

# BMJ Open Resuscitative endovascular balloon occlusion of the aorta (REBOA): a scoping review protocol concerning indications – advantages and challenges of implementation in traumatic non-compressible torso haemorrhage

Omar Bekdache,<sup>1</sup> Tiffany Paradis,<sup>2</sup> Yu Bai He Shen,<sup>2</sup> Aly Elbahrawy,<sup>1,3</sup> Jeremy Grushka,<sup>1</sup> Dan L Deckelbaum,<sup>1</sup> Kosar Khwaja,<sup>1</sup> Paola Fata,<sup>1</sup> Tarek Razek,<sup>1</sup> Andrew Beckett<sup>1,4</sup>

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For numbered affiliations see end of article.

## Correspondence to

Dr Omar Bekdache;  
[omar.bekdache@mail.mcgill.ca](mailto:omar.bekdache@mail.mcgill.ca)

## ABSTRACT

**Introduction** Haemorrhage remains the leading cause of preventable death in trauma. Damage control measures applied to patients in extremis in order to control exsanguinating bleeding from non-compressible torso injuries use different techniques to limit blood flow from the aorta to the rest of the body. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is regaining momentum recently as an adjunct measure that can provide the same results using less invasive approaches. This scoping review aims to provide a comprehensive understanding of the existing literature on REBOA. The objective is to analyse evidence and non-evidence-based medical reports and to describe current gaps in the literature about the best indication and implementation strategies for REBOA.

**Methods and analysis** Using the five-stage framework of Arksey and O'Malley's scoping review methodology as a guide, we will perform a systematic search in the following databases: MEDLINE, EMBASE, BIOSIS, COCHRANE CENTRAL, PUBMED and SCOPUS from the earliest available publications. The aim is to identify diverse studies related to the topic of REBOA. For a comprehensive search, we will explore organisational websites, key journals and hand-search reference lists of key studies. Data will be charted and sorted using a descriptive analytical approach.

**Ethics and dissemination** Ethics approval is not necessary as the data are collected from publicly available sources and there will be no consultative phase. The results will be disseminated through presentations at local, national, clinical and medical education conferences and through publication in a peer-reviewed journal.

## INTRODUCTION

Mortality resulting from haemorrhage remains the leading cause of preventable death. In the case of an abdominal trauma with exsanguinating—life-threatening—injuries, laparotomy

## Strengths and limitations of this study

- This scoping review is a novel review approach applied for the first time to this topic and will offer an overarching picture on the variety of clinical indications, application and implementation of resuscitative endovascular balloon occlusion of the aorta.
- Findings will have implications on researchers for recognising the pearls, pitfalls and contextual variations in implementation strategies.
- This review will comprise broad inclusion criteria (peer-review journal and Grey literature) without assessing the quality of the articles included, which gives the breadth and comprehensiveness of the research protocol while respecting the scoping review guidelines.
- Scoping reviews are primarily descriptive in nature and therefore quantitative data analyses are considered to be one of the relevant limitations.
- Findings will be limited to articles written in English.

followed by rapid abdominal aortic clamping has been an important initial step to prevent haemorrhagic death. Recently, there has been a movement towards less invasive techniques to manage non-compressible haemorrhage, such as resuscitative endovascular balloon occlusion of the aorta (REBOA). The actual concept of endovascular aortic occlusion for transient haemorrhagic control is not new. This technique was originally reported in 1954 by Lieutenant Colonel Carl W Hughes who performed the procedure on two critically ill soldiers.<sup>1</sup> Although both patients did not survive, the potential of its use as a resuscitative measure was proven. Later on, a study comparing REBOA to the standard method

of laparotomy and abdominal aortic clamping revealed a higher survival rate among the REBOA group.<sup>2</sup> However, it is important to note that REBOA is not a permanent solution; rather it is a temporary haemodynamic stabilisation of the patient prior to surgical management. A recent systematic review examining the outcomes of REBOA in the literature discusses the importance of a maximum aortic occlusion time of 60 min. This study also draws attention to the fact that most studies report on mortality outcomes with little information on the occlusion zone and complications.<sup>3</sup>

Our scoping review will provide a snapshot of the old and current, evidenced and non-evidenced based guidelines used in REBOA. It will identify empirical facts that inform researchers on the current practices of REBOA and possible gaps in knowledge. The primary objective of this research is to map the available evidence on the techniques and protocols of REBOA found in peer reviewed and Grey literature. Additionally, this scoping review will contribute to defining the challenges of implementation, as well as the clear set-up of comprehensive quality indicators and competency assessment of the technique.

## METHODS AND ANALYSIS

### Patient and public involvement

Patients and/or public were not involved in this study. The results will be disseminated through presentations at local, national, clinical and medical education conferences and through publication in a peer-reviewed journal.

To the authors' best knowledge, there is no existing published evaluation of the new generation of REBOA catheter in the trauma settings, which make a scoping review interestingly pertinent to this topic area. We will perform a systematic search in the following databases: MEDLINE, EMBASE, BIOSIS, COCHRANE CENTRAL, PUBMED and SCOPUS from the earliest available publications. Start date of data collection was January 2018. End date of the study is November 2018. This scoping review follows the scoping review framework developed by Arksey and O'Malley,<sup>4</sup> which has been enhanced further by Levac *et al*<sup>5</sup> and Joanna Briggs Institute (JBI).<sup>6</sup> The results will be reported following the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines.<sup>7</sup> This method includes the following five steps: (1) identifying the research question; (2) identifying relevant studies balancing breadth and comprehensiveness; (3) study selection using an iterative team approach; (4) charting the data and (5) collating, summarising and reporting the results as they relate to the study purpose and implications of the study findings for policy, practice and research.

### Stage 1: identifying the research question

Based on our described objectives, this primary review seeks to identify the following parameters:

- ▶ *Benefits of REBOA*: What are the clear indications, pitfalls and advantages of its use compared with other available modalities?

- ▶ *Application of REBOA*: Which selective population will benefit the most from its application through comprehensively designed algorithms?
- ▶ *Implementation of REBOA*: What are the challenges of the adoption of the technique into the armamentarium of advanced trauma centres? Special attention will be paid to the credentialing, quality indicators and competency assessment parameters.

In addition, emphasis will be focused on the following points:

1. Mapping the existing literature on REBOA technique.
2. Identifying features needed for the successful implementation of REBOA into trauma programmes.
3. Clarifying the important variables necessary for the evaluation of the technique, its outcome and its efficacy.
4. Reporting the complications and long-term outcomes associated with REBOA.
5. Identifying areas for future development.

We hypothesised that the current literature could be categorised in order to identify critical knowledge gaps and help in guiding future research activities.

### Stage 2: identifying relevant studies

A comprehensive review was developed with the help of an experienced health sciences librarian at the University of McGill using specific Medical Subject Headings terms and keywords related to REBOA to capture the relevant literature accurately. The search strategy follows the three-step approach recommended by JBI scoping review guidelines.<sup>5</sup> The search was initially conducted using Medline electronic database and saved to ensure reproducibility of the search results (box 1). Second, we identified relevant related terms and keywords ('balloon occlusion', 'embolisation, therapeutic', 'therapeutic occlusion', 'aorta', 'aorta occlusion', or 'artificial embolisation', combined with 'resuscitation', as well as 'REBOA'). The quest will be supplemented by a vast grey literature search through Google Scholar, organisational websites of various relevant organisations, our institutional database, conference abstract or reviews to identify any related studies. Finally, we will screen the bibliography of selected articles to identify articles relevant to this scoping review. We will frequently seek feedback from

#### Box 1 Search strategy developed for MEDLINE using Population, Intervention, Comparison, Outcome frame

##### Identify key concepts and provide synonyms of the following:

- ▶ *Population*: Resuscitative endovascular balloon occlusion of the aorta (REBOA) procedure data.
- ▶ *Intervention*: Data collected on the implementation of REBOA, complications and the variables used to evaluate its efficacy.
- ▶ *Comparison*: Successful REBOA performance and implementation versus non-successful.
- ▶ *Outcomes*: Identify key features needed to implement the REBOA technique and identify important variables to collect in order to evaluate its efficacy.

our research team to refine our search strategy and we will contact authors of relevant primary studies or reviews for further information if needed. We will also assess the quality of our search protocol using the PRESS 2015 Evidence-Based Checklist guidelines.<sup>8</sup> All references will be imported into an online bibliographic management programme (EndNote Library) ensuring the removal of duplicates. We will report the search strategy for the databases as outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.<sup>9</sup>

### Stage 3: study selection

Two independent reviewers (TP and YB) will apply a two-step approach screening to determine the eligibility of articles according to their inclusion and exclusion criteria. The eligibility criteria will be developed in consensus by the research team and serve as a filter for relevant sources. The first step will consist of a title and abstract scan and the second will entail a full-text review of all identified citations from step one. A second reviewer (OB) will intervene in case of scepticism of the first reviewers about inclusion eligibility of specific titles and abstracts. A sample of the retrieved articles (ie, 20%) will be screened by the second reviewer (OB) to ensure a consistent application of the eligibility criteria for inclusion in the review. Disagreements about study eligibility of the sampled articles will be discussed between the three reviewers until a consensus is reached and we will confer to a third reviewer (AB) if no agreement is reached.

### Inclusion criteria

The inclusion criteria are formulated based on the ‘Population, Intervention, Comparison, Outcome’ framework recommended by Schardt *et al* to improve searching PubMed for clinical questions.<sup>10</sup>

### Exclusion criteria

The following were excluded:

1. Cadaveric studies.

Table 1 Inclusion and exclusion criteria	
Inclusion criteria	Exclusion criteria
Studies describing the implementation of REBOA at the facility level	Cadaveric studies
Studies reviewing the outcomes of REBOA use in trauma care including	Animal studies
Studies describing REBOA use in trauma and emergency medicine	
Studies reporting complications of REBOA usage	
Studies reporting junctional bleeding at the groin level	
Studies reporting REBOA insertion in zones one and three	
Studies describing REBOA use in non-compressive haemorrhage	

REBOA, resuscitative endovascular balloon occlusion of the aorta.

2. Animal studies.

Inclusions and exclusions criteria are summarised in table 1.

### Stage 4: data charting

The research team will develop a data-charting form (table 2). Since a scoping review aims to provide a comprehensive view of the literature, data extracted from relevant studies will include general information about each article such as author, publication year, country, study purpose, settings, methodology, outcomes, key findings, reported challenges and limitations.

Table 2 Draft charting form

Study characteristics	First author last name Publication year Country Topic Purpose Publication type Study design Institutional academic status Funding
Technical analysis	Location of insertion Catheter size Time to deployment Artery accessed Type of access Guided insertion Type of guidance Zone of deployment Imaging to confirm the position Volume Partial occlusion Intermittent occlusion Occlusion time Deflation time Time of sheath removal Location of sheath removal CFA repair CFA imaging Training level of performer Accredited course versus peer training Credentials of performer Specialty of performer
Mechanism and severity	Mechanism Injury Severity Score Injury location Type of injury Subsequent surgical procedure Operation performed
Major outcome	Blood and blood product use Follow-up Complications Incidence of complications Type of complications Mortality Cause of death

CFA, common femoral artery.

In addition, we will extract information specific to areas of REBOA indication and protocol implementation. Data will include the topic of the article, the type of study (review, commentary, primary research), paper design and study settings. The data charting form will be refined during the full-text screening to capture all pertinent information from each study. Articles that meet the eligibility criteria will be organised in data charting form using Microsoft Excel database. Three reviewers (TP, YB and OB) will pilot the data extraction form to answer the relevant research question.

### Stage 5: synthesising

The fifth stage described by Arksey and O'Malley framework<sup>4</sup> for collating and summarising data will involve a descriptive numerical summary. We will summarise the quantitative data in a table outlining the overall number of studies, countries, topics, type, year of publication and study designs. Next, we will organise, stratify and analyse the themes identified from all studies. Our research team will constantly refine the data analysis.

### ETHICS AND DISSEMINATION

This review will be the first scoping review to examine the literature 'At Large' in relation to the topic of REBOA. We anticipate that the results will identify the different modalities of the application of REBOA through designated trauma centres.

Ethics approval is not necessary as the data are collected from publicly available sources and there will be no consultative phase. The results will be disseminated through presentations at local, national, clinical and medical education conferences and through publication in a peer-reviewed journal.

#### Author affiliations

<sup>1</sup>Department of Trauma and Acute Surgical Care, McGill University Health Centre, Montreal, Quebec, Canada

<sup>2</sup>Faculty of Medicine, McGill University, Montreal, Quebec, Canada

<sup>3</sup>Department of Surgery, Medical Research Institute, Alexandria University, Alexandria, Egypt

<sup>4</sup>Department of Surgery, Royal Canadian Medical Services, Montreal, Quebec, Canada

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