy, and total hysterectomy. PPH includes not only atonic hemorrhage, but also birth canal lacerations and uterine inversion. Hemostatic procedures differ according to etiology. Even among atonic hemorrhages, the hemostatic strategy is based on the bleeding site, the presence or absence of retained placenta, and delivery mode (vaginal delivery or cesarean section).

Indication and purpose

Recently, there have been reports describing the effectiveness of REBOA for PPH [28,29]. REBOA may be used more proactively to manage PPH in the future. However, providers must bear in mind that application of REBOA is not equal to establishment of hemostasis; it is solely a temporary measure controlling arterial blood flow. PPH is often accompanied by coagulopathy, as observed in polytrauma. In both cases, hemorrhage and coagulopathy must be simultaneously managed promptly. The resuscitation team must have close contact with the blood bank, and a massive transfusion protocol (MTP) must be initiated.

Atonic hemorrhage is the most frequent cause of PPH. Hemostatic procedures for atonic hemorrhage include the intrauterine balloon (e.g., Bakri® postpartum balloon), angioembolization of the uterine artery, and hysterectomy. Administration of oxytocic agents, tranexamic acid, and early activation of the MTP are also crucial. REBOA works as a bridge to angioembolization or hysterectomy and also functions as a proximal control during the operation.

Approach and pitfalls

The femoral artery approach is usually the first choice. There are some pitfalls specific to patients with PPH. First, the lower abdomen is stretched during the postpartum period, leading to low puncture. Ultrasound guidance is recommended to identify the common femoral artery and not the superficial femoral artery. Second, the lithotomy position is the standard for obstetric pelvic examination, where femoral puncture is impossible. The resuscitation and obstetric teams should create a consensus in advance. The patient needs to maintain the supine split-leg position during the puncture procedure at the groin. After sheath placement, the leg on the sheath side shall be extended to avoid bending the sheath. Only the contralateral leg should be raised, and the sheath side remains extended during pelvic examination.

Level of the balloon occlusion

Zone 3 is the standard occlusion level in patients with PPH. In case of impending cardiac arrest, the level of the

balloon occlusion should be Zone 1 to increase the proximal blood pressure, even when Zone 3 is anatomically sufficient to regulate the arterial flow. The ovarian artery may strongly supply the pregnant uterus. Although Zone I occlusion is required to regulate the ovarian artery flow, bilateral uterine artery control through Zone 3 REBOA is usually sufficient. The risk of Zone 1 REBOA must be considered, as it can cause ischemia of the visceral organs. The level of aortic occlusion must be chosen according to the hemodynamics, assumed bleeding site, and risk of ischemia.

Although REBOA insertion without fluoroscopy guidance has been reported, accurate Zone 3 placement while going in blind or with ultrasound guidance is technically difficult because Zone 3 is a short segment. The umbilicus is an external landmark of the aortic bifurcation. After placement, the balloon position should be checked with radiography or fluoroscopy before inflation.

The following are the technical tips for blind positioning in Zone 3. First, aim at a slightly higher level (approximately 30 cm) without fixing the catheter. Next, inflate the balloon to complete occlusion. Then, deflate a little (create a partial REBOA). Thereafter, draw the catheter back gently until resistance is met (the balloon is on the aortic bifurcation). Finally, inflate the balloon at Zone 3. This procedure is called the blind Zone 3 placement, but it has the risk of scratching the aortic wall. Another risk is balloon migration to the common iliac artery ("Zone 4") when the balloon is deflated excessively. Common iliac occlusion does not regulate pelvic arterial flow and induces lower-limb ischemia on the sheath side.

Multidisciplinary cooperation is the key to successful management and it involves multiple specialties: airway and respiratory management, pelvic examination and intrauterine balloon, massive transfusion, arterial access, REBOA, angioembolization, and surgery.

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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

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). The other authors declare that they have no conflicts of interest.

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Author Contributions

KS and MA was responsible for drafting, editing, and submission of the manuscript. YM critically appraised the manuscript. KS, MA, KI, MT, and YM contributed to the critical revision of the manuscript for important intellectual content and provided intellectual input to the research and manuscript. All authors read and approved the manuscript.

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Resuscitative Thoracotomy and Aortic Cross-Clamp and Resuscitative Endovascular Balloon Occlusion of the Aorta

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In traumatic hemorrhagic shock, there are situations where rapid aortic occlusion is required. In such cases, the best aortic occlusion should be determined based on the situation. Therefore, it is essential to understand the various types of aortic occlusion, their characteristics, and their indications. However, aortic occlusion is not hemostasis but temporary proximal control of arterial bleeding; definitive hemostasis should not be delayed even if blood pressure is elevated after aortic occlusion. We describe the indications, characteristics and implementation of each aortic occlusion and the comparison between resuscitative thoracotomy with aortic cross-clamp (RTACC) and resuscitative endovascular balloon occlusion of the aorta (REBOA). It is not necessary to discuss the superiority or inferiority of RTACC and REBOA. The appropriate determination of a combination of these tactics will increase the range of strategies and tactics.

Keywords: *Resuscitative Thoracotomy and Aortic Cross-Clamp (RTACC); Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA); Abdominal Aortic Compression/Occlusion*

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INTRODUCTION

There are three main methods of aortic occlusion. 1) cross-clamping the descending aorta after left antero-lateral thoracotomy [1]; 2) compressing the aorta above the celiac artery after laparotomy; and 3) resuscitative endovascular balloon occlusion of the aorta (REBOA) [2,3]. Cross-clamping of the descending aorta is performed during resuscitative thoracotomy and called resuscitative thoracotomy with aortic cross-clamp (RTACC). It is essential to understand the characteristics of each of these methods, including REBOA, and use

them appropriately according to the situation or in combination, depending on the situation.

Ethical Approval and Informed Consent

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

INDICATIONS FOR AORTIC OCCLUSION

The algorithm for aortic occlusion is shown in Figure 1.

First, if the patient is hemodynamically unstable, early access to the femoral artery should be started in parallel with resuscitation [4]. If femoral artery access is rapidly achieved, REBOA is more advantageous than RTACC due to minimally invasive aortic occlusion [5]. Moreover, early arterial access makes REBOA more advantageous in terms of quickness than RTACC [6]. However, in an aging society such as Japan, even when early arterial access is achieved, it is often difficult to safely insert a guidewire or catheter through the artery

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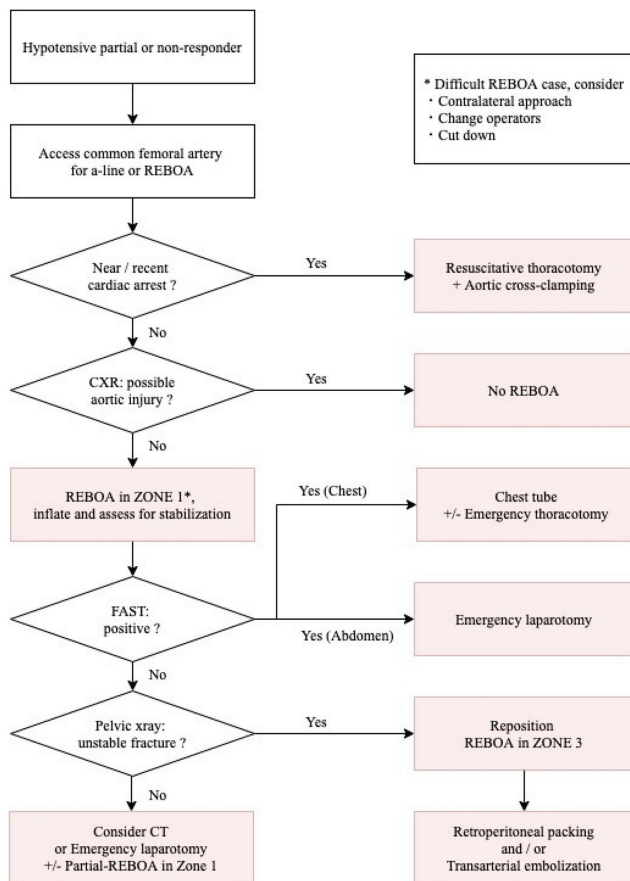


Figure 1 The algorithm for aortic occlusion.

due to vascular meandering, so it is desirable always to be ready to switch to RTACC.

In cardiac arrest or impending cardiac arrest, RTACC is more advantageous than REBOA in terms of quickness and accuracy [7]. On the other hand, in situations of non-impending cardiac arrest, the method of aortic occlusion should be selected according to the expected significant site of injury, whether arterial access is achieved or not, and the skill and proficiency of staff or the facility.

In the case of a thoracic aortic injury suspected by chest X-ray or ultrasonography, REBOA is not indicated because guidewire and catheter manipulation [5], as well as the elevation of blood pressure after occlusion, may exacerbate the injury and make it fatal [8]. If there is no suspect of thoracic aortic injury, REBOA should be placed in Zone 1, proceeding to resuscitation and hemostasis.

If a massive hemothorax is shown in the chest X-ray or Focused Assessment with Sonography for Trauma (FAST) is positive in the intrathoracic cavity, a chest tube should be placed, and emergency thoracotomy should be considered based on the amount of drainage and vital signs. If FAST is positive in the intraperitoneal cavity, emergency laparotomy should be performed.

When an unstable pelvic fracture is revealed in the pelvis X-ray with negative FAST, REBOA should be

moved from Zone 1 to Zone 3, followed by angioembolization, retroperitoneal packing, and external fixation.

In the absence of an unstable pelvic fracture, the most common source of bleeding that causes shock despite “triple-negative” (chest and pelvis X-ray and FAST are all negative) may be non-cavitary hemorrhage, including high retroperitoneal hemorrhage. Traditionally, fundamental principles of Advanced Trauma Life Support (ATLS)[®] [9,10] and Japan Advanced Trauma Evaluation and Care (JATECTM) [11], Japanese trauma guidelines, include the policy that treatment should be prioritized to computed tomography (CT) diagnosis; thus, emergency laparotomy should be performed to investigate the cause of injury, even in the triple-negative situation. A CT scan in such a situation is beyond the current guideline. However, in such cases, a contrast-enhanced CT scan with partial REBOA in Zone 1 may be an option if the facility can perform a CT scan of shocked patients quickly or provide care in a hybrid emergency room (ER) [12,13].

If the primary source of bleeding is in the abdomen and open abdominal hemostasis is performed, abdominal aortic occlusion may be an option. In particular, it may be chosen in situations where laparotomy can be started quickly but femoral artery access is not yet achieved. When interventional radiology (IR) is chosen as hemostasis, abdominal aortic occlusion is not an option, and REBOA can be performed. However, if the cause of hemorrhagic shock requiring aortic occlusion is diagnosed as abdominal trauma, the principle of the treatment should remain that open abdominal hemostasis should be performed. IR after resuscitation with REBOA may be an option only when the cause of shock is a parenchymal organ injury (liver or spleen injury), and IR can be performed immediately to stop the bleeding in a hybrid ER or when a CT scan can be performed quickly [14].

Abdominal aortic compression is not an option in an isolated pelvic fracture. The Zone 3 REBOA is a good option anatomically when diagnosed as an isolated pelvic fracture. RTACC must be chosen in patients with cardiac arrest or impending cardiac arrest or in patients without arterial access.

Do not stick to a single aortic occlusion method even when chosen or attempted. Depending on the situation, alternative methods should be considered, and “plan B” should be chosen at any moment. For example, when REBOA is being attempted but arterial access is difficult to achieve, simultaneous attempts from another side, change of surgeon, or conversion to a cut-down technique should be considered. Furthermore, in case of impending cardiac arrest during the procedure, RTACC should be performed without hesitation.

Aortic occlusion is a “bridge” to definitive hemostasis, and too much time should not be taken to establish it. The priority is not to delay definitive hemostasis by surgery, IR, or the combination of both, and REBOA is a means to connect to that. Since aortic occlusion is not

hemostasis but temporary proximal control of arterial bleeding, definitive hemostasis should not be delayed even if blood pressure is elevated after aortic occlusion.

CHARACTERISTICS OF AORTIC OCCLUSION OTHER THAN REBOA

Resuscitative Thoracotomy with Aortic Cross-Clamp

Advantages and disadvantages of RTACC

RTACC is an aortic occlusion method that can quickly and securely clamp the aorta by identifying the descending thoracic aorta through direct visual inspection or manual palpation. It is characterized by its high degree of certainty and safety and is effective in treating impending cardiac arrest. It is often performed in resuscitative thoracotomy and can be performed simultaneously to relieve cardiac tamponade, hemostasis for cardiac, great vessel, pulmonary, chest wall injuries, prevention of air embolism, and direct cardiac massage [1,15,16]. Non-surgeons with good training and experience can perform it [17]; however, thoracotomy is a highly invasive procedure because it creates a new injury of Abbreviated Injury Scale (AIS) score of 3 points or more. There is a risk of postoperative bleeding, hypothermia, vascular injuries, intercostal arteriovenous injury, and spinal artery injury. In addition, if the patient has a history of thoracotomy or chronic lung disease with adhesions between the lung and pleura, it will take more time to perform the procedure. If the chest is left open for a long time, the patient is exposed to hypothermia as well as bleeding from the chest wall. It takes time and effort to close the chest. Also, it cannot be performed prophylactically like REBOA. RTACC requires a certain amount of clinical experience and simulation training because such rapidity and certainty depend on the performer's experience.

Tips and pitfalls of RTACC

It is necessary to develop a field of view that allows direct vision for definite aortic clamping. Since this may be difficult in the prehospital environment, aortic clamping may be performed by confirming the location of the aorta based on manual palpation. Since there is a possibility of incomplete clamping or insufficient clamping during transport, occlusion status must be checked frequently. When performing aortic clamping, the descending aorta can be easily visualized by dissecting the inferior pulmonary ligament and mobilizing the lung ventrally and cephalad. When clamping the aorta with Satensky clamp, it is possible to clamp the aorta with the parietal pleura if the descending aorta is protruding on the left side. However, in cases of shock, the aorta may collapse and be withdrawn to the mediastinum. In such cases, clamping the aorta with the parietal pleura

may result in incomplete occlusion. In this case, the parietal pleura is incised and dissected to expose the aorta, and the descending aorta could be clamped securely. If the aortic clamping takes a long time or incomplete occlusion is anticipated, manual compression of the aorta toward the vertebral body should be performed. Since aortic occlusion is a vital resuscitation technique for temporary hemorrhage control, incomplete occlusion must be avoided to avoid cardiac arrest and save the patient's life. Although manual compression requires a staff member's hand, there are some situations in which manual compression is more reliable than continued uncertain use of Satensky clamp.

Abdominal Aortic Compression/Occlusion

The abdominal aortic compression/occlusion is a method of supraceliac aortic occlusion performed on the premise of laparotomy [18]. This aortic occlusion is when the assistant manually compresses the proximal aorta of the bifurcation of the celiac artery in the lesser omentum as soon as the upper abdomen is opened at the time of crash laparotomy. Continuously, the laparotomy wound is extended to the lower abdomen, and hemostasis is performed. Abdominal aortic compression is immediately followed after crash laparotomy and can be performed without invasion because it does not create new damage due to aortic occlusion, unlike RTACC [19]. It is beneficial because hemostasis and repair of damaged organs can be performed in the same surgical field after rapid manual compression [20]; however, to shift from manual compression to the aortic clamping, it is necessary to expose the aorta by making a sharp incision in the right diaphragmatic leg after incising the lesser omentum, bluntly widening it with the fingers. Because this technique is a little complicated and requires familiarity and experience, it is often performed by manual compression or compression with a special compressor [21]. At the same time, securing arterial access and implementing REBOA is also a good option. It is important to note that there are situations where the manual compressions may interfere with hemostasis or repair of the injured organ. RTACC is appropriate in cases of concomitant thoracic trauma, and this procedure is not an option when laparotomy is not required. RTACC is appropriate in cases of concomitant thoracic trauma, and this procedure is not an option when laparotomy is not required. This method has the following disadvantages: it cannot be performed prophylactically as in RTACC, it takes a long time in cases of the previous laparotomy due to adhesions, and it is performed only by physicians who can perform laparotomy [18,20].

ADVANTAGES AND DISADVANTAGES OF REBOA COMPARED TO RTACC

See Table 1.

Table 1 Advantages and disadvantages of REBOA compared to RTACC.

<i>Advantages</i>	<i>Disadvantages</i>
Less invasive	Maximally invasive
Can be performed with only local anesthesia before administration of analgesics and sedatives or tracheal intubation	Cannot be performed unless arterial access is achieved
Prophylactic use or early utilization	Lack of rapidity (not always the case if arterial access is already achieved)
Adjusting the balloon inflation volume is possible according to blood pressure (partial REBOA)	Risk of complications such as ischemia and necrosis of lower limb, vessel injury or dissection
Can be performed by both emergency physicians and surgeons with endovascular training	Difficulty of applying or high risk of complications in elderly patients with arteriosclerosis or aortic tortuosity
Accurate and rapid placement can be achieved with ultrasound	Fluoroscopy is preferable for rapid and precise procedure

Advantages of Minimal Invasiveness

The most significant advantage of REBOA is that it is minimally invasive [3,22]. If arterial access is achieved, aortic occlusion can be performed quickly (reportedly more quickly than RTACC) and without invasion, such as creating a new open chest wound. In addition, RTACC and abdominal aortic occlusion require invasive surgical procedures such as thoracotomy or laparotomy, which require administration of analgesics and sedatives except in cardiac arrest, and are often preceded by secure airway management (usually tracheal intubation). The administration of these drugs in hemorrhagic shock increases the risk of hemodynamic instability and cardiac arrest. Therefore, the presence of anesthesiologists and/or trauma surgeons is essential for rapid and precise management, and these specialties should be involved from the beginning of trauma treatment.

On the other hand, REBOA can be performed with only local anesthesia in the inguinal region. Therefore, REBOA can be used not only for resuscitation but also for early utilization in a physiologically stable state, such as proximal control during investigating bleeding sites in exploratory laparotomy for intra-abdominal hemorrhage (“intraoperative REBOA”) [23,24], temporary hemodynamic stabilization during preparation or transfer for definitive hemostasis, and prophylactic use preparing for hemodynamic collapse before definitive hemostasis such as surgery or IR after detection of active bleeding. When the common femoral artery (CFA) access was difficult to achieve, the sheath can be placed into the aorta under direct vision. Thereafter, it can be removed under vision and the defect can be repaired. This is an option of arterial access of intraoperative REBOA.

In cases of multiple blunt trauma, even if hemodynamics are temporarily stable in the early phase of injury, sudden hemodynamic collapse often occurs during treatment. Different modalities (surgery, IR, external fixation, etc.) are often required to stop bleeding from multiple sources. Therefore, while performing priority hemostasis, REBOA can also provide temporary control for bleeding from other sites to help reduce blood loss and

maintain hemodynamic stability. For example, laparotomy is performed with Zone 1 REBOA first in patients with both abdominal and pelvic trauma. Once the abdominal bleeding is controlled, REBOA is moved to Zone 3. Intraoperatively, with additional pelvic retroperitoneal packing, a Zone 3 REBOA may be effective as a “bridge” between the procedure and transfer to the angiography room for pelvic fracture.

In other words, because of its less invasiveness and rapidity, REBOA can be used as a means of resuscitation and a means of preventing hemodynamic collapse until definitive hemostasis is achieved and as a temporary proximal control during surgery.

Advantages of Safety

There seems to be no disagreement about the usefulness of achieving arterial access before the hemodynamic collapse and the safety of ultrasound-guided puncture. On the other hand, it is unclear at what severity the benefits exceed the risk of prophylactic insertion of the REBOA catheter by upsizing the sheath. In addition to the risks associated with the insertion technique and physiological changes associated with aortic occlusion, there is also a delay until definitive hemostasis can be achieved. Since the benefits of REBOA vary depending on the trauma care system in each institution, neither a clear recommendation nor a criticism can be made so far, but it may be an option for the utilization of REBOA.

In addition, by adjusting the balloon inflation volume to partial REBOA, precise control of aortic occlusion strength can be easily performed, and the risk of complications can be reduced, which is an attractive feature of REBOA not found in RTACC. The procedure itself can be performed by both emergency physicians and surgeons with training.

Disadvantages of Rapidity and Certainty

The disadvantage of REBOA compared to RTACC is that occlusion cannot be performed unless arterial access is achieved. In addition, since it is necessary to insert the sheath, apply the REBOA catheter in the

appropriate position from the sheath, and inflate the catheter, it may take some time to perform aortic occlusion, making rapidity an issue when arterial access has not been achieved. As mentioned before, REBOA can be performed faster than RTACC once arterial access is achieved [6]; however, in elderly patients with arteriosclerosis and aortic meandering, the risk of complications such as aortic dissection, aortic injury, and thromboembolism is high. There is uncertainty that aortic occlusion with REBOA cannot be done due to the difficulty of sheath insertion or applying the catheter. On the other hand, the rapidity and accuracy would be improved when REBOA can be performed in an angiographic or fluoroscopic environment.

TO “REBOA AND RTACC” INSTEAD OF “REBOA VERSUS RTACC”

The number of studies comparing REBOA and RTACC is small and limited. These studies do not include the practitioner's expertise and experience, the target patients, and the conditions of the procedure (sheath diameter, device, etc.), so there is no evidence to conclude which is more useful currently. Therefore, we should consider the patient background (elderly, obese), site of injury (presence or absence of chest trauma, perforating or blunt), circulatory dynamics (resuscitative, proximal control, prophylactic), facility environment (resuscitation room, operating room, angiography room, hybrid ER), and the skill of the practitioner (surgeon, emergency physician, IR physician), taking into account the available resources according to the situation and conditions. It is crucial to consider the available resources and determine the appropriate treatment. It is not necessary to discuss the superiority or inferiority of RTACC and REBOA. The appropriate determination of a combination of these tactics will increase the range of strategies and tactics.

Converting from RTACC to REBOA

In particular, RTACC should be performed promptly for impending cardiac arrest or cardiac arrest. Consecutively, early conversion to REBOA can be helpful [25]. While RTACC can be performed by opening the chest with only a scalpel and a Cooper, there is a risk of hemorrhagic shock caused by the procedure itself due to postoperative bleeding from the chest wall, unexpected complications in the thoracic cavity, bleeding due to traumatic coagulopathy, and hypothermia because the thoracotomy is performed without any hemostatic manipulation at once. Therefore, if it is no longer necessary to keep the chest open after aortic clamping, we should strive to prevent hypothermia by early chest wall hemostasis and chest closure. If rapid conversion to REBOA can be achieved after ensuring the speed and certainty of RTACC, it will be easier to secure the field

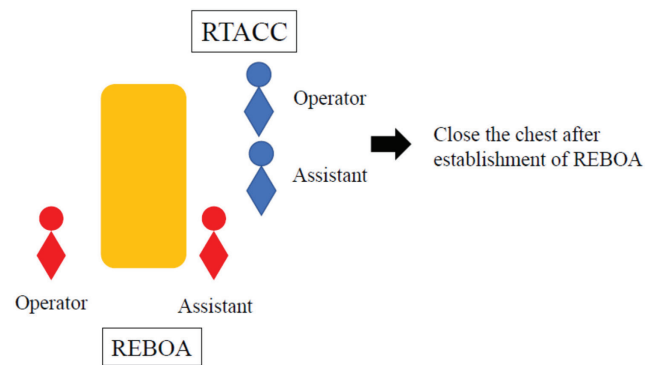


Figure 2 Conversion to REBOA from RTACC.

of view during chest wall hemostasis, and early chest closure will lead to the prevention of hypothermia and reduction of chest wall bleeding (Figure 2).

Conversion of Open Aortic Clamping to REBOA

The strategy of converting to REBOA after abdominal aortic compression/occlusion is also helpful. As soon as REBOA is established, the assistant's hand compressing the aorta in the abdominal cavity can be removed, and the view of the surgical field can be improved (Figure 3). There are some opinions and arguments that abdominal aortic compression is sufficient for temporary bleeding control and does not need to be converted to REBOA. Indeed, if a massive blood transfusion is performed quickly, the injury site is a single injury, and temporary hemostasis can be achieved quickly by manual maneuver, the operation can be completed without conversion to REBOA. However, in the case of complex injuries such as complicated intra-abdominal organ injuries, vascular injuries, retroperitoneal organ injuries, and severe pelvic fractures, and when there are multiple targets to be controlled during laparotomy, REBOA can be helpful as an aortic occlusion method because of its advantage in securing the operative field view.

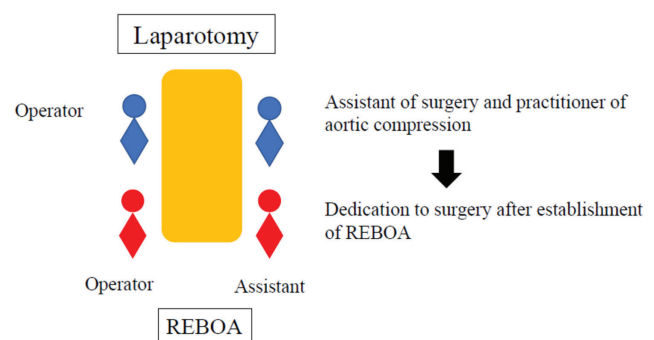


Figure 3 Conversion to REBOA from abdominal aortic compression/occlusion. Consider converting to REBOA before or even during laparotomy.

REBOA as an Adjunct to Definitive Hemostasis

Venous bleeding can be easily controlled by packing with gauze, but arterial bleeding cannot be controlled without ligation or angioembolization. Especially in retroperitoneal organ injuries and aortic injury, it is often difficult to reach and identify the bleeding site. The patient may have a compound injury. In such cases, REBOA can temporarily control arterial hemorrhage, making it much easier to reach and identify the bleeding site. In addition, it is useful for complex revascularization. Thus, REBOA can be used for resuscitation and temporary proximal control during hemostasis, which can be a major adjunct to definitive hemostasis.

CONTROVERSIAL ISSUES REGARDING REBOA AND RTACC

REBOA versus RTACC

Several studies, including two meta-analyses, have shown a reduction in mortality in the REBOA group compared with the RTACC group, suggesting the superiority of REBOA [26,27]. However, as a limitation, all meta-analyses were observational studies, not randomized controlled trials. In addition, the studies analyzed are not purely comparative due to overlap in cases and backgrounds. Some reports that the RTACC group had significantly higher chest AIS score and lower probability of survival (Ps) than the REBOA group [28]. Therefore, the target patients in the RTACC and REBOA groups are definitely different, so the difference in indications must be recognized [29].

Comparison by the Presence of Cardiac Arrest or Site of Injury

It has been reported that REBOA is superior when aortic occlusion is performed before cardiac arrest (AORTA2 study) [30]. As a limitation, 80% of the patients in the AORTA2 study were cardiac arrest patients, and the number of non-cardiac arrest patients who were actually compared was less than 30 in each group. The report by Matsumoto et al. [31] summarizes data from the Japan Trauma Data Bank, which is biased in terms of background and does not show the superiority of REBOA or RTACC.

Comparison by the Time Factor

It has been reported that the time to aortic occlusion is shorter with RTACC than with REBOA if arterial access is already achieved [6]. Therefore, RTACC should be chosen if the patient is already in impending cardiac arrest on admission. On the other hand, when arterial access is achieved, the time to aortic occlusion is significantly shorter with REBOA than with RTACC [6], appropriate recognition of patients who may require

REBOA and early achieving of arterial access may improve prognosis [4].

As a comparison of other time factors, REBOA has been reported to have a shorter chest compression interruption time, higher end-expiratory partial pressure of carbon dioxide (EtCO₂), and a higher rate of return of spontaneous circulation [32]. In other words, the quality of resuscitation may be higher than that of RTACC. Of course, it should be noted that if thoracotomy is required for reasons other than resuscitation or open-chest cardiac massage, such as repair of chest injury, comparing REBOA with RTACC itself would be meaningless.

TECHNICAL ASPECTS OF RESUSCITATIVE THORACOTOMY

Resuscitative thoracotomy (RT) is performed to release cardiac tamponade, hemostasis and repair of cardiac injury, hemostasis of intrathoracic or chest wall bleeding, prevention of air embolism, open-chest cardiac massage, and cross-clamping the thoracic descending aorta (RTACC).

A suitable approach for these purposes is the left anterolateral thoracotomy. A skin incision is made by a scalpel in the left fourth or fifth intercostal space along the rib from the left margin of the sternum to the midaxillary line. Then, the upper rib margin is incised with Cooper's scissors, and the pleural wall is opened manually for rapid entry into the thoracic cavity. A finger is inserted into the thoracic cavity at that point, and using Cooper's scissors as a guide, the intercostal muscles and the parietal pleura are separated along the upper rib margin to open the chest without damaging the lung. Once the chest is opened, a thoracic retractor is applied to widen the incision. When only poor view could be obtained, the incision should be widened, but if widened dorsally and cut into the latissimus dorsi, it may result in excessive bleeding. When widening to the sternal side, be careful not to injure the internal thoracic artery.

In the event of cardiac arrest, immediately begin cardiac massage while making a sharp incision to open the pericardium, check for cardiac injury, and stop bleeding. Then, the inferior pulmonary ligament should be dissected, the descending aorta should be cross-clamped, and if necessary, the pulmonary hilum should be clamped. If there is bleeding from the chest wall, such as from intercostal arteries, stop the bleeding. If the patient has a right massive hemothorax, right cardiac injury, or aortic injury in the ascending arch, a left anterolateral thoracotomy followed by a right anterolateral thoracotomy and transverse sternal dissection should be performed to create a clamshell thoracotomy.

Following the algorithm for the indication of RT [33,34], RT should be performed for cardiopulmonary arrest patients with vital signs within 10 minutes for blunt trauma, 15 minutes for stab injury, and systolic blood pressure below 60 mmHg before arrival at the

hospital, and aortic occlusion should be performed. If cardiac contraction is present, aggressive resuscitation should be performed, including repair for cardiac injury, control of bleeding for intrathoracic or extrathoracic hemorrhage, and hilar clamping for air embolization. If there is no cardiac contraction but cardiac tamponade is present, open the pericardium and perform the cardiac repair. If there is no evidence of cardiac tamponade, stop resuscitation.

CONCLUSION

Each aortic occlusion technique has advantages and disadvantages. Trauma practitioners need to understand and utilize the rapid and appropriate method of occlusion. The aortic occlusion technique is a bridge to hemorrhage control, rather than a salvage technique. Early definitive hemostasis must be achieved, and occlusion is not the goal. Conversion to REBOA from RTACC can be a rapid and rational aortic occlusion procedure in traumatic cardiac arrest/impending cardiac arrest cases, especially in blunt 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

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). The other authors declare that they have no conflicts of interest.

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A Guide to Femoral Arterial Access for Resuscitative Endovascular Balloon Occlusion of the Aorta

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Arterial access is essential in the resuscitation of trauma and hemorrhagic shock patients and can be effectively used for rapid endovascular treatment such as resuscitative endovascular balloon occlusion of the aorta (REBOA) and interventional radiology (IVR), continuous invasive hemodynamic monitoring, and frequent blood tests. In the REBOA procedure, obtaining arterial access is the first and most critical step. Arterial access can be obtained in three ways: (1) blind/landmark technique, (2) ultrasound-guided technique or (3) surgical cutdown technique. Regardless of which technique is chosen, it is crucial to recognize external landmarks before implementing any technique. In ultrasound-guided puncture, there are two types of techniques: short-axis puncture and long-axis puncture. There are two methods for actual puncture: the single-wall puncture method and the double-wall puncture method. In cases of hemorrhagic shock, the double-wall puncture method is advantageous when it is necessary to obtain arterial access quickly and reliably. The cutdown technique is useful when the femoral artery cannot be identified through ultrasound guidance or cannot be punctured for a long time owing to puncture-induced hematoma or obesity. This technique should be used without hesitation if it is evaluated to be more rapid and reliable than an ultrasound-guided puncture.

Keywords: *Blind/Landmark Technique; Ultrasound-Guided Technique; Surgical Cutdown Technique; Short-Axis Puncture; Long-Axis Puncture; Single-Wall Puncture Method; Double-Wall Puncture Method*

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INTRODUCTION

Obtaining arterial access should be one of the top priorities during resuscitation of patients with trauma or hemorrhagic shock. Access can be used for both REBOA and angioembolization [1–4]. Not only would it lead to quick

activation of endovascular procedures, but it would also allow prompt invasive hemodynamic monitoring and repeat blood sampling during resuscitation. Furthermore, the inguinal approach allows quick access to both the artery and vein in a single sterile area. Even when the upper half of the body is occupied with procedures such as endotracheal intubation, thoracotomy, chest compressions, or defibrillation, the groin area should be easily accessible [1,5]. Large-bore venous access can be used for fluid administration or blood transfusion; therefore, the sheath should not be removed, even when it was inadvertently positioned in the vein. Removing the sheath would necessitate compression at the insertion site and cause a delay in the next puncture. Often, you should aggressively try to obtain both arterial and venous access if the patient is in shock.

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Hereby, we review the important aspects of femoral vessel anatomy and our recommended vascular access techniques for optimal REBOA and subsequent endovascular resuscitation in time-critical situations.

Ethical Approval and Informed Consent

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

METHODS OF OBTAINING ARTERIAL ACCESS

Failed attempts to obtain arterial access would lead to more blood loss, more delay in the subsequent intervention, and loss of the option of various endovascular procedures. Therefore, arterial access must be obtained rapidly and securely.

Arterial access can be obtained in three ways: (1) blind/landmark technique, (2) ultrasound-guided technique, or (3) surgical cutdown technique [6–11]. Historically, the blind technique was the mainstay of the puncture method. However, blood vessels are not always located at anatomically predicted locations. In particular, when the artery and vein overlap, there is a possibility of penetrating the vein. For obtaining access and prevention of complications, such as puncture-site hematoma formation, the ultrasound-guided technique is recommended for obtaining an arterial access [7,10].

The blind technique is not usually recommended, but occasionally it is inevitable, in situations where you do not have access to ultrasound, for example. Do not fixate on a single technique. If it does not work, immediately consider moving on to a different technique, including surgical cutdown [8–10].

In obese patients, exploration of the subcutaneous tissue is an option to shorten the distance to the vessels and subsequently confirm the location using ultrasound. Understanding the characteristics of each technique and using these techniques flexibly is essential, but the ultrasound-guided technique should be the standard approach [6,7,10,12].

Ultrasound-guided punctures have been reported to have higher technical success rates, improved secondary outcomes, and lower numbers of punctures and puncture times compared to percutaneous approaches using anatomical landmarks and palpation, although the primary outcomes were not significantly different [6,7,10]. In addition, there are some reports that access-related complications such as bleeding and hematoma are low and others that there is no difference, and no definite opinion has been obtained [6,7,12–19]. However, emergency arterial access is particularly challenging due to several factors. Due to the urgency, there is little time available for the ultrasound anatomical assessment, preparation, and performance of the procedure. Once the pulse is lost, vasoconstriction and loss of pulse make it difficult to identify the artery and confirm it with the ultrasound. In

the case of cardiac arrest, chest compressions can result in significant torso movement, making it even more difficult. Patients with hematomas, edema, or obesity may have anatomical changes that interfere with ultrasound visualization. The presence of atherosclerosis or other abnormalities also makes the technique more difficult [4]. A study regarding emergency femoral access for REBOA demonstrated no difference in overall complication rates, incidence of specific complications, and relative risk of complications between echo-guided puncture and blind percutaneous approaches in non-compressible torso hemorrhage (NCTH) patients with shock requiring REBOA [20]. In addition, comparisons of arterial access methods concerning the time factor have revealed no significant differences between percutaneous and surgical cutdown approaches or ultrasound-guided percutaneous access versus blind access [20–22]. In a study on emergency femoral access for REBOA, the results showed that for arterial access in hypotensive NCTH patients requiring REBOA, a percutaneous approach using anatomical landmarks and palpation was used more frequently without increased complications, access attempts, and mortality compared to ultrasound-guided femoral artery access [20].

TIMING OF OBTAINING ARTERIAL ACCESS

After the decision to use REBOA has been made, it still takes at least several minutes to occlude the aorta because procedures such as obtaining an arterial access, inserting the REBOA catheter, and inflating the balloon are to be performed. Therefore, if you recognize any possibility that the patient might require the use of REBOA (which should happen much earlier than the actual decision to use REBOA), you must start the preparation for the procedure as early as possible [1–3,23,24].

Obtaining arterial access is the first and most critical step of the REBOA procedure. In patients with hemorrhagic shock, the femoral artery becomes unpalpable and the lumen of the vessel becomes narrowed [1]. The complication rate of vessel injuries and puncture-site hematoma increases because the technical difficulty of the puncture becomes more challenging. It has been reported that the survival rate decreases by 10% as the time to obtain an arterial access is delayed by 10 min; therefore, early arterial access is essential [1]. The following situations are reasonable indications for early arterial access in trauma: shock, positive Focused Assessment with Sonography for Trauma, suspicion of pelvic fracture, and multiple trauma. Early arterial access would also be helpful in trauma patients when the cause of shock was unclear at first but turned out to be retroperitoneal hemorrhage or, in non-traumatic patients, intrinsic intra-abdominal hemorrhage [1–3,23,24].

When obtaining arterial access in the early stages of trauma care, it may still be uncertain whether REBOA using an 18-G arterial line or small sheaths (4 Fr/5 Fr) is

sufficient. The decision to obtain arterial access and the decision to use REBOA should be made separately. Indications for obtaining arterial access should be much broader than indications for initiating REBOA. Using small sheaths as initial access is more common and preferable than using larger profile sheaths compatible with REBOA. As mentioned above, sheaths inserted in the early stages can be used for monitoring invasive hemodynamic, conducting blood tests, and identifying access routes for other endovascular procedures [24]. After the decision has been made to use REBOA for aortic occlusion, the sheath should be upsized to a larger sheath size that supports the insertion of REBOA [13].

In addition, the size of the guidewires packed in the product must be paid attention to. The guidewire size varies among products; some are packed with 0.025-inch guidewires (Rescue Balloon®) and some are packed with 0.035-inch guidewires (Block Balloon®). The guidewire may not pass through the sheath or catheter because of the difference in size. To avoid unnecessary trouble during an emergency procedure, the specifications of the REBOA product going to be used must be known beforehand. In particular, Rescue Balloon® has three different guidewires: 0.035-inch guidewire for sheath insertion, 0.025-inch 145-cm guidewire for femoral artery approach, and 0.025-inch 240-cm guidewire for brachial artery approach.

PRACTICE OF ULTRASOUND-GUIDED PUNCTURE

Preparation

Our recommended items for ultrasound-guided arterial puncture

The items presented here are those we recommend, but some items may be obviated in the event of a time-sensitive emergency arterial access situation.

- Sheath introducer set (4 Fr or 5 Fr)
- Syringe
- Saline or heparinized saline
- Suture kit
- Local anesthesia
- Gauze
- Large surgical drape
- Ultrasound equipment
- Sterile ultrasonic probe cover

Priming Procedure (Figure 1)

- (1) Open the stopcock
- (2) Flush the sheath introducer (outer cannula) at will with the saline
- (3) Close the stopcock
- (4) Insert the dilator (inner cannula) into the sheath introducer (outer cannula)
- (5) Flush the dilator (inner cannula) with saline

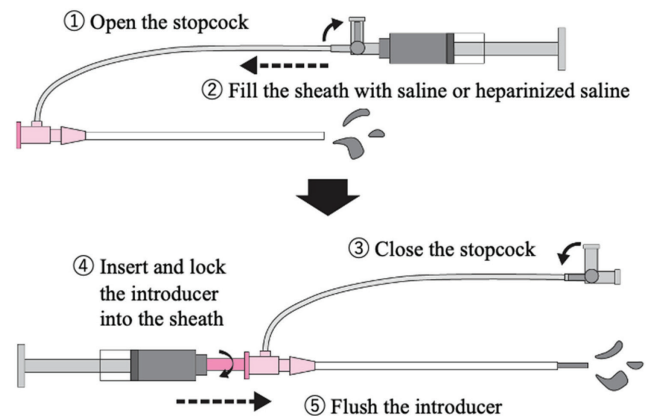


Figure 1 Priming procedure of the sheath.

In the most urgent setting, flushing with saline may be omitted before puncture. The lumen of the sheath introducer will fill with the backflow of the blood and then be flushed with saline.

Puncture Site

The common femoral artery (CFA), brachial artery, and radial artery are used as arterial accesses. In emergency situations, the CFA is commonly selected for several reasons:

- (1) Easy to palpate and puncture because of the anatomical location and size.
- (2) Manual compression is achieved easily with the femoral head.
- (3) The risk of erroneous puncturing is relatively low because the arteries and veins are located in parallel.
- (4) May reduce the risk of occlusion due to dissection or spasm.

Simultaneous bilateral femoral access can be considered according to the hemodynamics or subsequent procedures (REBOA, interventional radiology, surgery). The CFA branches into the superficial femoral artery (SFA) and deep femoral artery (DFA). Arterial access must be obtained from the CFA (above the bifurcation). The CFA is found just medial to the midpoint of the inguinal ligament (halfway between the pubic symphysis and the anterior superior iliac spine) in the inguinal crease region [25–28]. When fluoroscopy is available, puncture occurs between the center and one-third level of the femoral head [11]. The CFA and common femoral vein (CFV) do not completely overlap at the level of the inguinal ligament, with the CFA located lateral to the CFV (Figure 2a). As these vessels move toward the lower extremity, the CFV is positioned dorsal to the CFA (Figure 2b), and at the level of the sartorius muscle, the CFA completely lies on top of the CFV (Figure 2c). Therefore, when puncturing at this level, care should be taken because the CFA is collapsed during shock or cardiac arrest, and the needle may penetrate the anterior and posterior walls of the

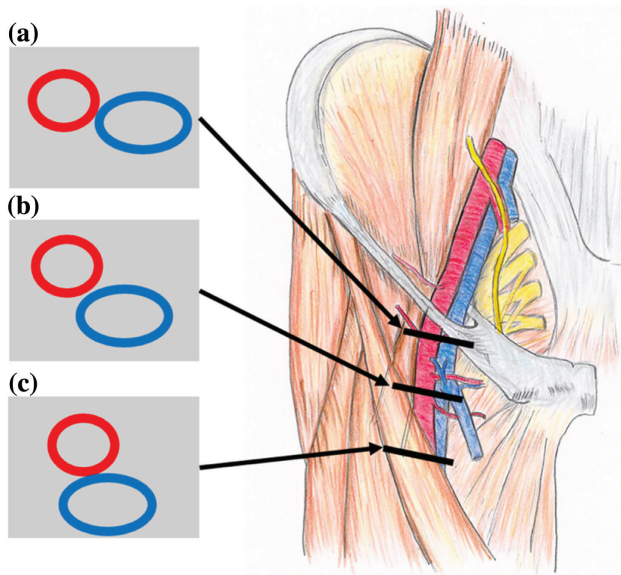


Figure 2 The relative position of CFA and CFV.

CFA and enter the CMV. Because of the above, there is strong support today for the use of ultrasound to visualize the vessel and obtain vascular access to increase success rates and reduce complications. Ultrasound-guided puncture is also strongly recommended for time-critical CFA or CFV access, and we consider it to be of paramount importance for success.

The risk of performing a high-level puncture is intra-abdominal puncture or peritoneal or retroperitoneal hematoma [24,29–34]. On the other hand, a low-level puncture may result in SFA puncture, guidewire migration to the DFA via the SFA, and arteriovenous puncture [24,29–31]. In addition, large-bore arterial access in the SFA could result in leg ischemia. The external landmarks are shown in Figure 3.

In obese patients, the inguinal ligament is located on the cranial side of the inguinal skin crease. It should be noted that obese patients have a more cephalad location of the inguinal ligament and CFA than expected compared to non-obese patients [4]. Therefore, the inguinal

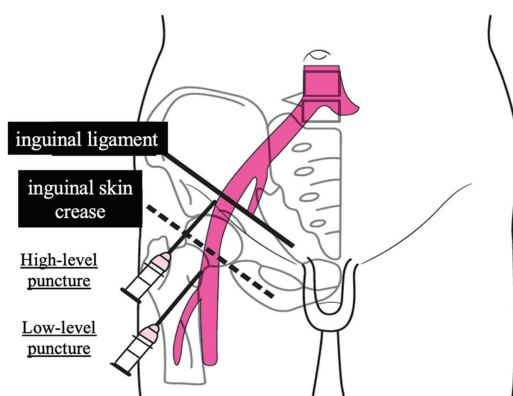


Figure 3 Landmark of the body surface at the time of puncture.

ligament should be identified with the pubic symphysis and the anterior superior iliac spine. Furthermore, in obese patients, the distance from the skin to the artery may be very long, and when an echo is performed, it may be difficult to identify the femoral artery within the range of the echo screen. In such cases, the cutdown method described below can be used in combination to reduce the distance from the echo probe to the artery, making identification of the artery on the echo easier [4]. The SFA may be the most palpable if the bifurcation of the CFA is high-level [32,33]. If the puncture position is determined only by the inguinal skin crease or palpation, the position may be inappropriate (often too low). Confirm the puncture site with fluoroscopy (femoral head) or ultrasound (bifurcation) guidance to avoid misplacement [18,29,35,36].

During severe hemorrhagic shock, when a cardiac arrest or the cardiac arrest is imminent, the femoral artery is vasoconstricting and its diameter is smaller than during normotension, making it difficult to obtain arterial access. In addition, in the state of cardiac arrest, the arterial and venous pressure waveforms are the same due to chest compressions for cardiopulmonary resuscitation (CPR), making it difficult to distinguish them reliably. In addition, when normal arterial pressure is lost, the arteries tend to collapse due to surface compression by the echo probe. Furthermore, the movements and vibrations induced by CPR make not only ultrasound imaging but also puncture and access to the artery difficult [4].

Procedure

There are two types of techniques for ultrasound-guided puncture: short-axis (SA) puncture and long-axis (LA) puncture [37–42].

Short-axis puncture

In the SA puncture method, a probe is applied perpendicularly to the artery to create a short-axis view. With this method, the center of the anterior wall of the artery can be confirmed at the moment of puncture (Figure 4). Therefore, the SA method is preferred as the first choice for an emergency. It is the only possible choice in the case of non-flat skin (obesity) or insufficient space for LA placement (pediatric case or short neck). Because this method does not provide the entire length of the puncture path on a single scanning plane, the operator needs to continue capturing the needle tip according to the advance of the needle [37–42].

To securely capture the needle tip, the probe should be located slightly anterior to the puncture site. Imagine that the needle tip enters the scanning plane. The needle tip should be recognized before the tip reaches the anterior wall of the artery and then the probe should be tilted (alternatively, slide the probe forward) until the tip disappears from the screen. As the needle is advanced slowly,

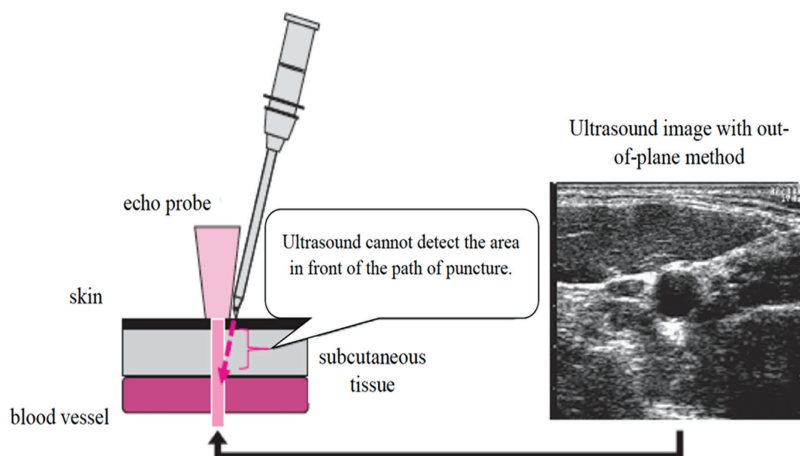
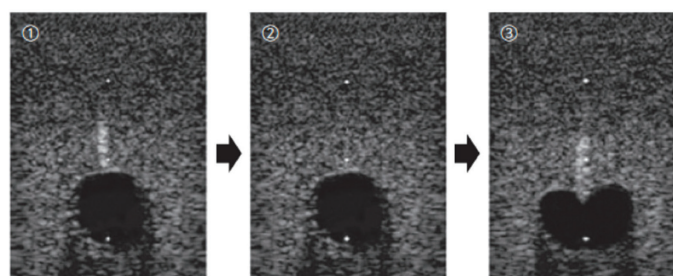


Figure 4 Short-axis puncture (out-of-plane method).



① The needle tip appears from the middle. ② Disappear the needle tip from the screen once (by tilting or moving the probe forward). ③ When the puncture needle is advanced again, the needle tip appears on the anterior wall of the vessel.

Figure 5 Needle tip visualization in short-axis puncture.

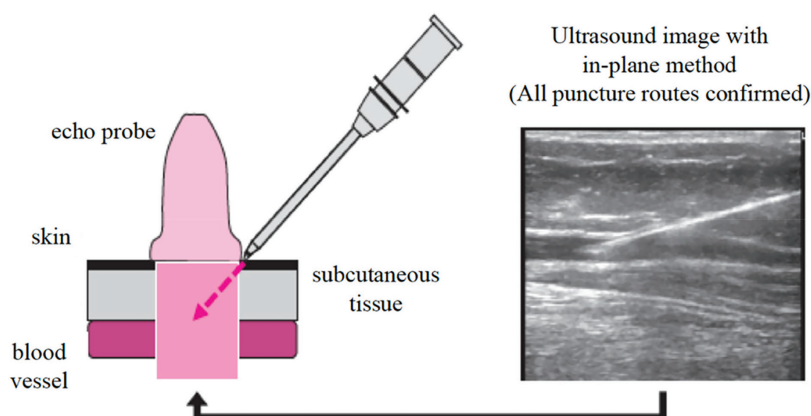


Figure 6 Long-axis puncture (in-plane method).

the tip appears again. These processes are repeated until the tip arrives at the anterior wall (Figure 5) [37–42].

Long-axis puncture

In the LA puncture method, a probe is inserted parallel to and immediately above the artery to create a LA view (Figure 6). This method provides the entire puncture route on a single scanning plane. Since this method does

not visualize the center of the anterior wall (unlike the SA puncture method), it concentrates on keeping the probe on the centerline of the artery (Figure 7). The needle guide helps avoid deviation from the puncture route [37–42].

Advantages and Disadvantages of Both Methods

LA punctures can help visualize the entire puncture route, but the probe must be maintained parallel to the

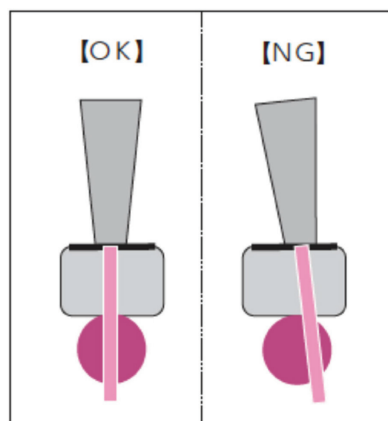


Figure 7 Schema of drawing from the center of a blood vessel with ultrasound guidance (long-axis puncture).

artery. In contrast, SA punctures help visualize the needle tip and the center of the artery. However, the probe must be constantly adjusted (tilted or slid) to recognize the needle tip because the entire puncture route cannot be visualized on a single plane. The advantages and disadvantages of each technique described above must be understood [37–42].

In both methods, we comprehend how and where the arteries run. The three-dimensional anatomy and depth of the target artery via a pre-scan (sweep scan and swing scan technique) should be recognized. After confirming the bifurcation of the CFA to the SFA and DFA, puncture the CFA, the segment cephalad to the bifurcation; sterilize the access area; and provide local anesthesia, as needed [37–42].

We investigated whether emergency arterial access was obtained by the LA or SA method in 15 emergency hospitals and emergency centers in Japan in 2021, and it was revealed that 1 institution performed LA punctures and 14 institutions performed SA punctures.

In addition, we performed a literature search in comparing LA puncture versus SA puncture in vascular access. As a result, there was no significant difference in first-pass success rate, mean time to success, mean number of attempts to success, or hematoma incidence

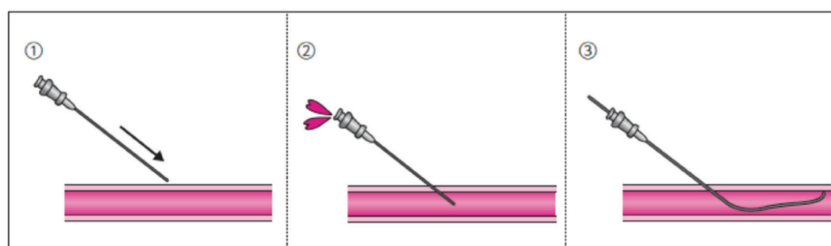
between LA and SA punctures in overall vascular access [43,44]. As far as we could search, there were no studies limited to emergency arterial access to the femoral artery in adults comparing LA and SA punctures. In a study of pediatric femoral artery access, the initial puncture success rate was significantly higher for LA, the mean time to successful initial puncture and total catheter insertion time were significantly shorter for LA, and complications were not significantly different [42]. In addition, there were reports of higher success rates, shorter cannulation times, and significantly less posterior wall damage with LA punctures and no difference in radial artery access [45–47]. Regarding venous line access, there are some reports that SA puncture has a higher success rate than LA, others that there is no significant difference, and others that LA puncture has a lower complication rate and fewer punctures [39,48,49]. Therefore, there is no clear consensus on which is superior.

CATHETER (SHEATH) INSERTION PROCEDURE

Puncture with Puncture Needle and Check for the Backflow of Blood

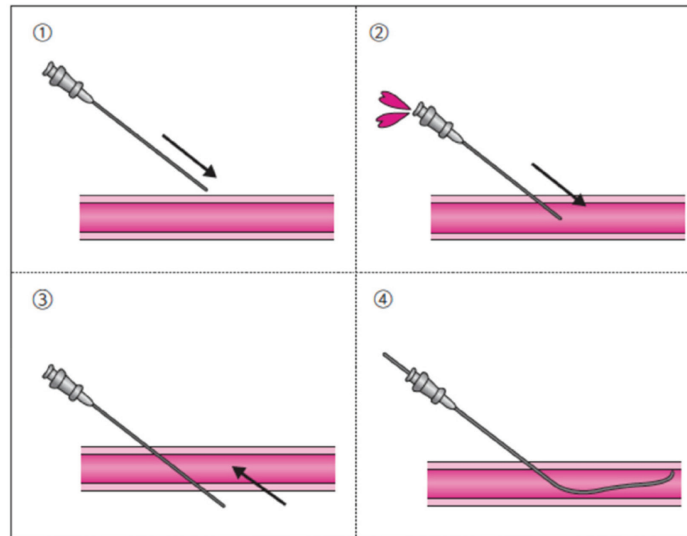
Single-wall puncture method

In this method, the needle is advanced into the lumen of the vessel by penetrating only the anterior wall. The guidewire is advanced while holding the needle when the backflow of blood is confirmed (Figure 8). This method is advantageous for patients with coagulation disorders, including those on anticoagulant or antiplatelet medications. It does not involve a puncture of the posterior wall and thus does not form a hematoma behind the posterior wall. The outer tube must also be firmly inside the blood vessel when using a puncture needle with an inner and outer tube. If the momentum of the backflow is insufficient after removal of the inner tube (similar to a metal needle), the needle tip may not have entered the artery. When only a slow backflow is observed, the needle tip may be within the anterior wall. There is a risk of arterial dissection or extravascular implantation if the guidewire is advanced in this condition [34,50].



① Advance the needle into the lumen of the vessel, ② when it is confirmed that the tip of the needle has entered the lumen of the vessel, ③ advance the guidewire.

Figure 8 Schema diagram of the single-wall puncture.



① Advance the puncture needle, ② when confirming back flow of the blood, advance the needle further to penetrate the posterior wall, ③ after penetrating the posterior wall, pull the puncture needle, ④ when confirming back flow of the blood, insert and proceed the guidewire

Figure 9 Schema diagram of the double-wall puncture.

In addition, using a small-diameter puncture needle (e.g., micropuncture kit) makes it easier to puncture the anterior wall because of the minor collapse of the lumen by the puncture pressure. The micropuncture kit generates slow backflow, even when placed correctly. In addition, the small-profile guidewire does not provide “unpleasant” resistance when the wire is advanced in the dissection or extravascularly. Thus providers may feel it is challenging to recognize the difference between correct and incorrect placement.

Furthermore, in patients with hemorrhagic shock, vessel diameter changes are smaller. The lumen collapses more easily under puncture pressure. As a result, a single-wall puncture may become challenging and unreliable.

Double-wall puncture method

In the double-wall puncture, the puncture needle is first advanced into the lumen, which is confirmed by the backflow; then, the needle is advanced further until the backflow disappears. Next, the inner tube is removed in the case of a puncture needle with an inner and outer tube. Furthermore, the outer tube is pulled out slowly while lying down until the backflow is reliably observed. Finally, the guidewire is advanced while the backflow is maintained (Figure 9) [34,50].

The double-wall puncture method confirms the backflow of blood by applying a pulling force, unlike a pushing force in the single-wall puncture method, and the lumen can be captured more reliably. Therefore, the double-wall puncture is more effective than the single-wall puncture if the puncture needle is placed securely in

the blood vessel. The risk of posterior hematoma is usually negligible. The high-level puncture should be avoided; otherwise, the retroperitoneal hematoma may spread owing to ineffective compression.

How to Advance the Guidewire

First, when advancing the guidewire, the hand that grasps the outer tube (or metal needle) should be fixed to the patient and not moved. After confirming the backflow of blood, the outer tube should be held firmly, and the guidewire should be advanced. If fluoroscopy is available, the tip of the guidewire should be checked visually by the operator while simultaneously feeling resistance to advancing.

When the guidewire is inserted correctly, the resistance felt from the guidewire will be minimal. If any resistance is met, particularly at the beginning of guidewire advancement, it is an indication that the tip was not positioned in the vessel. In such a case, the backflow should be rechecked. Particular attention should be paid when micropuncture kits are used. When resistance is felt after advancing the wire smoothly, the wire may have strayed into a branch vessel instead of the correct route of the external iliac artery. This may occur in low-level punctures, especially in obese patients. The angle of the puncture needle becomes steep, and the wire may enter through the SFA to the DFA. The solution is to reinsert the guidewire from the beginning or check the guidewire route using fluoroscopy or portable X-ray. When advancing a guidewire under non-fluoroscopic guidance in an emergency room or resuscitation room, it is essential to

concentrate entirely on the resistance felt on advancing because this cannot be checked in real-time.

Confirmation of guidewire advancement is performed using a combination of fluoroscopy, portable X-ray, and ultrasound. Ultrasound-guided confirmation of the guidewire in the target vessel before dilation is a safe method that is recommended during central venous catheter insertion. The same procedure is also helpful in arterial puncture; however, it recognizes the risk of hematoma at the puncture site. The entire length of cannulation of the outer tube along the guidewire may decrease the hematoma when using an inner/outer tube-type puncture needle.

In addition, during the advanced guidewire procedure, it is sometimes observed that the puncture needle is dislodged from the vessel's lumen. In that case, the entire puncture needle and guidewire system should be removed and the puncture site should be firmly compressed.

How to Advance a Sheath Catheter Using the Over-The-Wire Method

When removing the outer tube of the puncture needle and advancing the catheter sheath, the puncture point is compressed firmly to prevent hematoma formation. When advancing the catheter sheath system into a blood vessel, first ensure that the guidewire is coming out of the back end of the catheter sheath. The catheter sheath is then advanced while grasping the straightened guidewire to prevent it from straying into the blood vessel. When the catheter sheath system is advanced, resistance is always checked with the hand holding the catheter sheath system. If resistance is present, insertion of the catheter sheath should be discontinued. If the catheter sheath is 4 Fr or 5 Fr, a skin incision is often unnecessary. However, if there is resistance in the skin when inserting the catheter sheath, a skin incision facilitates dilatation with a dilator.

Flush the inside of the catheter sheath with saline or heparinized saline and secure it

The catheter sheath should be flushed with saline or heparinized saline and secured to the skin to prevent it from slipping. Since the patient may then be moved to another location, the catheter sheath should be firmly secured to the skin with sutures. In such a case, the catheter sheath and its hub should be sutured and secured to the skin.

Catheter Sheath Management

After obtaining the arterial catheter sheath, flush with saline or heparinized saline. The sheath is then used for REBOA or endovascular treatment etc. When used for bleeding control, avoid flushing with heparinized saline as much as possible. After endovascular treatment is completed or REBOA is no longer needed, it should be

removed as soon as possible due to the risk of thrombosis. For some reason, if the sheath is to be preserved, it should be used as an arterial pressure line or flushed intermittently or continuously with saline or heparinized saline [51–60]. When used as an arterial pressure line or for continuous flushing, it is often administered at 3 ml/h [51–60]. Studies comparing the efficacy of saline and heparinized saline flushes as flush solutions on arterial line patency have shown no difference in patency (or pressure waveform changes), with some reports indicating that the addition of heparin does not reduce the incidence of thrombosis [51–53,55–59,61], and others indicating that saline shortens the life of the arterial line due to occlusion [54,60]. However, when used as an arterial line for a long duration, heparinized saline has been reported to have better patency, lower flush frequency, and no side effects such as heparin-induced thrombocytopenia (HIT) [51]. Studies comparing continuous versus intermittent flushing of arterial lines have, as far as we have been able to investigate, been performed in transfemoral cerebral angiography, and there were no significant differences in the development of new embolic signals between the groups [62].

In conclusion, it is advisable to remove arterial sheath catheters as soon as possible, but if the sheath is left in place, intermittent or continuous saline flushing may be sufficient for a short period of time. However, if the sheath is to be used for a long-term period, such as a continuous arterial pressure line, it is recommended that heparinized saline be used.

CUTDOWN

Indication

In the case of obesity and thick, soft tissues, for example, it is technically challenging to perform ultrasound-guided puncture and the blind method while palpating the femoral artery pulse. Differences in the proficiency of the ultrasound-guided puncture technique itself may occur among practitioners. The cutdown method also requires a certain level of proficiency in surgical techniques, and individual differences in proficiency among practitioners may occur. The operator should not hesitate to use the cutdown method if the operator determines that it can be faster or more reliable than an ultrasound-guided puncture. There are no absolute indications for the cutdown method of securing the artery, but rather relative indications based on the patient's condition and the surgeon's skill level. Specifically, the following are typical scenarios that require cutdown procedures: both femoral arteries are punctured several times, but the artery is not hit; failure to identify the femoral artery by ultrasound guidance due to puncture-induced hematoma or obesity; and inability to puncture for a long time. When an operator is proficient in the cutdown, the method should change at the scene [4,8,9].

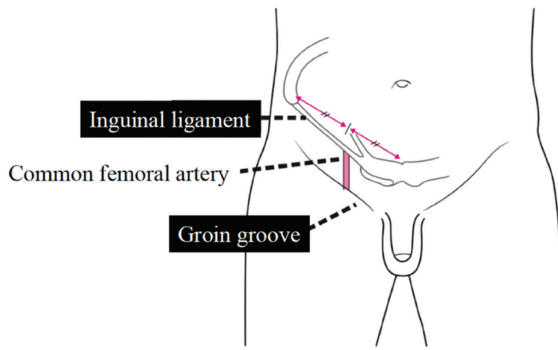


Figure 10 Body surface landmarks during skin incision.

Advantages and Disadvantages

The cutdown method can be more reliable than the ultrasound-guided puncture method if the femoral artery is exposed and punctured under direct vision. It can be performed under local anesthesia. In addition, the technique is such that it can be performed by non-vascular surgeons with appropriate training. The disadvantage is that it may not be as quick as an ultrasound-guided puncture. It can be performed faster with more experience but requires more surgical training than other methods. It is recommended that cutdown items be set up in advance to save time. Since this is a surgical procedure, there is a risk of bleeding, infection, and secondary injuries. When securing the femoral artery by puncture is challenging, the femoral artery is sometimes exposed to cutdown. The catheter sheath is obtained by the direct puncture method, which requires time for fixation and wound closure after catheter sheath placement. For fixation, puncturing the blood vessel after penetrating the skin with a puncture needle provides better fixation after inserting the catheter sheath [4,8,9,63,64].

Anatomy and Landmark

Landmark

The landmark of the skin incision is the inguinal ligament. However, the inguinal groove between the abdomen and thigh is sometimes mistakenly thought of as the inguinal ligament, resulting in a skin incision made lower on the extremity than expected. It should be noted that the inguinal ligament is located between the superior anterior iliac spine and the pubic symphysis, and 3–5 cm cephalad of the inguinal groove between the abdomen and thigh (Figure 10) [8,9,11].

Type of skin incision

There are two main skin incision methods for cutdown: oblique and longitudinal incisions. A vertical incision is preferred for emergency cases because it allows the wound to be extended and the surgical field to be developed easily. The oblique incision provides better wound healing after closure and less visible wound scarring than the longitudinal incision. However, it is not suitable for emergency cases because it requires time to expose the blood vessels.

Anatomy of the femoral artery and the pathway to reach the femoral artery

After emerging from the inguinal ligament, the CFA branches posteriorly lateral to the DFA, approximately 4 cm caudal to the SFA (Figure 11). Since it is rare to find a vascular branch in the anterior surface of the CFA, after detachment of the anterior surface of the vessel and incising the vascular sheath, the anterior wall of the vessel is exposed, and the detachment proceeds to cranial and caudal while maintaining that layer. Suppose the detachment proceeds without exposing the anterior wall

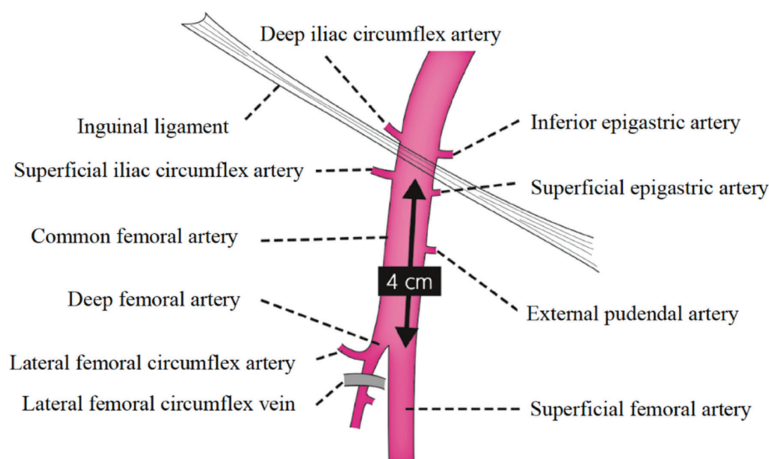


Figure 11 Branch vessels of the CFA.

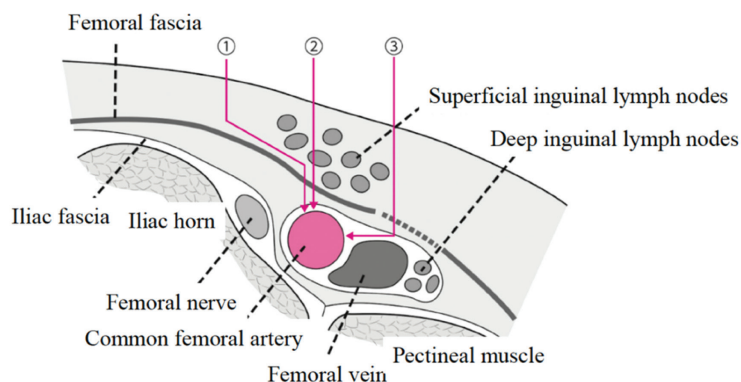


Figure 12 Pathway to reach the vascular sheath.

of the blood vessel. In such cases, it may injure the blood vessel branches and take a long time to detach the vessel, resulting in a delay in securing the blood vessel. Another way to reach the vascular sheath is from the medial or lateral side, avoiding the superficial inguinal lymph nodes in the subcutaneous tissue just above the vessels. However, this is not suitable for emergencies. Reaching the femoral artery vertically at the shortest possible distance from just above the femoral artery pulsation is a shorter exposure time (Figure 12) [26,27,36,65].

Procedure

Skin incision

When palpating the femoral artery pulsation, the skin incision should be assumed directly above the pulsation, longitudinally across the inguinal ligament, one-third to

the head, and two-thirds to the lower extremities. To avoid a lower puncture, a skin incision should be made at a height that exceeds the inguinal ligament. If the pulsation is not palpable, the skin incision should be performed from the midpoint of the superior anterior iliac spine and pubic tubercle to the cranial and caudal, assuming a vertical length of about 10 cm (Figure 13). The area from the lower umbilicus to the knee should be sterilized and covered with a drape, and local anesthesia should be administered to the assumed site. As described above, oblique incisions provide good wound healing. However, in emergency cutdowns, longitudinal incisions are advantageous because of the ease of wound extension and because they run in the same running directions of the blood vessel [4,8,9].

Subcutaneous tissue to the femoral fascia

When the subcutaneous tissue is incised with electrocautery, it reaches the femoral fascia (Figure 14). Subsequently, the superficial abdominal wall arteries and veins and the superficial iliac circumflex arteries and veins may be visible, but in that case, ligation and hemostasis are performed. When the femoral artery is reached

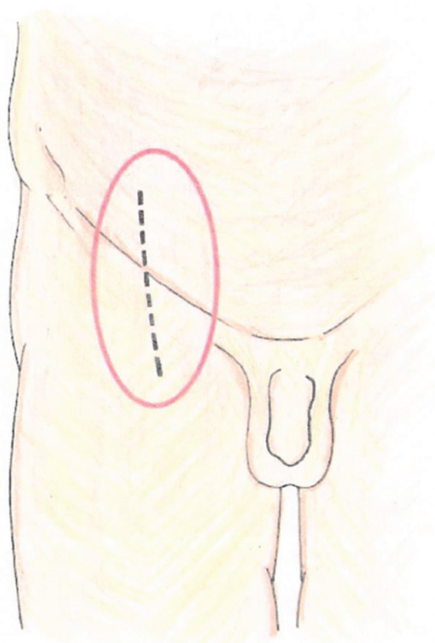


Figure 13 Skin incision.

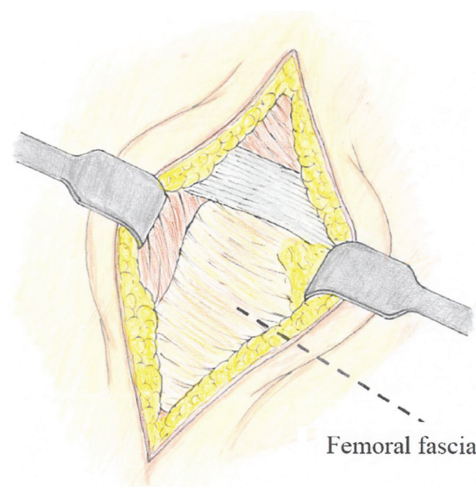


Figure 14 Exposure of the femoral fascia.

at the shortest distance, there are superficial inguinal lymph nodes that should be ligated or electrocauterized as much as possible to avoid postoperative lymphatic fistula or lymphocele. If there is not enough time, it can be performed after securing the catheter sheath. These maneuvers are performed using a wound retractor or a muscle hook by an assistant to expand the wound and develop the surgical field. However, if these preparations are not available and an assistant is not present, the surgeon should spread the wound using the index finger and the middle finger of the left hand [4,8,9].

Exposure of the femoral artery

When the femoral fascia is reached, the pulsation can be felt more clearly than through the skin, and puncture in this state may be an option. In addition, the ultrasound-guided puncture is more reliable in this state and may be helpful in obese patients. Puncture at this stage is advantageous in terms of speed. However, since the puncture is performed without taping the vessel, there is a risk of hematoma formation, persistent bleeding, and inability to perform a second or subsequent puncture if the double puncture method is used because there is not enough tissue around the vessel and compression is not effective. The point is to puncture without advancing the peeling too profoundly.

An incision through the femoral fascia reveals the vascular sheath. When the vascular sheath is incised sharply, the CFA is exposed (Figure 15). Exfoliation of the vascular sheath proceeds to the cephalic and caudal sides. On the caudal side, the bifurcation of the SFA and the DFA is exposed. Once the CFA is exposed, it should be taped and punctured while raising it using traction (Figure 16).

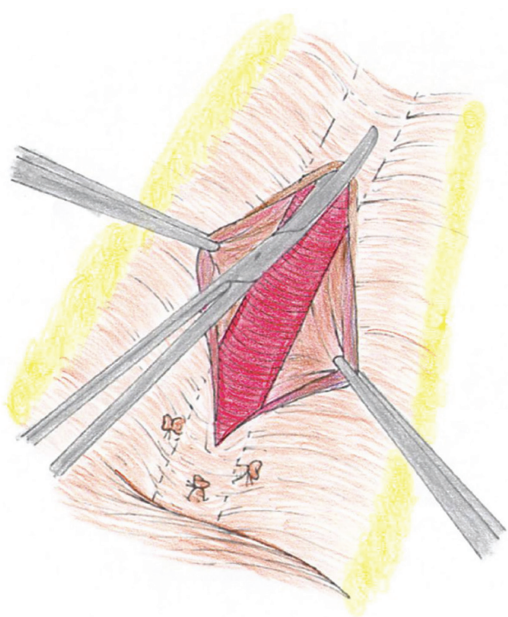


Figure 15 Exposure of the CFA.

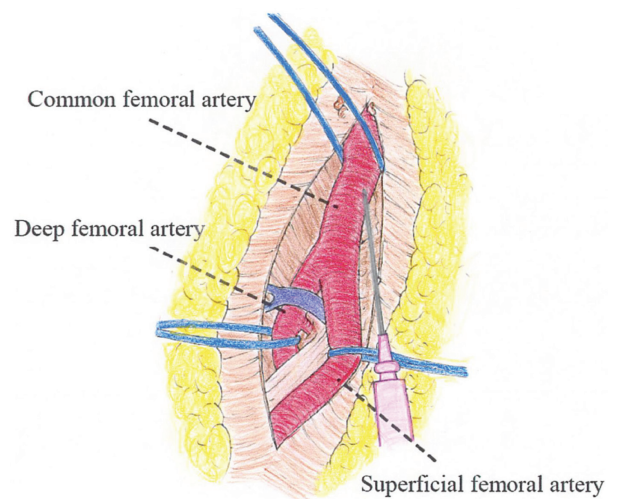


Figure 16 Taping and puncture of the CFA.

This avoids puncture of the posterior wall, facilitates the capture of the vessel lumen, and helps control bleeding in cases of puncture failure. Taping of the SFA and DFA would further ensure bleeding control. However, it may not be a priority in the emergency vascularization phase (taping all vessels is necessary when suturing vessels to remove large sheaths or cannulas). When taping, it is vital to incise the vascular sheath, expose the anterior wall of the artery, exfoliate the posterior wall from both lateral walls, carefully pass behind the posterior wall with vascular detachment forceps, and secure it with taping tape. Forcibly passing the detachment forceps from the outside of the vascular sheath without incising it, unintentionally passing the forceps to the posterior wall of the artery without ensuring that the lateral wall to posterior wall is exfoliated, pushing the forceps directly into the artery despite resistance to the forceps, and carelessly pointing the forceps tip upward without passing the forceps to the opposite side are avoided because they may cause posterior wall damage and branching damage to the artery (especially damage to the DFA), which may take more time and make hemostasis more difficult.

Insertion of the catheter sheath

After the CFA is exposed, the catheter sheath is inserted through the anterior wall of the vessel. The method of inserting the catheter sheath is the same as that for percutaneous insertion. However, suppose that the double-wall puncture method is performed when the artery is completely exposed. In such a case, it will be difficult to control bleeding from the posterior wall of the artery; consequently, this procedure is avoided as much as possible. To prevent bleeding around the insertion site, a purse-string suture is performed with a polypropylene (Prolene®) around the planned insertion site before inserting the catheter sheath, and the suture is ligated or tightened with a tourniquet after insertion of the catheter.

ter sheath. However, these procedures may be performed in emergencies after catheter sheath insertion because there is no time to spare. If the tourniquet is used, the suture can be used directly for ligation and closure of the insertion site when the catheter sheath is removed. Once the catheter sheath is obtained, the REBOA catheter insertion procedure is initiated.

Wound closure and catheter sheath fixation

Since the catheter sheath obtained by cutdown is much easier to dislodge than by percutaneous puncture, it should be firmly secured outside the wound once the wound is temporarily closed. If a Nelaton® catheter is used as a tourniquet, the Nelaton® catheter and mosquito pen are placed in the wound, and the wound is closed with sutures.

When there is a tendency to bleed due to coagulopathy, temporary closure by packing gauze around the sheath and inside the wound is helpful for wound closure. In addition, puncturing the blood vessel after penetrating the skin with a puncture needle during puncture may provide better fixation after sheath placement. This is especially useful when an oblique incision is used [4,8,9].

SUMMARY

The critical first step in establishing REBOA is access to the vessel itself, a time-critical procedure. Access to the femoral artery is the most practical method. Without rapid vascular access, effective REBOA and subsequent hemostasis will be difficult to achieve. Since time-critical REBOA and hemostasis can be lifesaving, the time required for initial vascular access has a significant impact on the outcome. The practitioner should be familiar not only with the anatomy of femoral vascular access, but also with vascular access techniques such as ultrasound-guided percutaneous puncture, femoral vascular cutdown, and sheath catheter insertion.

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

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). None of the other authors have any conflicts of interest to declare.

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Author Contributions

FN was responsible for drafting, editing, and submission of the manuscript. YM critically appraised the manuscript. YM, KY, TS, KI, and TM contributed to the critical revision of the manuscript for important intellectual content and provided intellectual input to the research and manuscript. All authors read and approved the manuscript.

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Techniques for Performing Resuscitative Endovascular Balloon Occlusion of the Aorta

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Although resuscitative endovascular balloon occlusion of the aorta (REBOA) is a useful technique for achieving temporary hemostasis until radical hemostasis is achieved, it is necessary to understand and learn its correct use to avoid complications. The procedure of REBOA preparation, insertion, balloon inflation and deflation, and removal and the key points of the technique at each stage are described in this article. In addition, it expounds on the complications of REBOA and REBOA inflation time.

Keywords: Aortic Zone; Over-the-Guidewire Technique; External Landmark Method; Down Stream Migration; Partial or Intermittent REBOA; REBOA Management (REBOA Controller)

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INTRODUCTION

The use of REBOA catheters is mainly indicated for hemorrhagic shock. Even in hemorrhagic shock, if the bleeding points are in the head and neck region or chest, REBOA is not indicated, and resuscitative thoracotomy of aortic cross-clamping (RTACC) should be chosen. If REBOA is indicated, two people should perform balloon catheter insertion. Even if an operator is experienced, he/she cannot hold the catheter to stabilize its position while inflating the balloon. The operator and assistant must prepare for the insertion procedure on the sterile drape. This article demonstrates each procedural process of REBOA catheter insertion, balloon inflation, balloon deflation, and catheter removal. Commercially available REBOA catheters include wire-required devices and wire-free

devices. The over-the-wire technique reduces the risk of vascular injury due to catheters and is an essential procedure used universally in all endovascular procedures. The wire-free device can be inserted with a simple procedure, but the procedure for a wire-required device is a little more complicated and will be explained with emphasis.

Ethical Approval and Informed Consent

Ethical approval was not required. Written informed consent was not required.

ARTERIAL ACCESS

Early arterial access for trauma patients with hemorrhagic shock can lead to rapid access to REBOA and Interventional Radiology (IR). It has been reported that a 10-minute delay in arterial access reduces the survival rate by 10% [1]. So early access is critical. Arterial access can be divided into three methods: blind method (landmark method), ultrasound-guided method, and cut-down method, but the ultrasound-guided method is the first choice for arterial access, so we will explain how to perform ultrasound-guided arterial access. The sheath used for arterial access is a 4-Fr or 5-Fr sheath.

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ACCESS LOCATION

The femoral, brachial, and radial arteries are all used for access, but the femoral artery is most used in emergencies. The common femoral artery (CFA) branches into the superficial femoral artery (SFA) and the deep femoral artery (DFA), but the CFA should be punctured without fail. The CFA runs slightly medial to the midpoint of the inguinal ligament, between the inguinal ligament and the inguinal groove. If fluoroscopy is available, puncture at the level of the middle to one-third of the head of the femoral bone.

THE METHOD OF PUNCTURE AND SHEATH INSERTION

After confirming by ultrasound that the SFA and the DFA join to form the CFA, the puncture location is determined. After that, the area around the puncture site is disinfected, and local anesthesia is administered. The CFA is visualized in the axial or long axis by ultrasound and punctured. After confirming reversed blood flow, insert the guidewire to the CFA. If there is resistance, the mantle of the needle may not be positioned in the vessel, or it may have strayed into a branch vessel. No resistance will be felt if the guidewire is correctly placed in the vessel. Once the guidewire is inserted correctly, remove the mantle of the puncture needle. Confirm that the guidewire is protruding from the back end of the sheath. Grasp the guidewire to prevent it from straying into the body and place the sheath in the vessel.

FIXING THE SHEATH

The sheath is flushed with saline or heparinized saline, and then the sheath and skin are sutured and fixed.

MATERIALS FOR REBOA DEPLOYMENT

The items required to use the REBOA catheter are shown below:

- REBOA catheter kit (balloon catheter, stylet, suture with needle, needle holder, scalpel, syringe with lock, puncture needle, sheath dilator, guidewire, swab, disinfectant tray, drape)
- Ultrasound or fluoroscopy
- Saline or diluted contrast media: 20–40 ml (for balloon inflation)
- Saline or 5–10 U/min heparinized saline (for flushing the catheter)
- Suturing apparatus.

PREPARATION OF THE BALLOON CATHETER

Prepare the REBOA catheter itself before insertion. For non-fluoroscopic insertion, the landmark method is used to determine the insertion length of the catheter. When inserting under fluoroscopy, it is not necessary to determine the catheter insertion length in advance.

Over-Deflate the Balloon

Connect the empty locking syringe to the three-way stopcock of the balloon lumen and apply negative pressure to remove the air from the balloon (Figure 1). Test dilation of the balloon before insertion should never be performed as it breaks the neatly folded balloon, resulting in balloon injury.

Flush the Catheter Lumen

After removing the stylet, flush the catheter with heparinized saline (Figure 2). The stylet must be kept sterile

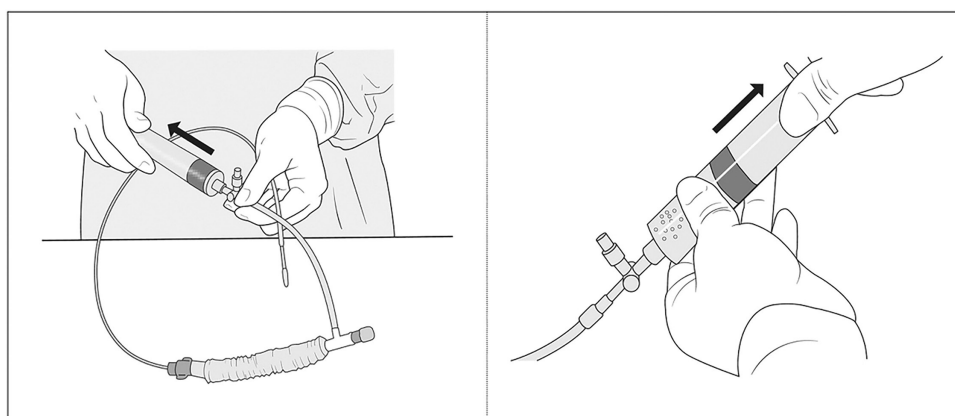


Figure 1 Removal of the air in the balloon. Connect the empty locking syringe to the three-way stopcock of the balloon lumen and apply negative pressure to remove the air in the balloon (do not remove the wrapping).

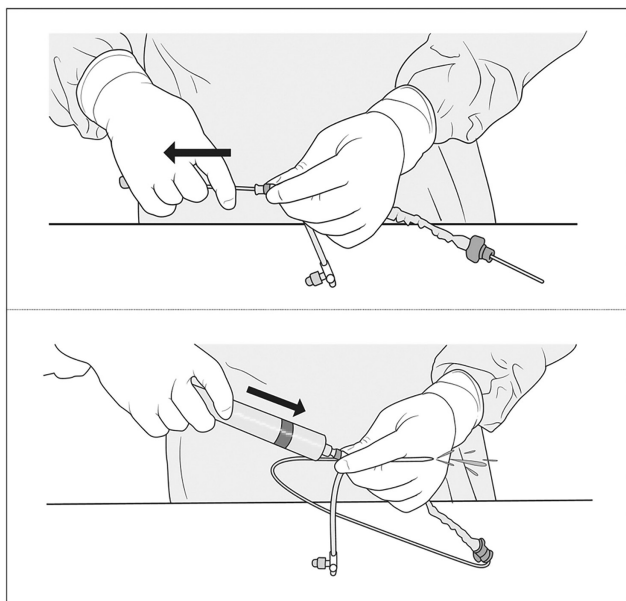


Figure 2 Flushing of the catheter. Remove the stylet once, and flush the catheter lumen.

as it will be used later. Be careful not to drop the stylet on the floor (as is often the case in an emergency).

Plan the Insertion Length

Plan the guidewire and balloon catheter insertion length according to the external landmark method under non-fluoroscopic conditions (Figure 3). The aortic zones are defined as Zones 1, 2, and 3 [2]. The target zone is selected based on the physiological state (hemorrhagic shock and impending cardiac arrest) and the assumed anatomical location of the injuries.

Regardless of the balloon catheter position, the tip of the guidewire should be located at the root of the left subclavian artery, which has the second intercostal space as a landmark. The guidewire tip is placed at the second intercostal space, and the assistant holds the guidewire at the sheath entrance position to measure the distance.

The landmark in Zone 1 is the xiphoid [3], and in Zone 3, the umbilicus. The balloon is placed above the external landmark of the target zone. Higher placement (nipple level) is safer when the zone is targeted because balloon migration occurs after inflation. Note that the balloon, not the catheter tip, should be above the target external landmark when the distance is measured [4]. Do not insert the guidewire or catheter beyond the second intercostal space to avoid straying into or damaging the left subclavian artery or left common carotid artery.

When fluoroscopy is available, pre-insert measurement can be omitted. Recognize the target zone by the vertebrae level and confirm the movement of the wire or catheter.

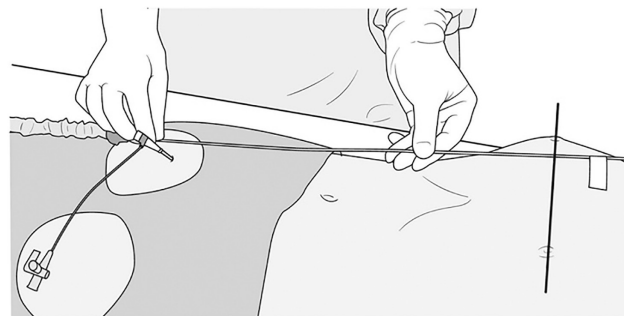


Figure 3 Determination of insertion length with the landmark method.

INSERTION OF THE REBOA CATHETER

Before inserting a REBOA catheter, upsize from a small (4–5 Fr) sheath to a larger (7–10 Fr) using a guidewire. After inserting the guidewire into the sheath for the REBOA catheter, advance the REBOA catheter to the target position using the over-the-guidewire technique. Remove the guidewire, reinsert the stylet to stiffen the shaft, and inflate the balloon.

Secure the Arterial Access and Upsize the Sheath

After securing the small initial (4-Fr or 5-Fr) arterial access, the sheath should be upsized when deciding to use REBOA. Use the appropriate size for the REBOA catheter; a 7-Fr sheath is provided for Rescue Balloon® and Rescue ER (Tokai Medical Products), and 10 Fr is for Block Balloon® (Senko Medical). Insert a guidewire (usually 0.035 inches) into a small short sheath to secure the arterial lumen and then remove the sheath. Then use the over-the-wire technique to upsize the sheath for the REBOA catheter. An oversized (an 8-Fr sheath for a 7-Fr catheter) sheath makes catheter removal through the sheath easier.

Insert the Guidewire

Insert the guidewire through the sheath. If the guidewire is in the artery, there is no resistance. If you feel even a little resistance, the guidewire might have stayed in an arterial branch or outside the vessel. Particular attention should be paid, especially to elderly patients. Never insert the REBOA catheter before confirming the wire in the aorta, even when you have to rush to deploy REBOA as soon as possible. This will avoid further aggravation, by iatrogenic injuries, in a life-threatening condition.

Without fluoroscopy, ultrasound, or radiography, the short sheath can be upsized using a guidewire [5]. When using a Rescue Balloon or Rescue ER catheter, the compatible guidewire is 0.025 inches, smaller than the most commonly used 0.035-inch wire. Recognize the compatibility of the guidewire and catheter before insertion.

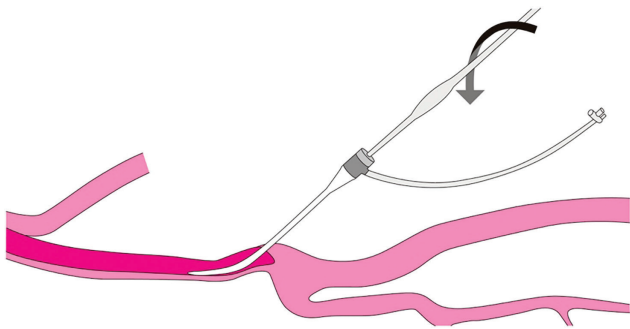


Figure 4 Insertion of the catheter for performing resuscitative endovascular balloon occlusion of the aorta. Insert while rotating clockwise in the sheath.

If it is difficult to insert the guidewire or if it is not possible to confirm the guidewire in the aorta, an approach from the contralateral femoral artery or left brachial artery may be performed at the same time. However, resuscitative thoracotomy with aortic cross-clamping or definitive hemostasis without aortic occlusion should always be considered.

Insert REBOA catheter with Over-the-Guidewire Technique

Remove the stylet from the catheter and flush the lumen with saline. Keep the stylet sterile and never drop it on the floor, even in a hectic resuscitation situation. Insert the guidewire first, followed by the catheter. The guidewire tip always precedes the catheter. These procedures are referred to as the over-the-guidewire technique. The catheter is advanced to the position measured using the external landmark method. Since the balloon wrapping is folded clockwise, rotating the catheter clockwise makes insertion smooth while inserting the REBOA catheter (Figure 4).

Make sure to grasp the end of the guidewire to avoid leaving the entire catheter in the artery. Keep the position of the guidewire tip to avoid staying in the carotid or subclavian artery or cardiac cavity when it is inserted deeply. If the guidewire is unintentionally dislodged, the catheter is more advanced than the guidewire, a risk factor for vascular injury. The operator or the assistant should grasp the guidewire during the entire procedure to ensure reliable guidewire manipulation. This is one of the reasons why a two-person maneuver is recommended. In particular, hydrophilic-coated guidewires require attention because they can be easily dislodged.

Replace the Guidewire with the Stylet

Never inflate the balloon immediately after catheter insertion. This is the biggest pitfall. Remove the guidewire and replace it with the stylet to stiffen the shaft before balloon inflation, preventing downstream migration. (Figure 5) The balloon moves significantly distally,

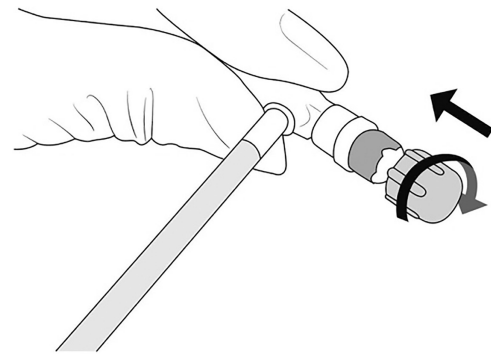


Figure 5 Insertion of the stylet. Before inflation of the balloon, replace the guidewire with a stylet.

especially in the small-profile catheter [6]. If the balloon is inflated without the stylet, the REBOA catheter will bend under arterial pressure. Once the catheter bends, the lumen collapses, and the stylet may not be inserted. If the catheter is bent more severely, it may not be removed from the sheath.

INFLATION OF THE BALLOON AND FIXATION OF THE CATHETER

Inflate a balloon to occlude the aorta. After inflation, the REBOA catheter may migrate, or the sheath may deviate. Fix both the catheter and sheath and the sheath and skin to prevent migration. An exclusive physician (REBOA controller) who is dedicated to monitoring the REBOA should manage the REBOA from the start of inflation to the removal of the catheter.

Inflate the Balloon Safely

With an assistant grasping the sheath and catheter, the operator slowly injects saline (or diluted contrast medium) through the balloon lumen. The three-way stopcock is locked when the inflation balloon volume reaches the target. There are three methods for determining the injection volume: 1) inflate until the tactile feedback is met; 2) observe the proximal arterial pressure; 3) the distal arterial pressure disappears [7]. The proximal pressure is usually measured in the radial artery. The distal pressure can be measured through the contralateral sheath or the side port of the oversized sheath. Balloon overinflation may cause iatrogenic aortic injuries. Distal pressure measurements can decrease the risk of overinflation [8].

Suppose that the operator inserts the REBOA catheter alone. An experienced operator may be able to grasp both the catheter and sheath with the left hand while inflating the balloon with the right hand. However, a third hand is required when it is time to lock the stopcock. Hence, an assistant is essential during the procedure.

Fix the Catheter and Sheath to Avoid Migration

After the three-way stopcock is locked, the sheath and catheter are secured. After balloon inflation, the catheter is subjected to aortic pressure. If the catheter itself is not secured, it exits the sheath. Fix both the catheter and sheath and the sheath and skin to prevent migration. Suture or adhesive tape should be used for secure fixation. The tape may be better as a temporary fixation, considering possible correction of the balloon catheter after radiography or fluoroscopy.

Tips for the Management of Balloon Inflation

Liquid for the balloon injection

The preferred liquid to be injected into the REBOA balloon is saline or a two-fold diluted iodine contrast medium. The visibility of the balloon with fluoroscopy is much better when using a contrast medium. On the other hand, the contrast may make it difficult to remove the catheter through the sheath because of incomplete deflation due to its viscosity. The undiluted contrast medium makes balloon images too dense with fluoroscopy.

Occlusion time

Balloon inflation should be performed immediately if the patient is in hemorrhagic shock that requires REBOA. The delayed decision for REBOA may induce hemodynamic collapse and cardiac arrest. Immediate definitive hemostasis must be achieved, and the duration of aortic occlusion should be as short as possible. Although there is insufficient evidence, balloon inflation is considered when the systolic blood pressure is below 70 mmHg [1]. Complete Zone1 REBOA should not be used if patients cannot proceed to a hemorrhage control within 15 min. Total occlusion time over 30 min is associated with increased ischemic complication and risk of mortality [9–12]. There is also no sufficient evidence of an acceptable duration of aortic occlusion. As a possible solution to ischemic sequelae, partial or intermittent REBOA is utilized to allow extended occlusion time.

Early definitive hemostasis and shorter aortic occlusion duration should always be considered.

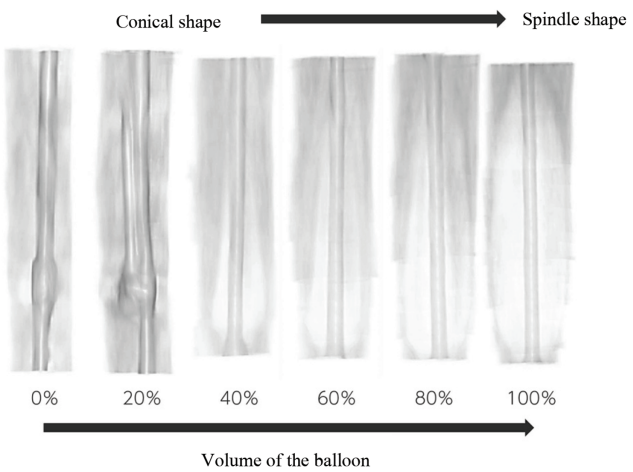


Figure 6 Changes in balloon shape due to balloon inflation volume.

Inflation volume and balloon shape

The relationship between the injection volume and balloon diameter differs depending on the REBOA product used, as shown in Table 1. Therefore, this relationship should be understood in advance. When the balloon is inflated, the balloon first becomes conical. With a further injection, the balloon starts to contact the aortic wall. The aortic occlusion effect increases according to the area of contact with the aortic wall. The balloon shape changes to a spindle shape as the contact area increases (partial REBOA). Finally, inflation results in a complete REBOA (Figure 6) [7]. Thus, the arterial pressure on the proximal side does not necessarily increase in proportion to the balloon injection volume (Figure 7) [7].

Management of the aorta occlusion

If proximal pressure monitoring has already been placed in the radial or brachial artery, the balloon is inflated gradually while checking the response of the pressure elevation. Elevation in proximal arterial pressure can determine sufficient aortic occlusion. The balloon should be inflated while palpating the radial pulse when proximal arterial pressure is not obtained. The contralateral femoral artery pressure can also judge complete occlusion

Table 1 Relationship between inflation volume and balloon diameter/shape.

	Balloon Diameter		
	20 mm	25 mm	30 mm
Inflation volume of the balloon (1)*	10 ml	15 ml	20 ml
Inflation volume of the balloon (2)**	25 ml	35 ml	45 ml

The diameters of the thoracic aortic and abdominal aortic arteries are generally $\phi 25\text{--}30\text{ mm}$ and $\phi 20\text{--}25\text{ mm}$, respectively. In the shock state, the aortic diameter becomes smaller. *Rescue Balloon® (Tokai Medical Products). **Block balloon® (Senko Medical).

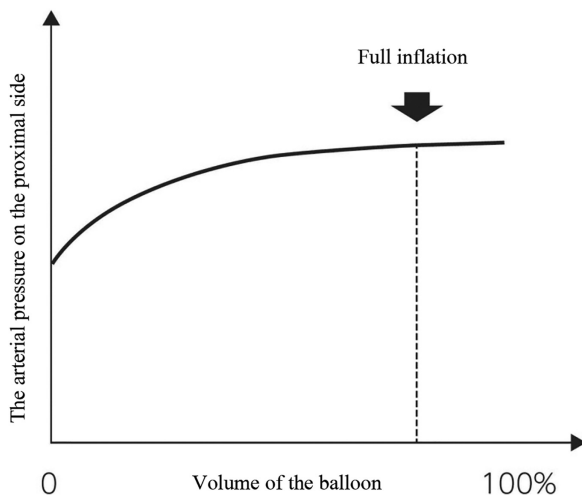


Figure 7 Changes in balloon diameter and proximal arterial pressure with balloon inflation.

when the pulse pressure disappears. When no arterial pressure is available, resistance to contact with the aortic wall is the only way to determine a complete aortic occlusion. However, tactile feedback may be challenging to recognize and is often overinflated. In patients with hemorrhagic shock, a decreased aortic diameter results in complete occlusion with a smaller volume than expected.

DEFLATION OF THE BALLOON

When hemodynamics become stable, consider using partial REBOA to reduce distal ischemia. Once the circulation is stable and definitive hemostasis is achieved, fully deflate the balloon.

Aortic occlusion time with REBOA is preferably as short as possible. When hemodynamics stabilizes and bleeding control is achieved, deflation should be attempted as soon as possible. The balloon inflation volume has to be gradually deflated by 1–2 ml while observing the arterial pressure of the upper limbs. For balloon deflation, cooperation between the physician in charge of REBOA management (REBOA controller), the hemostatic surgeon (interventional radiologist or surgeon), and the anesthesiologist is crucial. The REBOA controller may be a concurrent post as a commander for overall trauma treatment or an anesthesiologist proficient in managing REBOA. However, it may be challenging to serve concurrently as a hemostatic surgeon. The blood pressure always drops during balloon deflation. When balloon deflation occurs, particularly from complete aortic occlusion, the blood pressure often drops sharply because the vascular bed distal from the REBOA increases rapidly even if the blood volume is filled before balloon deflation.

Removal of the REBOA Catheter

If definitive hemostasis is achieved and hemodynamics become stable after complete deflation, remove the

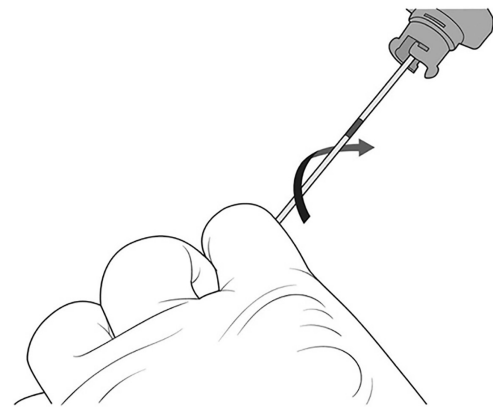


Figure 8 REBOA catheter removal practice. The REBOA catheter can be removed smoothly by turning the entire catheter clockwise while holding the sheath.

REBOA catheter as soon as possible. Consider leaving the catheter when the re-collapse is expected, or a massive transfusion is still required after hemostasis. Keep evaluating the injury and correcting the coagulopathy. Consider the risk of thrombus formation and then remove or leave the catheter.

Through or Together with the Sheath

Removing only the REBOA catheter from the sheath is ideal but not always possible. There is less risk of vascular damage if the catheter can be removed as it exits the sheath. Moreover, it is possible to avoid difficulty in manual compression for achieving hemostasis after sheath removal when the patient's coagulation is not normal.

Further, there is an advantage in that it can be prepared for reinsertion when the patient is in a state of shock again owing to rebleeding. Therefore, we recommend removing the REBOA catheter while leaving the sheath. When removing the Rescue Balloon® and Rescue Balloon®-ER catheter, the 9-Fr sheath is recommended, but empirically, the 8-Fr sheath can be used to remove the catheter safely. In many cases, the REBOA catheter can be removed through a 7-Fr sheath using the following techniques.

Deflate the Balloon Completely

Incomplete deflation of the balloon causes the removal of the REBOA catheter from the sheath to fail. It is vital to aspirate the lumen of the balloon catheter completely. In particular, when a contrast medium is used for balloon inflation, a small amount of contrast medium may remain because of its high consistency.

Remove the Catheter

It is easier to remove the REBOA catheter from the sheath by pressing it and slowly rotating it clockwise (Figure 8). In Rescue Balloon® and Rescue Balloon®-ER,

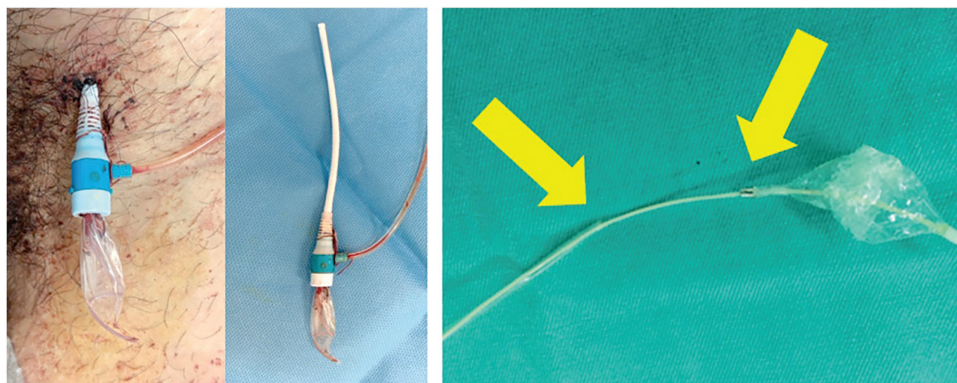


Figure 9 A case of balloon rupture due to forcible removal of the resuscitative endovascular balloon occlusion of the aorta catheter from the sheath. Left, ruptured balloon. Right, balloon damaged during catheter removal, and the end of the balloon moved to the tip (arrows).

the catheter marker can be confirmed when the balloon reaches the tip of the sheath. If there is any resistance at the time of removal, do not forcibly pull it out. This forcible procedure can lead to balloon rupture and damage to the catheter (Figure 9). Not only will the balloon be ruptured, but the shape of the sheath tip will be deformed, making it impossible to remove the REBOA catheter as it leaves the sheath. Therefore, first, if any resistance is present, check if the balloon is sufficiently deflated. Second, return the catheter into the artery, and change the shape of the balloon by inflating it slightly. Then, try to remove the REBOA catheter again using the above method.

Sheath Removal and Hemostasis Achievement

In principle, manual compression is selected for hemostasis in the case of a 7-Fr sheath. The sheath is removed to cause pulsatile bleeding for a moment while the SFA is compressed, and then complete compression is initiated. This process aims to brush away the thrombus around the sheath to not flow into the lower limbs. Consider removing the catheter when hemostasis is completely achieved, and the patient's coagulopathy is corrected. Manual compression should be maintained for approximately 20 min. In contrast, sheaths of ≥ 10 -Fr require compression for ≥ 30 min, and the use of hemostatic devices or surgical procedures can also be considered. Because each hemostatic device has its characteristics for use, manual compression is considered more reliable if the user has little experience with these hemostatic devices.

Follow-up After Catheter Removal for Access-Related Complications

After sheath removal, follow-up should be performed while paying attention to the occurrence of complications such as hematoma at the puncture site, pseudoaneurysm, iatrogenic arteriovenous fistula, and lower

extremity arterial thrombosis. If an arterial branch in the inguinal region was penetrated at the time of REBOA insertion, a large hematoma might expand after sheath removal, which may require endovascular treatment.

In Case of Leaving the REBOA Catheter or the Sheath

A shorter time of aortic occlusion and arterial sheath placement can reduce REBOA-related complications and access-related complications. However, in patients with recurrent unstable hemodynamics due to insufficient hemostasis after complete balloon deflation or those dependent on massive transfusion or anticoagulant therapy, keeping the REBOA catheter indwelling with balloon deflation is possible. If the patient's hemodynamics deteriorate during the night shift when definitive treatment is not available immediately, we can inflate the deflated REBOA again. The long-term indwelling of artificial materials induces a thrombus around the REBOA catheter or the arterial sheath, and this thrombus causes distal embolization, such as lower limb ischemia. Therefore, when we reuse the REBOA catheter, we must consider patient safety and decide on a case-by-case basis, considering the advantages and disadvantages. We have no high-quality evidence for the concrete time when the deflated REBOA catheter can be left in place. If only the REBOA catheter is removed and the arterial sheath is left in place, we can avoid the risk of thrombus around the REBOA catheter. However, because of the risk of clot formation in the lumen of the arterial sheath, the arterial sheath should be used for blood pressure monitoring or continuous flow injection.

COMPLICATIONS

In using REBOA, it is necessary to consider the complications that may occur during each process. The incidence of complications from REBOA use is 3.6–18%, and deaths due to complications have been reported in some cases [13–17].

Complications with Arterial Access

The most common complications are retroperitoneal hematoma and intra-abdominal and retroperitoneal organ injury due to high puncture and mispuncture of SFA and DFA due to low puncture. The mispuncture of SFA may lead to being a risk of lower limb ischemia.

Complications with Insertion of the REBOA Catheter

If the guidewire strays into a branch of the aorta, it may cause branch artery damage, arterial dissection, or extravasation. Even if the guidewire is positioned correctly, the REBOA catheter may not be inserted if there is vascular tortuosity, atherosclerosis, or calcification. If REBOA catheter insertion is impossible, do not hesitate to change tactics. For example, switch to RTACC and so on.

Complication with Position of REBOA Catheter

If the REBOA catheter is positioned between the left subclavian artery and the heart beyond Zone 1, it will block the cerebral arterial flow and cause myocardial damage. Balloon in Zone 2 will cause intestinal ischemia and renal damage due to blockage of blood flow in the abdominal branch. If the REBOA catheter is placed below Zone 3, that is, in the iliac artery, which may cause complete limb ischemia, vascular injury, or rupture of the limb artery. To prevent downstream migration of the catheter, always remember to reinsert the stylet before balloon inflation.

Complication with Balloon Inflation

Since balloon overinflation can cause vascular injury and balloon rupture, it is necessary to avoid the overinflation of the balloon while monitoring blood pressure. Moreover, keep in mind that if the injuries are central than the balloon inflation site, increased arterial pressure on the central side may exacerbate bleeding.

Complication with Balloon Deflation

Deflation of the balloon can lead to rebleeding and ischemia-reperfusion injury. Caution should be exercised because the ischemia-reperfusion injury may cause refractory hypotension, hyperkalemia, and metabolic acidosis [10]. When deflating the balloon, it is essential to monitor the upper extremities' blood pressure and do so slowly and gradually in 1–2 ml increments while using adequate fluids, blood transfusions, and vasopressor.

Complication with Indwelling Sheath

In some cases, patients are admitted to the intensive care unit with the sheath in place to prevent rebleeding after removing the REBOA catheter. Leaving the sheath in

place for a long time may cause vascular embolism or ischemia in the lower limb, which leads to reduction incision for compartment syndrome or thrombectomy for thromboembolism [18,19]. After sheath indwelling, continuous observation of the lower extremity on the side of indwelling is essential to check for ischemia.

CONCLUSIONS

Although REBOA is a valuable technique for controlling bleeding until radical hemostasis is achieved, it is essential to use it appropriately to avoid complications from insertion to removal. We must understand and master the appropriate techniques for REBOA use.

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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

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). None of the other authors have any conflicts of interest to declare.

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Author Contributions

YK was responsible for drafting, editing, and submission of the manuscript. TM critically appraised the manuscript. SS, KR, TM, and YM contributed to the critical revision of the manuscript for important intellectual content and provided intellectual input to the research and manuscript. All authors read and approved the manuscript.

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Present Strategy for REBOA Management After Catheter Placement: A Current Suggestion From the Japanese Society of DIRECT

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Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been accepted as a useful bridging tool to definitive hemostasis in refractory hemorrhagic shock. Although there is insufficient evidence of the target blood pressure under the utilization of REBOA, it may be reasonable to avoid excessive blood pressure elevation. Invasive blood pressure monitoring proximal to the aortic occlusion is desirable during REBOA. The zone of the aorta is selected and changed according to the location of injuries and the physiological conditions. The key to successful REBOA management is to set up an independent REBOA coordinator for systemic management. This review article aims to explain the procedures of proper REBOA management, so as to fill the knowledge gap between educational courses, which highlight the indications and safe procedures of the device, and the critical settings faced in clinical practice.

Keywords: *Resuscitative Endovascular Balloon Occlusion Of The Aorta (REBOA); Trauma; Hemorrhagic Shock; Management*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been accepted as a useful bridging tool to definitive hemostasis in refractory hemorrhagic shock [1–4]. Its use increases the proximal pressure and regulates distal arterial bleeding, while simultaneously inducing visceral organ hypoperfusion and leg ischemia. Although REBOA is a less invasive aortic occlusion method compared with resuscitative thoracotomy, it has a high probability of complications. There have been several reports confirming the negative impact of REBOA from analysis of the trauma database [5–7].

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Teaching of the standard procedures of REBOA have been widespread through educational programs internationally [8,9]. An educational workshop program has been created in each region or country, and the procedure is simple enough for even non-vascular surgeons or non-interventional radiologists to understand. Despite the rapid growth of the REBOA educational program, complications have been observed by inappropriate management during the REBOA placement even though the right procedures have been followed in the right patients.

REBOA is a device for creating a grace period until hemostasis is achieved. The REBOA educational programs mainly highlight the indications and safe procedures of the device. The management of REBOA, such as arterial blood pressure monitoring and the target blood pressure, the selection and alteration of the deployment zone, and the non-technical skills of the multidisciplinary trauma team, have not been focused on or discussed. The purpose of this review article is to explain the proper management of REBOA so as to fill

the knowledge gap between the educational courses and the critical settings faced in clinical practice.

MONITORING ARTERIAL BLOOD PRESSURE

Proximal Arterial Blood Pressure Monitoring

Invasive blood pressure monitoring proximal to the aortic occlusion balloon is desirable during REBOA utilization. In addition to non-invasive blood pressure alone, proximal invasive blood pressure monitoring would allow for more comprehensive management of partial REBOA. In the process of gradual balloon deflation from complete to partial inflation, hemodynamic changes could occur abruptly, and a proximal arterial blood pressure line facilitates a safe transition to partial REBOA. If the proximal arterial blood pressure drops too much, then the balloon volume should be gradually increased again to restore blood pressure to an acceptable level guided by the proximal arterial pressure. If a separate arterial blood pressure line is used, it should be secured as soon as the status of shock is detected, ideally before insertion of REBOA, but it can be done at the same time or in the operating room or the angiography room. Some REBOA catheters have a feature that allows blood pressure measurement by connecting a pressure line, so securing a separate arterial pressure line is not necessary when using these types of catheters. The REBOA catheter balloon volume should be adjusted to maintain appropriate blood pressure during aortic occlusion because the purpose of REBOA is to control distal bleeding, maintain proximal blood circulation, and avoid circulatory collapse until hemostasis is achieved. REBOA adjustment usually refers to the transition from complete aortic occlusion with REBOA to partial REBOA. However, when it is started with partial occlusion and circulation can be maintained, it can also mean adjustment from partial to complete occlusion. If the target blood pressure can be maintained with partial REBOA, the balloon volume should be maintained. If not, the gradual increase of the balloon volume should be performed in order for the appropriate blood pressure to be acquired.

Among trauma patients with hemorrhagic shock, it is generally recommended that excessive blood pressure elevation is avoided prior to completion of hemostasis. [10]. The purpose is to suppress the increase in bleeding by permitting low blood pressure [10–12]. This also prevents dilutive coagulopathy and hypothermia by avoiding over-infusion of extracellular fluid to maintain blood pressure. Table 1 shows the advantages of blood pressure elevation and unsuitable situations when it should be avoided. Avoiding excessive blood pressure elevation decreases the amount of bleeding and blood transfusion, and may also avoid unnecessary aggravation of intracranial, cervical, and thoracic hemorrhages. This concept could be beneficial to the management of those hemorrhages. Meanwhile, severe traumatic brain

Table 1 The advantages of excessive blood pressure elevation and unsuitable situations when it should be avoided.

Advantages	Unsuitable situations
Reduce blood loss	Traumatic brain injury
Reduce overall IV fluid administration	The elderly*
Reduce blood product utilization	
Reduce dilutional coagulopathy	
Avoid hypothermia caused by excessive IV fluid administration	

*Excessive blood pressure elevation should be avoided in the elderly as well, but cerebral perfusion will likely be inadequate compared to younger patients, and setting the target blood pressure too low may be dangerous. IV, intravenous.

injury requires elevated blood pressure to maintain cerebral perfusion pressure [13]. Partial REBOA should be titrated to avoid excessive blood pressure elevation, and intracranial pressure monitoring should give us helpful information to enable the achievement of goal-directed partial REBOA management in hemorrhagic shock cases associated with traumatic brain injury.

For proximal arterial blood pressure monitoring during REBOA, arterial blood pressure lines, such as in the radial and brachial arteries, are secured in the upper limbs. In patients with shock status, successful arterial puncture is a challenge because of collapsed vessels. An arterial blood pressure line is required to manage patients with REBOA; however, the arterial line is only a means of monitoring and not a treatment. Definitive hemostasis should be prioritized rather than taking time to secure a proximal arterial pressure line. When securing a radial arterial pressure line is difficult before surgery or angiography, it should be performed alongside definitive hemostasis by abducting the arm (Figure 1). A non-invasive continuous hemodynamic measurement system is an option; however, it may not demonstrate accurate numerical calculations in severe shock.

Distal Arterial Pressure Monitoring

Distal arterial blood pressure monitoring is not as desirable as proximal monitoring. However, it would be easier to determine a complete occlusion if the distal arterial pressure can be monitored. Partial occlusion is better than complete occlusion for maintaining organ perfusion, such as, for example, in intestinal ischemia in Zone 1 management and lower limb ischemia in Zone 3 management [15]. If organ perfusion, especially intestinal ischemia, is not considered, the prognosis would be poor even if hemostasis is achieved. By measuring the distal blood pressure, we may be able to manage the distal organ perfusion more carefully. However, a quantitative organ perfusion method has not yet been established, and further investigation is needed. The disappearance of the distal pressure after balloon inflation accurately indicates complete occlusion. The method of distal



Figure 1 Ingenuity is needed when it is difficult to secure the invasive arterial pressure monitoring line of the upper limbs. (a) Initiate IR with the patient’s right upper limb extended. (b) During IR, the emergency physician or anesthesiologist in charge of general care continues to secure the invasive arterial pressure monitoring line of the upper limbs.

arterial blood pressure monitoring is as follows: (1) the use of an additional arterial sheath in the contralateral femoral artery (via bilateral femoral arterial access); (2) the use of a side port of an oversized arterial sheath (e.g., 8 Fr or a larger sheath for a 7 Fr REBOA catheter).

HOW TO CHOOSE THE AORTIC ZONES PROPERLY

Differences in balloon placement or zones affect the magnitude of hemodynamic changes and the severity of ischemic intensity during REBOA management.

Zone 1 should be selected if the anatomical location of the assumed injury is intra-abdominal or causes retroperitoneal bleeding, or Zone 3 if it can be localized to the pelvis area (Figure 2). Often, a zone cannot be

selected depending on the situation because REBOA is often used in clinical settings where no prominent bleeding site can be identified or in a physiologically disrupted state on the verge of cardiac arrest [16]. Although Zone 3 is anatomically reasonable for pelvic trauma, direct embolization should be performed instead of Zone 3 REBOA if the patient is not in imminent cardiac arrest and angioembolization is available immediately. Here, it should be recognized that there is a significant difference between Zones 1 and 3 in blood flow and blood pressure increase on the proximal side of the occlusion.

Bayer et al. reported that Zone 1 occlusion caused a significantly higher elevation in systolic blood pressure than Zone 3 occlusion [17]. Therefore, the proper use of zones should be decided upon from an anatomical viewpoint and according to the physiological conditions.

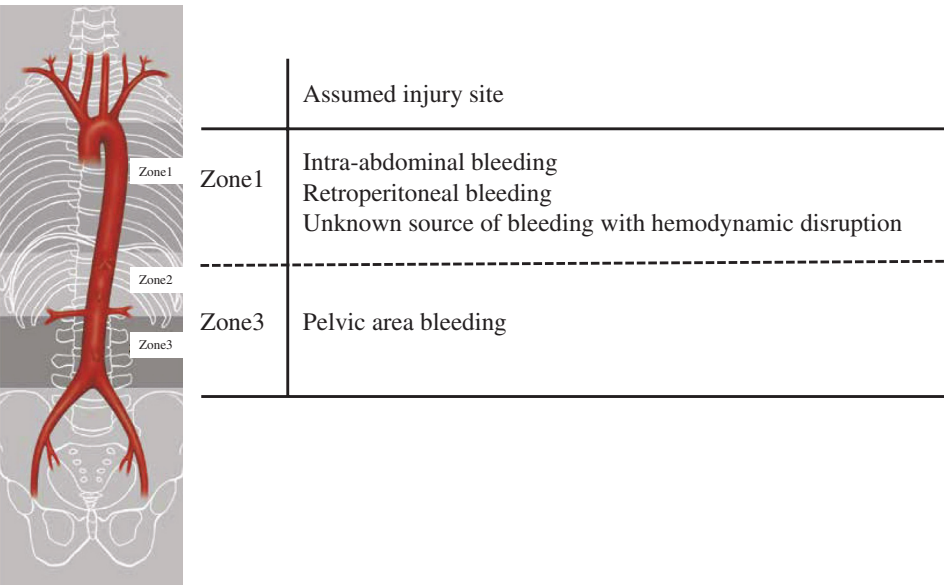


Figure 2 Aortic zone selection according to the injury site. Figure modified from Morrison et al. [14].

For example, if a patient has a single pelvic fracture but has an urgent cardiac arrest, it would be pragmatic and reasonable to choose Zone 1 instead of Zone 3. On the other hand, Zone 1 occlusion causes a wide range of blood reduction and vigorous ischemic intensity in the whole body. The permissible occlusion time is considered to be within 20 to 30 minutes. Moreover, this permissible occlusion time may be less than 20–30 minutes if the patient is in cardiac arrest, because there would have already been a period of time with no blood flow prior to the inflation of the REBOA balloon, which must also be included in the overall ischemia time. Resuscitative thoracotomy should be considered in the cardiac arrest case with chest injury.

REBOA may be contraindicated if the injury is associated with the proximal side of the balloon occlusion. REBOA may cause rapid proximal hypertension and promote bleeding. There are reports of increased bleeding due to head and chest injuries [18,19]. Johnson et al. reported that the use of REBOA did not exacerbate head trauma in a hemorrhagic shock model with head trauma in swine when circulating blood volume was reduced [20]. Bailey et al. also reported intermittent REBOA prolonged the intracranial hypertension after occlusion, using a model of penetrating head trauma with unreduced circulating blood volume [21].

There is no clear evidence that the use of REBOA in patients with proximal injury is associated with improved or worsened outcomes. However, there is no doubt that the use of REBOA in the presence of head, neck, and chest trauma should be carefully selected.

CHANGE OF THE BALLOON POSITION

The position (aortic zone) of the REBOA balloon may be changed. When the injured site is unspecified, and the patient is in impending cardiac arrest, a balloon is tentatively placed in Zone 1. If subsequent X-rays of the chest and pelvis and FAST examination reveal that the injury site is at the pelvic area, the balloon should be moved to Zone 3. In cases where the initial Focused Assessment with Sonography for Trauma (FAST) is negative and the pelvis is injured, the balloon should be placed in Zone 3. When intra-abdominal bleeding increases and FAST

becomes positive, or hemodynamics becomes more unstable, the balloon can be moved to Zone 1 (Figure 3).

Before moving the balloon's position, it is necessary to deflate the balloon in advance. Moving the REBOA catheter without deflation may cause iatrogenic aortic injury and spread mural thrombus resulting in the embolism of the visceral organs and lower extremities.

To move from Zone 1 to Zone 3, the catheter should be pulled to Zone 3 after deflation. However, it is necessary to confirm whether the balloon is precisely located in Zone 3 by fluoroscopy or X-ray. More care must be taken when changing from Zone 3 to Zone 1. There is concern about the cleanliness of reinserting a catheter that is outside the sheath and is no longer sterile. The procedure differs depending on whether the REBOA catheter is a wire-free device.

ER-REBOA™ (PryTime Medical Inc., Boerne, USA) and COBRA-OS™ (FrontLine Medical Technologies Inc. London, Canada) are wire-free devices. As with regular insertion, movement to Zone 1 must be made while paying attention to vascular damage. However, we should be aware of the risks of vascular injuries and the inability to advance the catheter when there is severe aortic tortuosity due to arterial calcification.

Rescue Balloon® (Tokai Medical Products, Aichi, Japan), Rescue Balloon®-ER (Tokai Medical Products, Aichi, Japan), Block Balloon™ (MERA, Tokyo, Japan), REBOA Balloon Kit™ (REBOA Medical, Norway) have a guide wire and are inserted by the over-the-wire technique. If the stylet is inserted, it should be removed once, the guidewire inserted, and the catheter then advanced to Zone 1. When REBOA is placed whilst in the emergency department, the guidewire is often not brought into the operating room. The guidewire may have already been scrapped or placed in an unclean field after implantation. When performing interventional radiology after placement of REBOA whilst in the angiography suite, the catheter may be safely advanced with fluoroscopy. Although not ideal, there may be cases where the catheter is blindly advanced. The risk of vascular injury by the tip of the catheter must be reduced as much as possible. In particular, when using a catheter (Tokai, MERA) that increases the rigidity of the shaft with the stylet, the stylet should be pulled out a few centimeters and the procedure undertaken

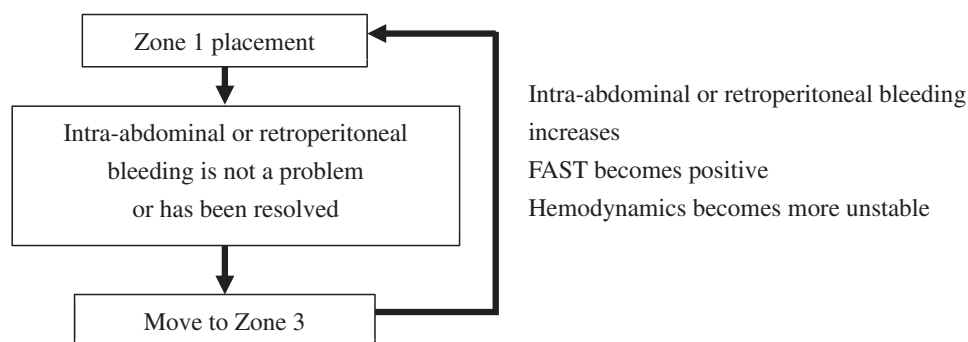


Figure 3 Flowchart of changing aortic zone.

slowly, with attention being paid to the fact that there is no resistance with its advancement.

A SYSTEM-WIDE MULTIDISCIPLINARY APPROACH – THE ROLE OF THE REBOA COORDINATOR

Zakaluzny et al. reported that REBOA was more than a tool or a technique, but rather a system-wide

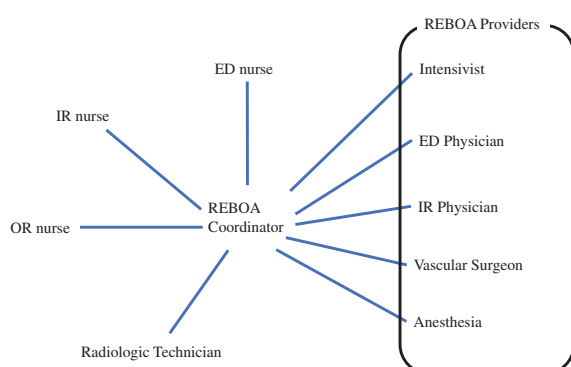


Figure 4 Organizational chart with the REBOA coordinator at the center. The REBOA coordinator can be a concurrent post, but it must not be covered by the operator of the surgery or interventional radiologist. Figure modified from Zakaluzny et al. [22]. OR, Operating Room. IR, Interventional Radiology. ED, Emergency Department.

multidisciplinary approach that spans numerous institutional disciplines and requires a management capability [22]. Specifically, an organizational chart is developed with the REBOA coordinator at the center, as shown in Figure 4, and practical methods are introduced with a checklist (Table 2) for each job and situation. Facilitating the communication of information between job categories and departments through simulations of REBOA insertions and other means will lead to the success of REBOA [23].

The role of the REBOA coordinator includes the following: (1) timekeeping of the occlusion time, (2) adjustment of the balloon in-flows such as partial REBOA and intermittent REBOA, and (3) management with attention to the prevention of REBOA catheter removal and deviation during patient transfer. In addition, the REBOA coordinator should consciously and closely coordinate with the surgical operators, intervention radiologists, and anesthesiologists. The REBOA coordinator can serve as a physician in any specialty as long as he or she understands these essentials. Emergency physicians, anesthesiologists, trauma surgeons, and Interventional Radiology (IVR) physicians are all candidates. The role of the REBOA coordinator is significant because the aim is to shorten the occlusion time and reduce the occlusion intensity. Since the role of this REBOA coordinator requires the ability to make

Table 2 Check list for REBOA implementation (adapted from Zakaluzny et al. [22])

Management Team

- Supervised by the chief of medical staff (the REBOA coordinator)
- Plan a comprehensive nurse-driven and provider supported quality assurance program
- Assure buy-in for additional resources needed in terms of call schedules and other purchases (i.e., fluoroscopy compatible operating room tables, digital X-ray machines)

Establish a core of providers interested and in agreement on implementation

- Adopt an algorithm for REBOA use
- Determine which catheter to use
- Establish plans for femoral artery access and specific devices for kits including hands-on practice to assure compatibility
- Establish what should be in a cut-down tray

Implementation in the Operating Room (OR)

- Establish REBOA kits and assure they are maintained
- Establish cut-down trays and assure they are maintained
- Assure OR fluoroscopy capability including OR beds
- Coordinate educational program with nurse/technicians in the OR

Implementation in the Emergency Department

(1) Meet with critical providers to determine how REBOA will be implemented in resuscitations

- Decide which providers will be gaining access and placing catheters; and assure appropriate training scheduled
- Establish provider roles and responsibilities during a resuscitation if REBOA is being placed, including establishing who will continue the resuscitation

(2) Meet with providers and nurses

- Establish the roles for nurses and radiological staff during REBOA placement
- Confirm the treatment flow (checking the location of REBOA and the treatment procedure) after the start of REBOA

comprehensive judgments for vital signs and surgical field conditions, emergency physicians and anesthesiologists will likely take on this role. It would be desirable to have a dedicated REBOA coordinator, but realistically, there are not usually enough human resources. If the surgical operator or the intervention radiologist is also the REBOA coordinator, the management of REBOA may be neglected, and the occlusion time and intensity may not be sufficiently controlled. Therefore, if there is a shortage of human resources, then it is suggested that staff with a broad perspective, such as the commander of the overall trauma care or the operative assistant as a director, should also serve as the REBOA coordinator.

LIMITATIONS

There is no definite evidence for monitoring arterial pressure or changing the balloon position. The recommendation is mainly based on the expert recommendation of the Japanese Society of Diagnostic and Interventional Radiology in Emergency, Critical Care, and Trauma (DIRECT), which has an extended history regarding REBOA placement or management.

CONCLUSION

In the management of REBOA, invasive blood pressure monitoring proximal to aortic occlusion is desirable, and when securing a radial arterial line is difficult, some ingenuity is required. The zone of the aorta is selected and changed according to the anatomical injury site and physiological conditions. The key to successful REBOA management is to set up an independent REBOA coordinator for systemic management.

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University School of Medicine, Tokyo) and Suguru Hitomi (Saitama Red Cross Hospital, Saitama).

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

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). None of the other authors have any conflicts of interest to declare.

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Author Contributions

YK was responsible for drafting, editing, and submission of the manuscript. TM critically appraised the manuscript. YK, ST, TM, and YM contributed to the critical revision of the manuscript for important intellectual content and provided intellectual input to the research and manuscript. All authors read and approved the manuscript.

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Partial Resuscitative Endovascular Balloon Occlusion of the Aorta and Intermittent Resuscitative Endovascular Balloon Occlusion of the Aorta

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Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a resuscitation procedure for severe hemorrhagic shock. While complete occlusion of the aorta could be effective for the control of blood flow, there is always a concern for ischemia-reperfusion injury of the distal organs from the balloon catheter. REBOA can control the degree of occlusion by changing the injection volume of the balloon catheter. Partial REBOA and intermittent REBOA are some of the strategies of REBOA, with which less ischemia-perfusion injury is done, rather than complete occlusion of the aorta, although evidence on partial REBOA and intermittent REBOA is still limited. This review aims to share the practical knowledge of partial REBOA and intermittent REBOA, thorough the current literature and Japanese multi-specialty expert consensus.

Keywords: *Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA); Partial REBOA; Intermittent REBOA*

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INTRODUCTION

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is not a hemostatic device [1,2]. It provides time until definitive hemostasis while avoiding cardiac arrest and stabilizing the hemodynamic state. Compared to resuscitative thoracotomy with cross-clamp, REBOA can control the degree of occlusion. Total occlusion of the aorta always has a concern for ischemia-reperfusion injury of the distal organs from the balloon catheter. Partial REBOA and intermittent REBOA are the strategies of the REBOA with which less ischemia-perfusion may be feasible.

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Zone 1 total occlusion may be needed in some critical situations; however, partial REBOA or intermittent REBOA with rapid and sufficient transfusion and immediate hemostasis could maintain hemodynamic stability and organ perfusion.

This review aims to share the practical knowledge of partial REBOA and intermittent REBOA, thorough the current literature and multi-specialty expert consensus in the Japanese Society of Diagnostic Interventional Radiology in Emergency, Critical care and Trauma.

Ethical Approval and Informed Consent

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

PARTIAL REBOA

REBOA can control the degree of occlusion by changing the injection volume of the balloon catheter. Partial REBOA is one of the strategies of REBOA, in which the distal blood flow of the balloon is conserved and the

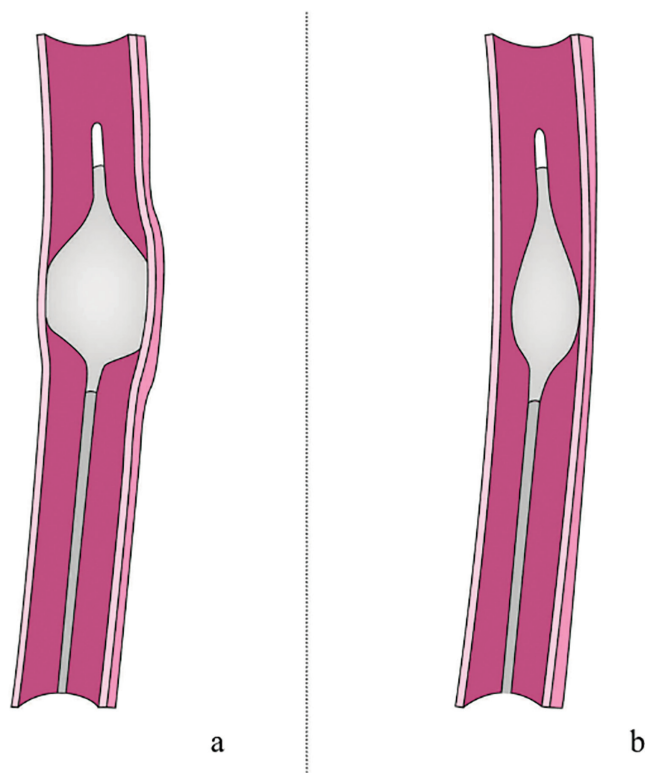


Figure 1 The schema of partial REBOA and total occlusion of the aorta. **(a)** In the situation of complete occlusion of the aorta, distal blood flow is restricted and ischemia-reperfusion injury is concerned. **(b)** Partial REBOA is able to maintain the distal blood flow of the balloon within the range of proximal perfusion kept.

range of proximal perfusion maintained (Figure 1) [3]. Partial REBOA could decrease ischemia-reperfusion injury because it could maintain the distal blood flow of the balloon and reduce ischemia of the intestine, liver, kidneys, and lower limbs [3,4]. Partial REBOA also achieves a mild change in blood pressure at the proximal side of the balloon and makes it possible to maintain continuous permissive hypotension [5]. In contrast, complete occlusion of the aorta could lead to proximal hypertension and increase the hemorrhage at the proximal side of the balloon [6]. Recently, studies concerning the effectiveness of partial REBOA have been increasingly published [7–17].

When partial REBOA is performed, the REBOA catheter is located at Zone 1 or Zone 3 appropriately after arterial access and the balloon is not inflated completely within the range of proximal perfusion maintained [18,19]. The degree of the partial occlusion is easily visualized if fluoroscopic guidance is available. However, in order to monitor the actual distal perfusion, a femoral sheath is placed at the other side of the REBOA for arterial pressure measurement. In other ways, a more than 1 Fr larger sheath for the REBOA catheter can measure distal arterial pressure using the side port of the sheath [18,20].

Although “partial REBOA” is used between “complete occlusion” and “no occlusion”, there is no clear

definition of occlusion strength. Furthermore, as mentioned above, hemorrhagic shock quickly changes the aortic diameter, and complete occlusion and partial occlusion can migrate towards each other. Due to this background, Matsumura et al. defined a clinically feasible and reproducible complete occlusion with an animal model using swine and proposed adjusting the occlusion strength of partial REBOA. In this report, complete occlusion is defined as “a condition in which the femoral artery pressure disappears”, and the balloon injection volume at that time is recorded. It is proposed to present the occlusion strength of partial REBOA as a percentage of the balloon injection amount at the time of complete blocking. When the proximal and distal arterial pressures were measured under different conditions from 0% to 100%, it was reported that the proximal arterial pressure remained almost unchanged up to 100% after a 60% balloon volume. The occlusion at 60% balloon volume while leaving the distal blood flow suggests that occlusion strength can increase the proximal arterial pressure [18].

Furthermore, the diameter of the aorta was shown to be related to the circulating blood volume in animal experiments [21]. In patients with hemorrhagic shock, the diameter of the aorta on computed tomography or angiography is often reduced, which suggests a decrease in circulating blood volume. As hemorrhagic shock advances and circulating blood volume decreases, the diameter of the aorta could be reduced, and partial REBOA could accidentally change to complete occlusion of the aorta. Sufficient transfusion and prompt hemostasis are essential for maintaining partial REBOA [22]. Monitoring the pulse pressure of the femoral artery (distal pressure of the REBOA) could prevent accidental changes from partial REBOA to total occlusion. Conversely, total occlusion could shift to partial REBOA if the circulating blood volume increased with sufficient transfusion and hemostasis. The pulse pressure of the femoral artery could help adjust the degree of partial REBOA.

INTERMITTENT REBOA

Total occlusion of the aorta at zone 1 has been considered to be within 20–30 minutes of peripheral ischemia. When prolonged total occlusion is necessary, the strategy of temporarily deflating the balloon to resume perfusion to peripheral organs for a while and then reinflating the balloon could be considered. This procedure is called intermittent REBOA [23]. There has been no reported clinical established method of intermittent REBOA. In some animal experiments, the REBOA balloon was completely deflated and inflated at intervals during the complete occlusion of the aorta [24,25].

According to experiments using a swine model, intermittent REBOA caused less-severe organ injury and improved the survival rate compared to total occlusion of the aorta [26]. However, there is little definitive evidence

regarding intermittent REBOA. Furthermore, there is no established appropriate interval between deflation and inflation for intermittent REBOA. When intermittent REBOA is performed with insufficient fluid resuscitation, rapid deflation of the balloon can lead to significant blood pressure reduction [25]. Hypovolemia and ischemia-reperfusion damage due to peripheral ischemia, could lead to persistent severe hypotension and cardiac arrest in the worst situation. Intermittent REBOA has an inevitable significant influence on arterial circulation; therefore, the coalition of all physicians is essential when intermittent REBOA is performed.

Few comparative studies have evaluated partial REBOA and intermittent REBOA. There is minimal evidence as to which of these two occlusion methods should be used. In a porcine hemorrhagic shock model, Johnson et al. studied a group with a 75-minute partial REBOA and a group with an intermittent REBOA after complete occlusion for 15 minutes and compared them [25]. There was no difference in survival between the two groups, but the partial REBOA group had a shorter complete occlusion time, and no rapid decrease in arterial pressure was observed. The method of transitioning to partial REBOA at the earliest possible stage, while observing hemodynamics after complete occlusion, will be easier to manage because hemodynamic fluctuations are less likely to occur. However, the evaluation of the safe occlusion strength in partial REBOA is currently insufficient.

LIMITATION

First, there have been no adequate studies on human concerning partial REBOA and intermittent REBOA. Although we have discussed the effectiveness of partial REBOA and intermittent REBOA, almost all the evidence is based on animal experts. We have presented a description based on the current literature and expert consensus, and we need more clinical studies to validate these ideas at present.

Second, in order to consider the partial REBOA and intermittent REBOA, balloon construction should be discussed. The balloon of the REBOA is commonly constructed by a compliant balloon. If a non-compliant balloon is selected, the balloon diameter is defined by the nature of the balloon catheter itself and the injection volume does not control the degree of the occlusion.

CONCLUSION

REBOA can control the degree of occlusion of the aorta, and partial REBOA and intermittent REBOA could allow safer management when compared to complete occlusion. While the definition and evidence of partial REBOA and intermittent REBOA have been limited, these methods could prevent less ischemia-reperfusion injury than complete occlusion of the aorta.

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

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). None of the other authors have any conflicts of interest to declare.

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Author Contributions

SH and YK were responsible for drafting, editing, and submission of the manuscript. TM critically appraised the manuscript. SH, YK, TM and YM contributed to the critical revision of the manuscript for important intellectual content and provided intellectual input to the research and manuscript. All authors read and approved the manuscript.

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Resuscitative Endovascular Balloon Occlusion of the Aorta Complications and its Management

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Numerous complications have been reported regarding the use of resuscitative endovascular balloon occlusion of the aorta (REBOA). Complications can be broadly classified into the following six categories: arterial access-related, REBOA catheter insertion-related, balloon positioning-related, balloon inflation-related, balloon deflation-related, and sheath placement and removal-related. REBOA operators must be knowledgeable about these possible complications and their management, along with its utility. A strong commitment to using REBOA safely and complication-free is essential to the skillful use of REBOA.

Keywords: Arteriovenous Fistula; Complications; Ischemia-Reperfusion Injury; Limb Ischemia; Pseudoaneurysm; REBOA

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INTRODUCTION

Various restrictions exist when using resuscitative endovascular balloon occlusion of the aorta (REBOA). First, the time is limited. Immediate hemostasis is required; therefore, an excessively time-consuming procedure to use REBOA must be avoided. Second, the preprocedural evaluation is insufficient. REBOA placement is frequently required before the computed tomography (CT) scan. Tortuosity of the aorta, presence or absence of aortic injury, or precise hemorrhage location may be unclear during the procedure. Third, the assessment method for the procedure is limited. Whether or not REBOA is

placed in the appropriate position may be difficult to confirm without fluoroscopic guidance. Fourth, the condition of the patient is poor. If the patient is in severe hemorrhagic shock, the femoral artery may be impalpable and difficult to visualize using ultrasound. Consequently, vascular access may be challenging. Moreover, in patients with pelvic or femoral fractures, it may be difficult to use the right puncture site because of groin swelling or the use of pelvic compression devices such as SAM Pelvic Sling™, bed sheet wrapping, or Pelvic Binder™ [1]. Fifth, hands-on experience is insufficient. Low-volume centers have limited cases with indications for REBOA placement. Therefore, the operator may be required to use REBOA before acquiring sufficient hands-on experience.

It is inappropriate to think that some complications related to REBOA are inevitable or permissible because of the restrictions mentioned above. Complication rates for REBOA have been reported as 3.6–18% [2–5], and complication-related deaths have been reported as well [2]. Operators must be strongly committed to using REBOA safely and complication-free.

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Ethical Approval and Informed Consent

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

ARTERIAL ACCESS-RELATED COMPLICATIONS

The first on the list of procedure-related complications related to REBOA is arterial access-related complications. Femoral artery puncture must be performed accurately in the appropriate position. Retroperitoneal hemorrhage and intra-abdominal/retroperitoneal organ injury due to high puncture and mispuncturing of the superficial femoral artery or deep femoral artery due to low puncture are typical complications. Mispuncturing of the superficial femoral artery or deep femoral artery leads to sheath placement in a narrow artery, causing limb ischemia. Repeatedly puncturing the artery or mispuncturing the vein may lead to troublesome hemorrhage or arteriovenous fistula formation. Unsterile procedures and infrequent use of prophylactic antibiotics are associated with a greater risk of wound infection [6].

Ultrasound-guided puncture is recommended for accurate arterial access [6–8]. When ultrasound is used, the artery can be visualized and artery identification becomes easier, even when the pulse of the femoral artery is not palpable. It also allows the visualization of the bifurcation of the superficial and deep femoral arteries, making it possible to puncture above the bifurcation securely. However, ultrasound use does not necessarily ensure easy arterial access for any operator. Operators inexperienced in using ultrasound may adversely cause complications and require longer procedure time, so adequate training is required to skillfully perform ultrasound-guided puncture.

REBOA CATHETER INSERTION-RELATED COMPLICATIONS

Typical complications associated with REBOA catheter insertion include guidewire management. Usually, when you advance the guidewire in the blood vessel, you should not feel any resistance, and when you do, you must not advance the guidewire any further. The risk is small if you are using a J-tip guidewire, but without fluoroscopic guidance, a totally unexpected movement of the tip of the guidewire may occur.

When you feel resistance advancing the guidewire, much attention is required since one of the following incidents may have occurred: migration into the contralateral common femoral artery, migration into the caudal vessels after forming a loop between the superficial and deep femoral arteries, aortic dissection, extravascular deviation, or migration into the deep circumflex iliac/inferior mesenteric/renal/superior mesenteric/celiac artery.

To ensure proper guidewire placement, operation under fluoroscopic guidance is the most reliable method,

but unless a hybrid emergency room is used, it is more likely that fluoroscopic guidance cannot be used during the early stages of trauma care. In such cases, a portable chest X-ray device or ultrasound must be used to check the position of the guidewire. Since the timing of the confirmation would be after the advancement of the guidewire, if you feel any unexpected resistance before advancing the guidewire to the length you planned using the landmark technique, you must sufficiently retract the guidewire to a certain length and re-advance the guidewire carefully.

Even if the guidewire is at the proper position, there are times when advancing the REBOA catheter over the wire becomes problematic. Severe tortuosity, arteriosclerosis, calcification of the aorta, and intravascular thrombus are the typical causes. When it is difficult to advance the REBOA catheter over the wire without confirming the proper guidewire location, this may be a signal that the guidewire position is not appropriate.

Do not adhere rigidly to the idea of using REBOA when you have trouble with arterial access or REBOA catheter advancement; always consider a different strategy. Causing substantial delay in hemostasis by insisting on carrying through a time-consuming procedure would be completely out of line. Always be flexible, and switching to resuscitative thoracotomy with aortic cross-clamping or even dropping the idea of aortic occlusion may be necessary sometimes.

BALLOON POSITIONING-RELATED COMPLICATIONS

REBOA must be placed in either zone 1 or zone 3, depending on the purpose. Inappropriate balloon positioning may lead to various complications.

When REBOA is placed above zone 1 (i.e., between the left subclavian artery and the heart), not only is blood flow to the brain obstructed, but the afterload of the heart is significantly increased, causing myocardial dysfunction and lethal complications. Zone 2 placement blocks blood flow to the abdominal branches, causing bowel ischemia and renal dysfunction [9]. Zone 2 placement does not play any role in trauma care. By placing REBOA below zone 3 (that is, within the iliac artery region), the following complications could occur: complete limb ischemia on the side of placement, vascular injury or rupture [10], and hemorrhage exacerbation from abdominal and pelvic injuries (Figure 1).

To place REBOA at the appropriate position, checking the location of the guidewire and REBOA catheter using fluoroscopic guidance, a portable X-ray device, or ultrasound is helpful [10,11]. When using a small-diameter REBOA catheter, re-inserting the stylet before balloon inflation is mandatory to prevent downstream migration (Figure 2) [12]. It is important to remember that a certain degree of migration occurs even when a stylet is used. If the fixation of the sheath or REBOA

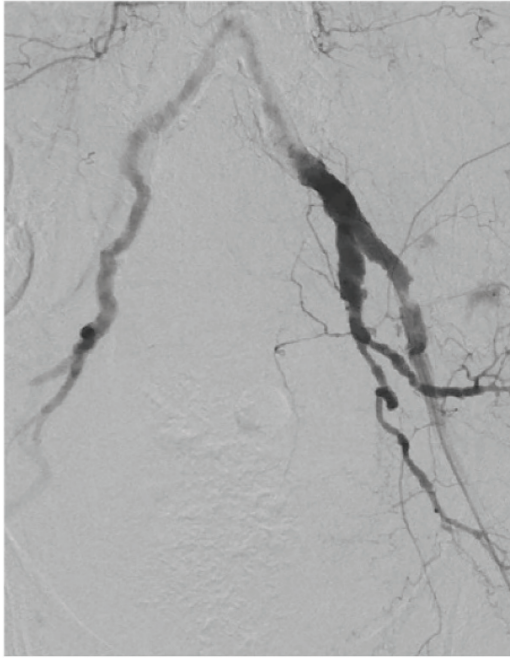


Figure 1 (Reprinted with permission from reference [10].) Common femoral artery (CFA) rupture due to balloon inflation at CFA.

catheter is weak at the groin, the REBOA catheter could come out of the sheath, or in some cases, both the sheath and REBOA catheter could be pushed back; therefore, careful attention must be paid to the puncture site when inflating the balloon.

BALLOON INFLATION-RELATED COMPLICATIONS

Typical examples of balloon inflation-related complications are vascular injury, vascular rupture, and balloon

rupture due to overinflation [13]. Since proximal blood pressure and blood flow rapidly increase after inflation, there is a possibility of worsening proximal hemorrhage (Figure 3) [14]. In particular, careful attention should be paid to patients with head or chest injuries. In addition, injuries that were not apparent due to shock may become evident by increased blood pressure and blood flow.

To prevent complications, it is essential to monitor blood pressure proximal to the site of occlusion. Balloon inflation must be performed cautiously while closely monitoring the proximal blood pressure. You should not blindly continue to inject the balloon when there is no observable responsive increase in blood pressure. In severe shock, even if the position of the balloon is appropriate and the balloon is already fully inflated, proximal blood pressure may not change, and continuing to inject in the balloon may cause vascular injury or balloon rupture due to overinflation. If it is possible to monitor the distal pressure, confirming the disappearance of pulse pressure would make it easier to avoid overinflation and appropriately manage partial REBOA. In animal studies, it has been shown that after the balloon volume reaches 60% of the volume needed for complete occlusion, even if the balloon is continuously injected, the proximal mean blood pressure remains unchanged [15].

Do not put too much trust in the strength of push-back you feel from the injection. If the circumstances permit, to decide the adequate injection volume, monitor the proximal blood pressure and the distal blood pressure, or use diluted contrast to inflate the balloon and check the balloon shape under fluoroscopy. By using a wide-diameter sheath (e.g., 8-Fr sheath for 7-Fr catheter), sheath pressure can be used to monitor the distal arterial pressure and estimate the degree of occlusion.

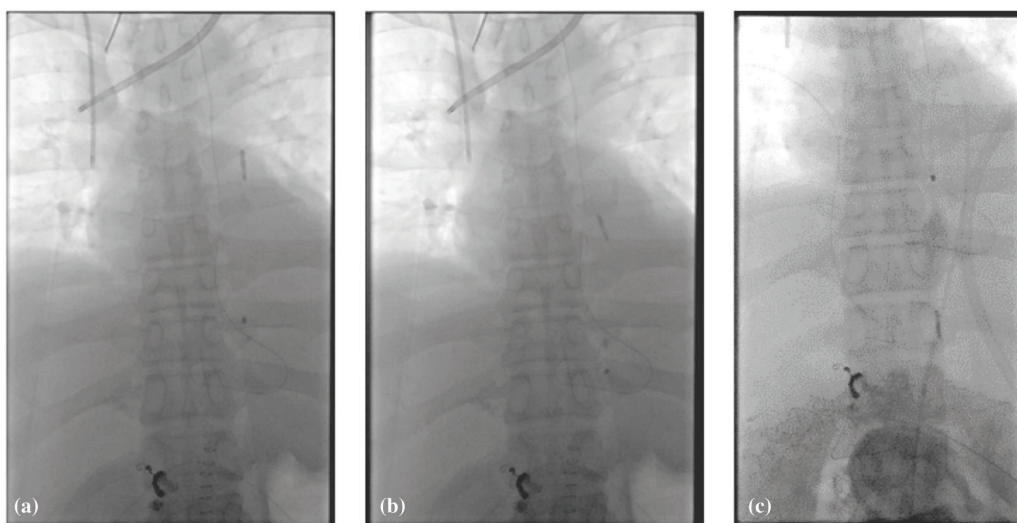


Figure 2 Examples of downstream migration. (a,b) Balloon is inflated after re-inserting the stylet. A certain degree of downstream migration occurs even if the stylet is inserted and the catheter is fixed. (c) The tip of the catheter turned over and migrated immediately after removing the stylet during an attempt to measure the proximal arterial pressure from the catheter.

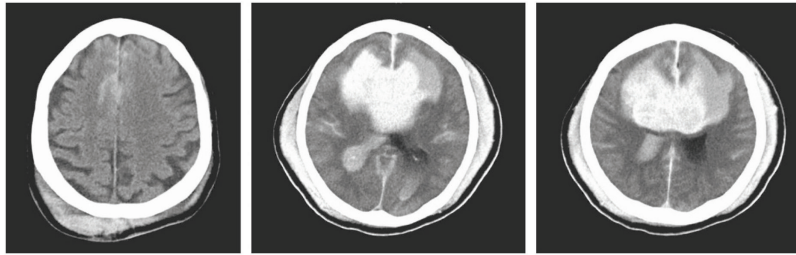


Figure 3 (Reprinted with permission from reference [14].) Cerebral hemorrhage significantly worsened after inflating the balloon.

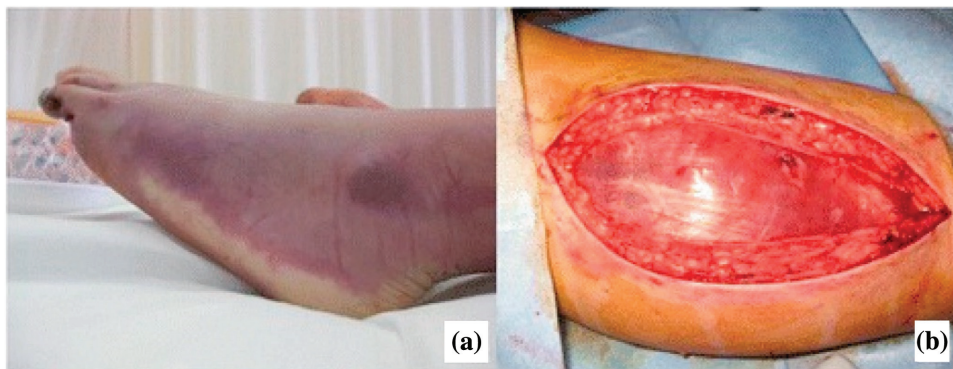


Figure 4 (Reprinted with permission from reference [17].) Compartment syndrome due to limb ischemia necessitating a relaxing incision.

When you cannot see an increase in blood pressure after inflation, if the position of the REBOA catheter has not yet been checked, the possibility is that the position of the balloon is inappropriate. Always deflate the balloon before adjusting the position of the REBOA. Otherwise, the large balloon could erratically enter an unintended vessel and cause unnecessary ischemia. Moreover, by pushing the REBOA catheter under high pressure, the REBOA catheter could abnormally bend inside the vessel.

By using partial REBOA or intermittent REBOA in combination with total occlusion, or by changing the balloon position from zone 1 to zone 3 after controlling for intra-abdominal hemorrhage, it should be possible to minimize the degree of ischemia-reperfusion injury. However, regardless of the strategy you decide to take on, keep in mind that a longer occlusion time is the most significant cause of an unfavorable prognosis. Rush for hemostasis and make every effort to shorten the occlusion time.

BALLOON DEFLATION-RELATED COMPLICATIONS

By deflating the balloon and thereby releasing aortic occlusion, a rapid decrease in afterload, rebleeding, and ischemia-reperfusion injury can occur. Massive amounts of metabolites due to ischemia-reperfusion injury (e.g., nitrogen oxide and inflammatory mediators) are released, and vasodilation, refractory hypotension,

hyperkalemia, and acidosis can rapidly develop [6]. Since rapid expansion of the vascular bed and vasodilation occur simultaneously, in the worst case, circulatory collapse could occur, which may cause cardiac arrest. In such cases, salvage of the patient may fail even if the balloon is reinflated [8,16].

If hemostasis is not yet achieved at the distal area of the occlusion, deflation of the balloon would immediately cause rebleeding. Therefore, as a general rule, deflation should be performed after the hemorrhage has been controlled. However, to minimize the effect of ischemia-reperfusion injury, the strategy of using partial REBOA before complete hemostasis or intermittent REBOA could be considered as an option. Since deflation could immediately cause cardiac arrest, the timing of deflation should not be solely decided by the REBOA controller alone; it should be considered and shared with the entire team.

When deflating the balloon, carefully and gradually draw 1 to 2 ml while monitoring the blood pressure in the upper limb. Since the vascular bed expands rapidly, be prepared to administer a sufficient amount of fluid or blood. Vasodilation due to ischemia-reperfusion injury could occur concurrently, and vasopressors may also be necessary. If circulation collapses, or if the hemorrhage becomes uncontrollable in the operative field, the balloon may need to be reinflated immediately. It is essential for the operator, REBOA controller, and anesthesiologist to work hand in hand to regulate the situation appropriately.

SHEATH PLACEMENT AND REMOVAL-RELATED COMPLICATIONS

After using REBOA, the sheath may be left in place for prompt arterial access, as a measure in case of rebleeding. However, it should be noted that thrombus formation and limb ischemia could occur when the sheath is left in place. Large sheaths, small blood vessels, and long-term placement all contribute to a greater risk of limb ischemia. Limb ischemia could cause the following: compartment syndrome necessitating a relaxing incision (Figure 4) [17], thromboembolism necessitating a thrombectomy or lower limb amputation [18,19].

Therefore, you should always bear in mind the possibility of these complications occurring after sheath placement, and you should continue to pay close attention to the blood flow and the appearance of the skin of the limb where the sheath is placed. Confirming the pulse wave on the oximeter is a convenient method of evaluation. If it is likely that a complication has occurred, it should be promptly evaluated using contrast-enhanced CT, ultrasound, or angiography. Although the use of small sheaths (7-Fr) minimizes the complication rate of sheath-related complications, including limb ischemia [20–22], complications still occur using 7Fr sheaths [8,23–25]. To take measures for thromboembolic events, continuous diluted heparin administration from the sheath may be considered [8,26].

If the sheath is considered unnecessary, it should be removed as soon as possible. Optimally, this should be done after the completion of hemostasis and after coagulopathy has improved. The most commonly used method of hemostasis after sheath removal is adequate manual compression. Using hemostatic devices or performing surgical vessel repair may be considered, depending on the operator's experience. Coagulopathy and low platelet count at the time of sheath removal, inappropriate compression position, insufficient compression pressure, and short compression time may all cause pseudoaneurysm formation, and delayed massive hemorrhage can occur.

If the position of the sheath was inappropriate or if the vein was mispunctured, an arteriovenous fistula could form after sheath removal. If these complications occur, covered stent insertion, percutaneous thrombin injection, or surgical angioplasty including patch angioplasty should be considered, in consultation with vascular surgeons and interventional radiologists. Adequate experience is required to manage sheath-related procedures complication-free.

CONCLUSIONS

REBOA operators must be knowledgeable about the possible complications and their management, along with its utility. A strong commitment to using REBOA safely and complication-free is essential to the skillful use of REBOA.

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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

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). None of the other authors have any conflicts of interest to declare.

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Author Contributions

TS was responsible for drafting, editing, and submission of the manuscript. KT, KI, TM, and YM contributed to the critical revision of the manuscript for important intellectual content and provided intellectual input to the research and manuscript. All authors read and approved the manuscript.

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Endovascular Strategy in Obstetrics

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Post-partum hemorrhage (PPH) requires medical resources to resuscitate hemorrhagic shock patients. The concept of damage control surgery in obstetrics has become widespread, and resuscitative endovascular balloon occlusion of the aorta (REBOA) can be a means of resuscitation in PPH. However, the potential benefits of endovascular strategies in obstetrics are not fully understood. This review aims to share the knowledge and experience of the endovascular strategy in the field of obstetrics among both interventional radiologists and obstetricians through the summary of the literature and multi-specialty expert consensus in the Japanese Society of Diagnostic Interventional Radiology in Emergency, Critical care and Trauma (DIRECT). The endovascular strategies include REBOA, arterial embolization, and common or internal iliac artery balloon occlusion (CIABO or IIABO). Uterine artery embolization achieves rapid definitive hemostasis while leaving fertility with a less invasive procedure. N-butyl-2-cyanoacrylate (NBCA) should be chosen as needed for coagulopathy. The obstetrics team (obstetricians and midwives) and the resuscitation team (doctors from emergency medicine, anesthesiology, interventional radiology, and nurses) would each have to develop a command system, and control and cooperate in parallel. The consensus for the timing of arterial access and the patient's positioning for pelvic examination and femoral arterial access should be established in advance.

Keywords: *Resuscitative Endovascular Balloon of the Aorta; REBOA; Post-Partum Hemorrhage; PPH*

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INTRODUCTION

Post-partum hemorrhage (PPH) puts two young people at risk. Considering the length of life that should have remained, the social loss is enormous if lives cannot be saved. The psychological burden on the bereaved families is usually significant. PPH requires abundant medical and human resources to resuscitate patients with hemorrhagic shock [1]. It is essential that collaboration occurs between obstetricians and emergency doctors, anesthesiologists, intensive care doctors, and interventional radiologists. The anatomy, pathophysiology, and hemostatic strategy of PPH are not fully understood among such multidisciplinary/multi-specialty teams. In many cases, hyperfibrinolysis occurs [2,3], and a large amount of blood is required for transfusion [4,5]. Cooperation with the blood bank is also crucial for a rapid and

massive transfusion protocol. In addition, collaboration with midwives, nurses, and neonatology is required [6]. This kind of multidisciplinary/multi-specialty collaboration is similar to the treatment of polytrauma. This review aims to share the knowledge and experience of endovascular strategies in perinatal resuscitation and hemostasis among both interventional radiologists and obstetricians through a summary of the literature and multi-specialty expert consensus in the Japanese Society of Diagnostic Interventional Radiology in Emergency, Critical care and Trauma (DIRECT).

As with a polytrauma strategy, promptness and certainty should be prioritized over minimal invasiveness in PPH. Bimanual uterine compression massage and Bakri® post-partum balloon are essential and effective hemostatic measures [7]. For maternal lifesaving, it is unavoidable that a total emergency hysterectomy is performed. The concept of damage control surgery in obstetrics has also become widespread. Thus, expedited definitive hemostasis contributes to maternal lifesaving in the most severe PPH. In addition, resuscitative endovascular balloon occlusion of the aorta (REBOA) has also been recognized as a means of resuscitation in PPH [8].

However, endovascular strategies in obstetrics have a wide variety of applications, including emergent versus elective cases [9,10], REBOA versus selective balloon

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Table 1 REBOA placement position and target injury.

	Zone 1	Zone 3
Top	Left subclavian artery	Renal artery
Bottom	Celiac trunk	Aortic bifurcation
Target area	Abdomen (supraceliac)	Pelvis (infrarenal)
Target injury	Spleen	Pelvic fracture
	Bowel and mesentery	Uterus
	Liver	Thigh
	Kidney	
	Impending cardiac arrest	
	Focus unknown	

occlusion [11], and total hysterectomy versus uterine artery embolization (UAE) [12]. The potential benefits may not be fully understood. This article discusses the utility, availability, and feasibility of endovascular strategies in obstetrics.

Ethical Approval and Informed Consent

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

SURGERY AND ENDOVASCULAR STRATEGY IN RESUSCITATION AND HEMOSTASIS

Surgery and interventional radiology (IR) are two sides of the same coin in a trauma hemostatic strategy. The usefulness of a hybrid strategy that combines their merits has been recognized. Arterial bleeding of pelvic fractures is controlled by arterial embolization, and bony and venous bleeding is controlled by external fixation and retroperitoneal packing [13]. For liver injury, portal vein/venous bleeding is controlled by perihepatic packing during emergency laparotomy, and arterial bleeding is subsequently controlled by hepatic artery embolization [14]. The packing can control the low-pressure (portal and venous) system [15], and angioembolization can control arterial hemorrhage [16]. Since both the spleen and uterus are resectable organs, the hemostatic strategy in PPH and spleen injury is similar: resection or preservation with angioembolization [17–19]. There are several similarities between the hemostatic strategies for trauma and PPH. REBOA can increase the proximal arterial pressure in hemodynamically unstable patients and regulate distal bleeding; thus, the patient needs to rush to achieve definitive hemostasis. Zone 1 REBOA is selected for abdominal organ injury such as the spleen, and zone 3 can be chosen anatomically for hemorrhage below the aortic bifurcation such as PPH [20,21] (Table 1). Zone 1 is indicated in impending cardiac arrest by PPH. Zone 3 REBOA cannot occlude the ovarian artery. Since the uterine blood supply in most gravid uteruses can be

regulated by zone 3 REBOA, it is the first choice in the PPH situation when considering the risk of visceral organ ischemia. REBOA is not a hemostatic procedure but an effective and feasible bridge to definitive hemostasis [22]. Bleeding patients need to undergo surgery or IR while using REBOA as a bridge. Surgical hemostasis includes splenectomy or hysterectomy, and angioembolization is most commonly used for endovascular hemostasis, which may preserve the injured organ.

Zone 3 REBOA, which is often chosen in PPH, induces minor ischemia-reperfusion injury compared to zone 1 REBOA in abdominal injury. In most cases of PPH, UAE or internal iliac artery embolization may be completed rapidly. Bilateral non-selective internal iliac artery embolization can be completed within 20–30 minutes, similar to pelvic fracture cases. The uterine artery, which is often enlarged to supply the pregnant uterus, can be cannulated even in an urgent PPH situation. There is a greater chance of selective embolization after stabilization by transfusion and embolization of the main bleeder. Although gelatin sponge particles are usually used in the clinical routine of emergent IR, they can be recanalized in coagulopathy. A liquid embolic agent independent of the coagulation status, such as n-butyl-2-cyanoacrylate (NBCA, Histoacryl®) or ethylene-vinyl alcohol copolymer (Onyx™), may work instantly, even in severe coagulation disorders [23]. When the microcatheter tip can reach the bleeding artery selectively in an obviously coagulopathic patient, a liquid embolic agent may be used as the first choice.

The multidisciplinary consensus among obstetricians, emergency physicians, and IR physicians on the risk of ischemia of the uterus leads to damage control procedures according to hemodynamics and coagulopathy. IR is not only a less invasive procedure but can result in more rapid hemostasis. Endovascular hemostasis may avoid additional injuries during surgery. While fertility becomes null after hysterectomy, preservation of the uterus after angioembolization may lead to subsequent pregnancy. The patient may feel resistance to the uterus's loss, even if the couple no longer hopes to raise a child. Despite the

risks of complications such as amenorrhea, placental malposition, and premature birth, the endovascular strategy has good compatibility with PPH. However, angiographic hemostasis differs from clinical hemostasis. Controlling angiographic arterial bleeding alone may not result in hemostasis. There should be no hesitation to convert to surgical hemostasis if bleeding cannot be controlled, such as persistent oozing due to coagulopathy.

BALLOON OCCLUSION IN OBSTETRICS: PROPHYLACTIC USE AND PROXIMAL CONTROL

REBOA and arterial embolization are not the only options under endovascular strategies in the field of obstetrics. Prophylactic selective balloon occlusion, such as common iliac artery balloon occlusion (CIABO) or internal iliac artery balloon occlusion (IIABO), contributes to reducing intraoperative bleeding in high-risk cesarean sections [11]. Prophylactic use of the balloon catheter in elective cases is a feature and benefit in obstetrics. Prophylactic balloon use makes the surgery safer and more comfortable, before uncontrollable hemorrhage and catastrophic conditions occur.

Both CIABO and IIABO are relatively simple vascular IR procedures. However, the procedure is usually performed by an interventional radiologist in an angiography or hybrid suite, while REBOA could be performed by any trained vascular/trauma or anesthesiologist team without fluoroscopy in the emergency room or operating room. IIABO cannot control the collateral flow from the external iliac artery; thus, previous research reported that it could not reduce bleeding [24,25]. A recent systematic review and meta-analysis, evaluating 29 articles, suggested IIABO in patients with placenta previa contributes to reducing intraoperative blood loss and hysterectomy [26]. Some recommend CIABO because it occludes both internal and external iliac arteries, but it also carries the risk of distal embolism of the leg. Meanwhile, IIABO can be immediately converted to angioembolization of the internal iliac artery in the case of PPH.

The occlusion effect of bilateral CIABO is the same as that of zone 3 REBOA. That is, a REBOA provider who received appropriate training plays the same role as an IR physician who can achieve the temporal arterial occlusion of bilateral CIABO, even if they are not IR physicians. A previous study compared the efficacy of IIABO, CIABO, and zone 3 REBOA. The results suggested that prophylactic balloon occlusion decreased blood loss and blood transfusion, especially in patients with CIABO and zone 3 REBOA compared to IIABO [27]. Moreover, maternal and fetal radiation exposure during REBOA placement requires only one or two images using a portable X-ray device or C-arm. The preoperative procedure can be completed within 30 minutes. REBOA creates a dry operative field, reduces intraoperative bleeding, and may reduce or avoid transfusion, especially in patients with placenta accrete [28–32]. It

reduces the risk of operative injury of the ureter or bladder during the damage control setting, thus helping to achieve delicate surgery is more straightforward.

A REBOA sheath used to be large, such as 10–12 Fr [33,34]. The femoral artery diameter of young women is small. The merits of proximal control and the risk of leg ischemia are compared prior to prophylactic use. Meanwhile, bilateral 5 Fr sheaths are usually placed in CIABO or IIABO. Although the 5 Fr sheath does not induce a significant risk of leg ischemia, both sides of the groin must be continuously compressed for several hours after the sheath is removed. Small-profile REBOA is compatible with a 7 Fr sheath [35]. A 7 Fr sheath is placed on one side, associated with a lower risk of leg ischemia and may be smaller than bilateral 5 Fr sheaths. More recently, 4 Fr-compatible REBOA was launched, and this is expected to provide safer REBOA placement [36].

There is a significant difference in policies depending on the facility or the operator regarding the selection of REBOA in zone 3 or bilateral CIABO/IIABO, and we cannot recommend which is beneficial. However, the potential for maternal and fetal safety during a high-risk cesarean section by the prophylactic placement of balloons is an attractive and valuable option.

MULTIDISCIPLINARY COLLABORATION IN PPH

Multidisciplinary collaboration among multiple departments and professions is essential for PPH. However, this is not an event that occurs every day. Perinatal health care providers cannot train themselves while undertaking daily routine work, even in high-volume centers. Simulation training is required to establish the perinatal critical care system, including regional transportation, command and control, resuscitation and definitive care, massive transfusion protocol, inter-departmental communication among obstetrics, emergency medicine, anesthesiology, and IR.

The obstetrics team (obstetricians and midwives) and the resuscitation team (doctors from emergency medicine, anesthesiology, interventional radiology, and nurses) would each have to develop a command system, and control and cooperate in parallel. Pelvic examination in the lithotomy position and obtaining femoral arterial access cannot be performed simultaneously when considering endovascular treatment. The order of pelvic examination and access may vary depending on the hemodynamics or assumed cause of PPH. These two procedures can proceed simultaneously at a hip abduction supine position with knee flexion, that is, ultrasound-guided femoral artery puncture at the right groin and left knee up for pelvic examination. Interruption of obtaining arterial access by lithotomy position without consensus should be avoided.

The Bakri balloon is a fundamental and practical device that provides temporary compression hemostasis and monitors genital bleeding. Its combination with

endovascular balloon occlusion contributes to temporary hemorrhage control. Placing a folded towelette under the patient's waist for smooth insertion of the Bakri balloon can be considered. The patient's posture can be adjusted for an easy and safe procedure by close communication between the obstetrician and emergency physician (who obtains arterial access) until the moment of puncture. Similar to trauma cases, the arterial sheath can be used for upsizing to the REBOA sheath or as access for embolization even when urgent REBOA deployment is no longer needed. Sharing the importance of early arterial access among emergency physicians, obstetricians, nurses, and midwives would result in a rapid response to PPH.

The balloon can be inflated longer in zone 3 than in zone 1 if it is placed correctly. When transporting a PPH case to a higher-level medical institution, zone 3 REBOA can be a good stabilization option for inter-hospital transport. Partial REBOA is also used in combination to avoid cardiac arrest and regulate arterial bleeding. The education of REBOA providers is crucial for the safe use of REBOA. However, early hemorrhagic shock detection, an early transport decision, and early definitive hemostasis are fundamental processes to save PPH patients. The power of REBOA should never be overestimated; it should always be remembered that it does not achieve hemostasis but is just a bridge.

CONCLUSION

There are various types of endovascular strategies used in the field of obstetrics. The use of REBOA includes resuscitative use to avoid cardiac arrest (zone 1 or zone 3), proximal control for hysterectomy (zone 3), and prophylactic use in high-risk cesarean sections (zone 3). It is essential to share the hemostatic strategy among resuscitation and obstetric teams in resuscitative use. The hip abduction supine position and knee flexion provide simultaneous pelvic examination and arterial access. Proximal control provides a dry operative field, especially in high-risk hysterectomies. Prophylactic REBOA use requires preoperative risk evaluation, but it has the advantages of less radiation exposure, shorter procedure time, and less patient burden than bilateral CIABO or IIABO. UAE achieves rapid definitive hemostasis while leaving fertility, with a less invasive procedure. NBCA should be chosen as needed for coagulopathy. Multidisciplinary collaboration and sharing of strategies would save two young lives in obstetrics.

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

Yosuke Matsumura was a clinical advisory board member of Tokai Medical Products (2015–2017). The other author declares that they have no conflicts of interest.

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Proactive Use of Whole-Body Computed Tomography and Resuscitative Endovascular Balloon Occlusion of the Aorta in Hemodynamically Unstable Trauma Patients

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It is well known that whole body computed tomography (WBCT) scans in hemodynamically unstable trauma patients (HUPs) should not be performed due to time concerns. Recently, with the shortening of CT scan time accomplished by quick preparation and scanning, WBCT in the patient population utilizing resuscitative endovascular balloon occlusion of the aorta (REBOA) in trauma cases could lead to better subsequent management, especially for patients with unknown bleeding points without known mechanism of injury, possible traumatic brain injury, and geriatric trauma with coagulopathy. During a CT scan with contrast, the REBOA balloon is not necessarily deflated further. The training of the CT scan team could shorten the CT room stay time to under 5 min. The images should be read quickly following focused assessment of the scans for trauma by trauma radiologists. REBOA–WBCT scans in HUPs with appropriate protocols and image readings might be the tool for choosing a better management in order to restrain hemorrhage.

Keywords: *Whole Body Computed Tomography; REBOA; Resuscitative Endovascular Balloon Occlusion of the Aorta; Hemodynamically Unstable Trauma Patients*

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INTRODUCTION

According to the American Association for the Surgery of Trauma, traumatic injury is responsible for more than 5 million deaths annually, and prompt in-hospital trauma management is important for the survival of major trauma patients [1]. An evaluation of bleeding sites, responsible

vessels, and the amount of hemorrhage is critical for rapid circulatory restoration in a hemodynamically unstable trauma patient. Whole-body computed tomography (WBCT) is the imaging modality of choice; however, its utilization for hemodynamically unstable trauma patients is controversial [2] because it takes time, where the time spent in the CT room may exacerbate the patient's condition beyond a "point of no return".

Resuscitative endovascular balloon occlusion of the aorta (REBOA) was developed to maintain proximal blood pressure and regulate the amount of arterial bleeding [3]. It may also give an opportunity for a CT scan enabling better subsequent management, as well as determining the presence or absence of traumatic brain injury [4,5]. Meanwhile, the arguments have continued for adequate balloon inflation, and as the amount of

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balloon volume is increased, the narrower the aortic lumen becomes, and the higher the possibility of complications such as lower limb ischemia [6]. For that reason, the time of REBOA utilization should be minimal.

Previous studies have mainly focused on efforts to shorten the procedure time performed in the CT room, and few studies have focused on the preparation necessary to decrease the whole process, which starts from the patient's arrival in the emergency department (ED). We call this the 'CT room stay time' (CTrST), and previous studies show that the mean time is about 16.8 min [7]. Clarke et al. reported that the probability of death among 243 hypotensive patients, bleeding from abdominal injuries and needing emergency laparotomies, increased by approximately 1% for each 3 min spent in the ED [8]. Thus, the shorter the CTrST, the higher the likelihood of patient survival. Shortening the CTrST may be good for lowering the rate of REBOA complications as well as improving the patient's prognosis.

In this article, the authors introduce the indication and adequate utilization of REBOA.

Ethical Approval and Informed Consent

Ethical approval was not required. Written informed consent was not required.

INDICATION OF REBOA-WBCT FOR TRAUMA PATIENTS

The golden hour theory of trauma management was proposed by Cowley [9–11], and the author states that the mortality rate triples for every 30-min increase from the time of injury to definitive care [12]. Those articles were published in the pre-endovascular era, and the equipment for diagnosis and management have now progressed beyond comparison. In addition to widely used chest and abdominal X-rays, focused assessment with sonography for trauma (FAST), which is easily performed at the bedside, is one of the most useful tools developed for evaluating hematomas that are unable to be inspected visually. However, this technique cannot "see" several important indications, such as the severity of bleeding, precise total amount of hemorrhage or number of bleeding sites. For those reasons, WBCT is the modality of choice, and the rationale for its use is as follows.

Unknown Bleeding Point Without Known Mechanism of Injury

When individuals with non-compressive blunt poly-trauma arrive at the ED, chest and pelvis plain X-rays as well as FAST are performed to look for possible sources of bleeding. These modalities can evaluate intrapleural or intraperitoneal abnormalities; however, extra-pelvic retroperitoneal hemorrhage due to kidney, paravertebral,

and lumbar artery injuries is often difficult to determine. Despite this, not all retroperitoneal bleeding is lethal, and requires invasive strategies such as surgery or interventional radiology (IR), particularly in elderly patients with coagulopathy. WBCT reveals the presence of hemorrhage, which could not be achieved without it and helps us to determine the best course of management.

Possible Traumatic Brain Injury

Patients with mild traumatic brain injury (TBI) may not have altered mental status upon arrival at the ED.

Especially within the context of coagulopathy, intracranial bleeding may proceed rapidly, which could lead to a robust deterioration of the patient's status, and its presence could change the order of subsequent management in patients who have other sources of bleeding, such as intraperitoneal hemorrhage. WBCT includes a plain head CT, which is sensitive and specific for hemorrhage within the skull. REBOA utilization could elevate intracranial pressure by obstructing the blood flow to the lower body; however, the use of partial occlusion instead of complete occlusion may avoid unnecessary hypertension.

Geriatric Trauma with Coagulopathy

Rapid aging of the population has been occurring worldwide [13]. Aging increases the anatomical vulnerability of having a traumatic hematoma, and combined with cognitive function decline, this makes it difficult to precisely evaluate its severity. Loose tissue in older people leads to the easy expansion of a hematoma, and anti-thrombotic agents may aggravate the severity of bleeding. These components result in unexpected bleeding occurring in unexpected sites within an unusually short span of time. In addition to this, older populations frequently have decreased cognitive function, and their altered mental status is sometimes difficult to evaluate whether their status is normal without information on their baseline vital signs and history of medications, such as anti-hypertensives. Therefore, the utilization of REBOA-WBCT could give us an objective evaluation of patient status and be justified in elderly patients with a suspicion of trauma with decreased cognitive functions as well as multiple anamnesis.

THE STATE OF REBOA AT CT SCANNING

There are debates on how much balloon inflation is appropriate for sufficient contrast enhancement of CT imaging. Matsumura et al. provide an example of its utilization (Supplementary Movie 1) [14]. They state that contrast enhancement could be achieved with partial occlusion although the contrast flow could be delayed compared to the state without balloon inflation. Even in the situation of a vulnerable patient whose

blood pressure is sustained only with complete occlusion, the contrast flow is still observed peripheral to the balloon; however, the potential complications of underestimation of extravasation must be considered in the interpretation of images.

HOW LONG IS TOO LONG? SHORTENING THE CT ROOM STAY TIME

The utilization of REBOA is, of course, not the fundamental management. REBOA-WBCT has an impact on subsequent management, especially in the situations mentioned above; however, it is itself not without complications. Therefore, the time for CT should be as short as possible to provide a better outcome.

No hospital without a trained trauma team accepts hemodynamically unstable trauma patients, because performing unfamiliar tasks is more time-consuming than completing routine ones. For this reason, specialist trauma surgeons are needed. IR for trauma patients has been widely used for rapid and precise management. In the same way, WBCT teams should also be trained. Matsumoto et al. have advocated prompt and rapid endovascular strategies in trauma occasions (PRESTO) [15].

When the patient arrives in the ED, the WBCT team begins to gather the information necessary for prompt CT scanning. They check the height of the stretcher, determine whether the patient can raise their arms and whether the intravenous line needs to be longer. Untangling the intravenous lines, electrocardiogram equipment and blood pressure cuff is an important task. In addition, removing any metallic objects that might appear as artifacts on the CT image is also essential. All the information is relayed to the radiology technicians in the CT room. The radiology technicians turn on the CT machine so that it is ready to scan, and adjust the height of the bed to match that of the patient's stretcher. Nurses prepare iodine contrast for use at any time.

Once the patient has been placed on the CT scan bed and the medical personnel have left the room, the contrast media injection is started. Scout image acquisition is skipped, and head CT scanning commences before the contrast media reaches the cerebral arteries. When the region of interest in the aorta is filled with contrast, which usually takes about 40 s, the arterial phase is started, followed by the venous phase. Once the scan is completed and the patient has left the room, the image evaluation is started immediately by a radiologist, which could be continued even in the operating room, and annotations are discussed. Using the PRESTO concept and a trained team, the CTrST was shortened to <5 min (Supplementary Movie 2). In the practice using a mannequin, the time was shortened further to <3 min (Supplementary Movie 3). As discussion of the CT annotations would help subsequent management, the short amount of time that this procedure takes was considered to outweigh the risk of further deterioration in most cases.

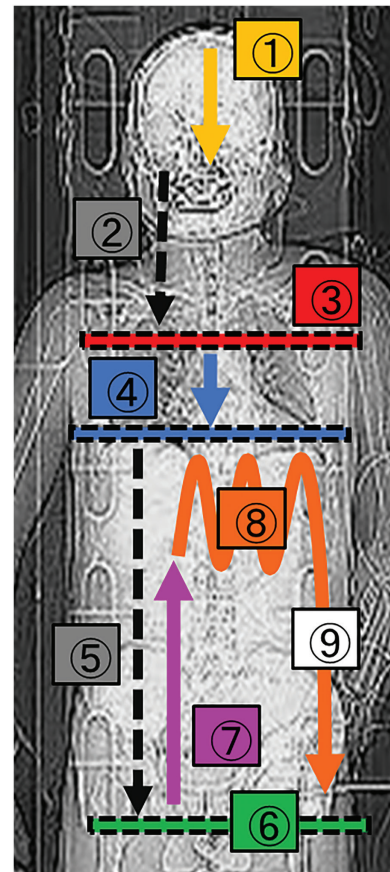


Figure 1 The reading order of the CT images during the focused assessment with computed tomography (FACT) for trauma protocol. Figures 2 to 5 explain details and examples.

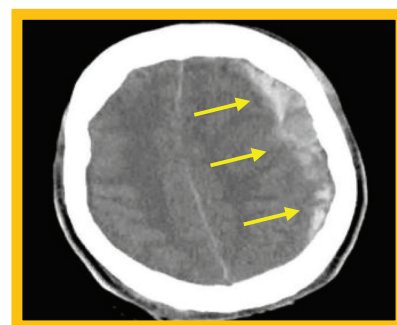


Figure 2 The image is assessed for the presence of potentially lethal intracranial lesions, such as massive hemorrhage in the mediastinal window. The neck is evaluated in the superior view. The image shows an intracranial hemorrhage.

OPTIMIZING UTILIZATION OF CT IMAGES

CT images must be read precisely to quickly acquire the information mentioned above. Ichinose et al.

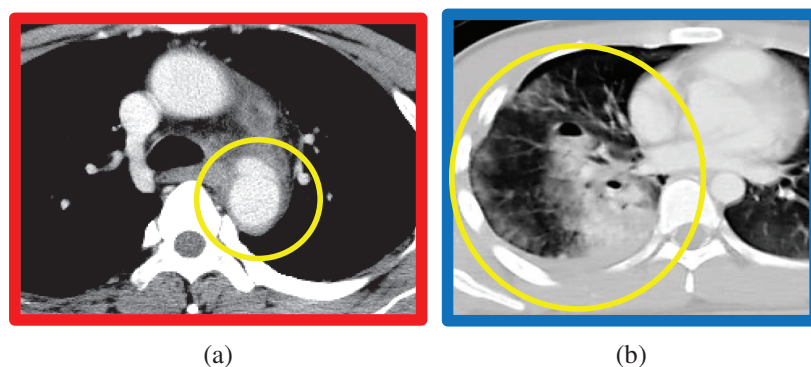


Figure 3 The thoracic area is evaluated for aortic injury and mediastinal hematoma. The lung window was changed at the level of the diaphragm, and a large lung contusion or pneumothorax, as well as a massive hemothorax, was viewed superiorly. Coronal views of the contrast-enhanced CT showing aortic dissection (a) and lung contusion (b).

recommended rapid reading of the CT pan-scan for trauma evaluation (focused assessment with computed tomography for trauma, FACT) [16]. FACT is a systematic method for appropriately annotating images, which is necessary for subsequent management (Figures 1–5) as the book “Current Practice and New Developments in Trauma” indicates [17]. Things to bear in mind are that extravasation could be underestimated, and that the circulatory status could be evaluated with the amount and distribution of hematoma. A trauma radiologist is the best person for that job, but they are not available at all sites at all times. If they are not on site, then an exclusive image evaluator should be chosen who concentrates on the image interpretation so that the remarks of the CT scan can be passed smoothly and quickly to the trauma team. Shortening the whole process, including the CTrST, should be considered for successful management.

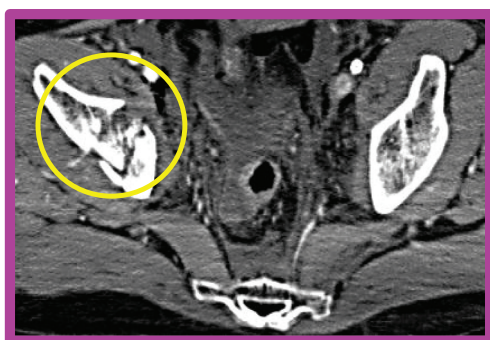


Figure 4 The upper abdomen was skipped, and the mediastinal window was acquired to evaluate hematoma in the rectouterine or rectovesical pouch. Then, the CT window was changed to the bone window, to check for massive fractures in the pelvis or vertebrae. The image shows right pelvic bone fracture in the bone window.

LIMITATIONS

There are several limitations to performing WBCT in hemodynamically unstable patients (HUPs). First of all, CT utilization is presupposed in those patients, and there is a possibility of its overuse. The scout image is skipped, which leads to additional radiation exposure. Also, in cases of total REBOA occlusion or necessitating REBOA volume increase in the CT room due to blood pressure deterioration, the occluding time would be long, and the ischemic and reperfusion injury would be severe. Hybrid emergency room could be a savior for those patients since surgery or IR could be performed seamlessly without patient transportation from the ED; however, there are often a limited number of facilities with the required machine. Regardless of the limitations, REBOA utilization could give a chance for WBCT in HUPs who satisfied appropriate indications, and there are possibilities of effecting better management.

CONCLUSIONS

Although utilization of WBCT with REBOA for hemodynamically unstable trauma patients has been considered to be contraindicated, a CT scan might provide better subsequent management, especially for patients with unidentified bleeding sources, an unknown mechanism of injury, coexisting TBI, or trauma in elderly with adequate knowledge of the protocols and interpretation. Shortening CTrST with the training of the CT scan team could lead to better management of patients so as to shorten the time length from trauma occurrence to completion of management.

Ethics Statement

- (1) All the authors mentioned in the manuscript have agreed to authorship, read and approved the

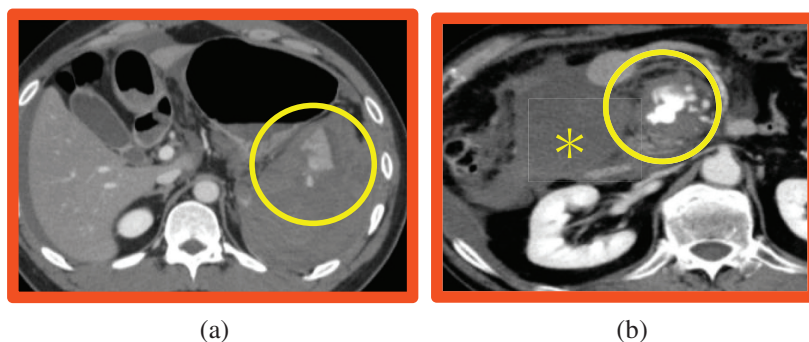


Figure 5 Massive injuries and contrast enhancement of the intra- or extra-abdominal organs are checked for in the upper abdomen view. Coronal views of contrast-enhanced CT showing the splenic hemorrhage (a) and intraperitoneal extravasation (b) with the hemorrhage indicated by an asterisk (*).

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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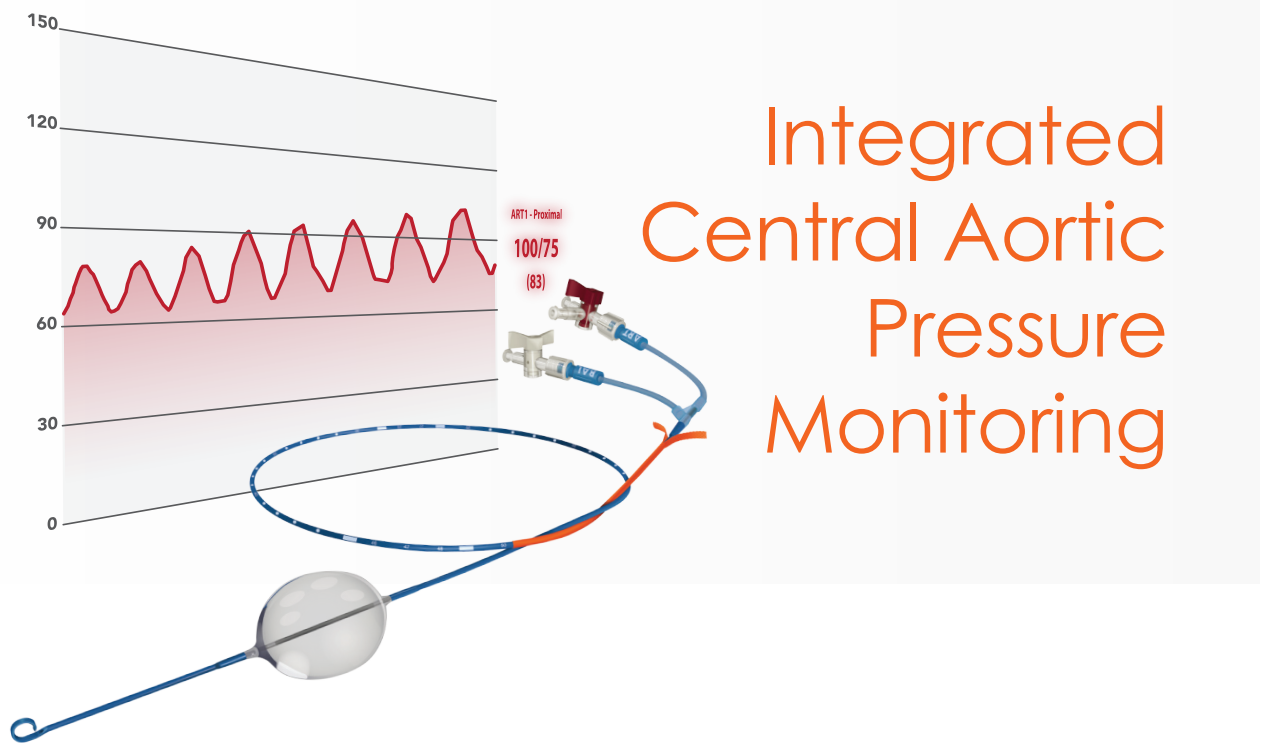
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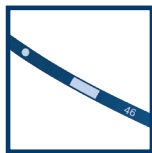
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www.reboamedical.com

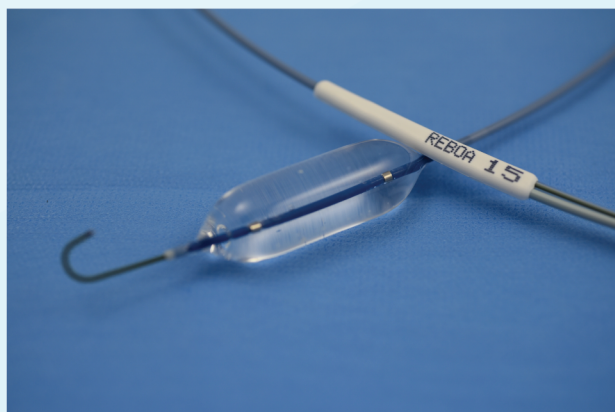
World's first complete REBOA kit,
indicated for temporary occlusion
of the aorta.

Kit contains; Reboa Balloon, drape, introducer, guidewire, and more. For more information, contact your local distributor or Reboa Medical directly.

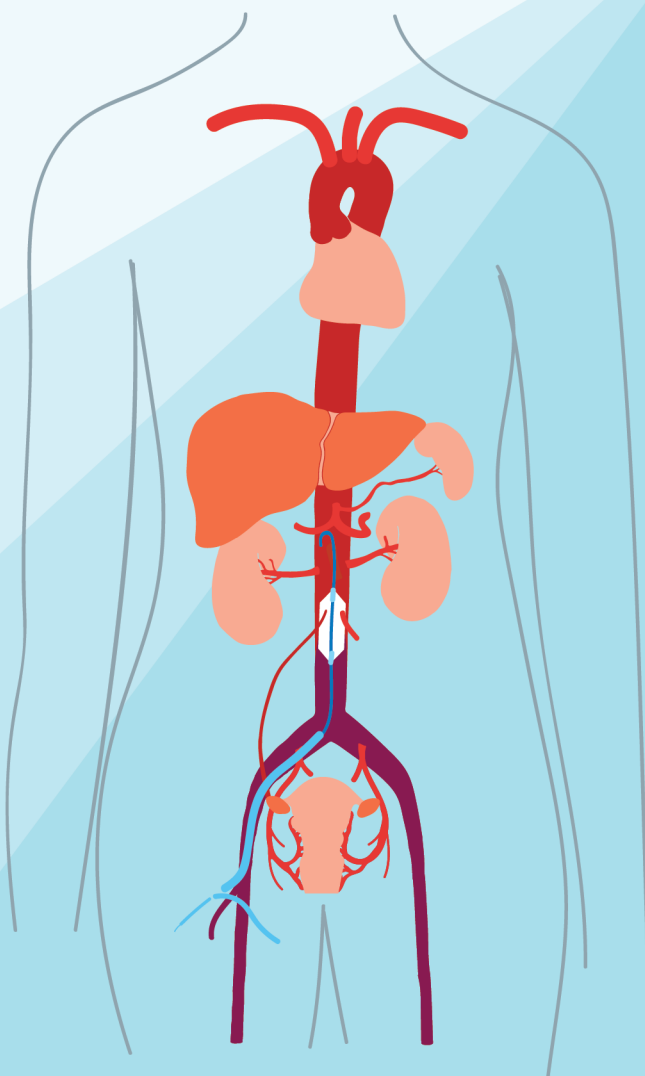
Product code	Balloon (Ø/L)	Fill volume	Introducer Size (included in kit)
RBK15305006	15/30 (mm)	8,0 mL	6F
RBK20305007	20/30 (mm)	15,0 mL	7F

*both kits are delivered with a 23 cm long introducer

The REBOA balloon is inserted using standard Seldinger technique.



Approved by CE, FDA, and Health Canada.



**"PROBLEMS CAN BE COMPLICATED.
SOLUTIONS CAN NOT"**

COBRA-OS™

**4Fr Aortic
Occlusion for
Better Patient Care.**



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Arterial Thrombus Removal

7



**Computer Aided
Mechanical Aspiration**

Product availability varies by country. Prior to use, please refer to the Instructions for Use (IFU) for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Please contact your local Penumbra representative for more information.

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