

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<u>http://bmjopen.bmj.com</u>).

If you have any questions on BMJ Open's open peer review process please email <u>info.bmjopen@bmj.com</u>

## **BMJ Open**

#### Resuscitative Endovascular Balloon Occlusion of the Aorta `REBOA': Indications – Advantages and Challenges of Implementation in Traumatic Non-Compressible Torso Hemorrhage: A Scoping Review Protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2018-027572
Article Type:	Protocol
Date Submitted by the Author:	29-Oct-2018
Complete List of Authors:	Bekdache, Omar; McGill University Health Centre, Surgery Paradis, Tiffany; McGill University Faculty of Medicine Shen, Yu Bai; McGill University Faculty of Medicine Elbahrawy, Aly; McGill University Health Centre Grushka, Jeremy; McGill University Health Centre Deckelbaum, Dan; McGill University Faculty of Medicine, Khwaja, Kosar; McGill University Health Centre Fata, Paola; McGill University Health Centre Razek, Tarek; McGill University Health Centre Beckett, Andrew; McGill University Health Centre
Keywords:	TRAUMA MANAGEMENT, ACCIDENT & EMERGENCY MEDICINE, Resuscitative Endovascular Balloon Occlusion of the Aorta, Damage control measures in trauma, therapeutic aortic occlusion, Trauma resuscitation

SCHOLARONE<sup>™</sup> Manuscripts

**BMJ** Open

### Resuscitative Endovascular Balloon Occlusion of the Aorta 'REBOA': Indications – Advantages and Challenges of Implementation in Traumatic Non-Compressible Torso Hemorrhage: A Scoping Review Protocol

Omar Bekdache <sup>1</sup> MD; Tiffany Paradis <sup>2</sup> BSc.; Yu Bai He Shen <sup>2</sup> BSc.; Aly Elbahrawy <sup>1,3</sup> MD; Jeremy Grushka <sup>1</sup> MD, MSc ; Dan L. Deckelbaum <sup>1</sup> MD, MPH ; Kosar Khwaja <sup>1</sup> MD, MSc ; Paola Fata <sup>1</sup> MD ; Tarek Razek <sup>1</sup> MD, FRCSC, FACS and Andrew Beckett <sup>1,4</sup>

MD, FRCSC, MSc.

- (1) Department of Trauma and Acute Surgical Care, MUHC
- <sup>(2)</sup> McGill University. Faculty of Medicine
- <sup>(3)</sup> Medical Research Institute, Alexandria University, Egypt
- <sup>(4)</sup> Royal Canadian Medical Services

<u>Correspondence to be sent to:</u> Omar Bekdache MD. McGill University Health Center. Montreal. Canada. (omar.bekdache@mail.mcgill.ca)

#### Abstract:

#### Introduction:

Hemorrhage 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 analyze 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 dates till January 15, 2018. The aim is to identify diverse studies related to the topic of REBOA. For a comprehensive search, we will explore organizational 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.

**Keywords:** Balloon occlusion of the Aorta – REBOA – therapeutic aortic occlusion – Damage control measures in trauma – Trauma resuscitation

#### **Article Summary**

#### 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 REBOA.
- Findings will have implications on researchers for recognizing 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
- Findings will be limited to articles written in English
- Contacts of researchers and experts for additional complementary information will be limited

#### **Introduction**

Mortality resulting from hemorrhage remains the leading cause of preventable death. In the case of an abdominal trauma with exsanguinating - life-threatening - injuries, laparotomy followed by rapid abdominal aortic clamping has been an important initial step to prevent hemorrhagic death. Recently, there has been a movement towards less invasive techniques to manage non-compressible hemorrhage, such as resuscitative endovascular balloon occlusion of the aorta (REBOA). The actual concept of endovascular aortic occlusion for transient hemorrhagic 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 amongst the REBOA group<sup>2</sup>. However, it is important to note that REBOA is not a permanent solution; rather it is a temporary hemodynamic stabilization 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 minutes. This study also draws attention to the fact

#### **BMJ** Open

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 nonevidenced 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 peered reviewed and Grey literature. Additionally, this scoping review will contribute to defining the challenges of implementation, as well as the clear setup of comprehensive quality indicators and competency assessment of the technique.

#### **Methods and Analysis:**

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. 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 Reviews and Meta-Analysis for Protocols (PRISMA-P) 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, summarizing 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:

- <u>Benefits of REBOA –</u> What are the clear indications, pitfalls, and advantages of its use compared to other available modalities?
- <u>Application of REBOA –</u> Which selective population will benefit the most from its application through comprehensively designed algorithms?
- <u>Implementation of REBOA –</u> What are the challenges of the adoption of the technique into the armamentarium of advanced trauma centers? 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
- Identifying features needed for the successful implementation of REBOA into trauma programs
- 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 hypothesized that the current literature could be categorized 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

Page 7 of 14

#### **BMJ** Open

librarian at the University of McGill using specific Medical Subject Headings (MeSH) 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 (Table 1). Second, we will identify relevant related terms and keywords ("balloon occlusion", "embolization, therapeutic", "therapeutic occlusion", "aorta", "aorta occlusion", or "artificial embolization", combined with "resuscitation", as well as "REBOA"). The quest will be supplemented by a vast grey literature search through Google Scholar, organizational websites of various relevant organizations, 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 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 program (EndNote<sup>R</sup> Library) ensuring the removal of duplicates. We will also report the search strategy for the databases in the online supplementary appendix as outlined in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement 9.

#### **Stage 3- Study Selection:**

Two independent reviewers (TP & 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 skepticism of the first reviewers about inclusion eligibility of specific titles and abstracts. A sample of the retrieved articles (i.e., 20 percent) 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 (PICO)' framework - recommended by Schardt, C et al. to improve searching PubMed for clinical questions <sup>10</sup>.

#### **Exclusion criteria:**

The following were excluded:

- 1. Studies describing the outcomes of REBOA use in non-trauma cases.
- 2. Studies including pediatric cases
- 3. Animal studies

Inclusions and exclusions criteria are summarized in table 2.

#### **Stage 4- Data Charting**

The research team will develop a data-charting form (Table 3). 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.

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 organized in data charting form using Microsoft Excel database. Three reviewers (TP, YB & OB) will pilot the data extraction form to answer the relevant research question.

#### **Stage 5- Synthesizing**

The fifth stage described by Arksey and O'Malley framework<sup>8</sup> for collating and summarizing data will involve a descriptive numerical summary. We will summarize the quantitative data in a table outlining the overall number of studies, countries, topics, type, year of publication, and study designs. Next, we will organize, stratify and analyze 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 centers.

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.

#### References

- nures 1. Hughes LCCW. Use of an Intra-Aortic Balloon Catheter Tamponade for Controlling Intra-Abdominal Hemorrhage in Man. Surgery, 1954;36(65).
- 2. Moore LJ, Brenner M, Kozar RA, et al. Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage. J Trauma Acute Care Surg. 2015;79(4):523-530; discussion 530-522.

ge 11 of 14	BMJ Open
3.	Gamberini E, Coccolini F, Tamagnini B, et al. Resuscitative Endovascular Balloon Occlusion of the Aorta in trauma: a systematic review of the literature.
4	World J Emerg Surg. 2017;12:42. Arksey H. O'Malley L. Scoping studies: towards a methodological framework
	Int J Soc Res Methodol 2005; 8:19–32.
5.	Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. Implement Sci 2010; 5:69.
6.	The Joanna Briggs Institute. Joanna briggs institute reviewers'manual 2015. 2015 https:// joannabriggs. org/ assets/ docs/ sumari/Reviewers- Manual_
	Methodology- for- JBI- Scoping- Reviews_2015_v2.pdf
7.	Moher D, Liberati A, Tetzlaff J, <i>et al.</i> Preferred reporting items for systematic reviews and meta-analyses: the PRISMA Statement. Open Med 2009; <b>3</b> :e123–30.
8.	McGowan J, Sampson M, Salzwedel DM, et al. PRESS peer review of electronic search strategies: 2015 guideline statement. J Clin Epidemiol 2016;75:40–6. 29.
9.	Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015:elaboration and explanation. BMJ 2015; 349:g7647–g7647.
10	9. Schardt, C., Adams, M.B., Owens, T. et al. Utilization of the PICO framework to improve searching PubMed for clinical questions. BMC Medical informatics and
	Decision Making. 2007, 7:16. 1186/1472-6947.
Autho	ors' Contribution - Author Statement:
	11

OB, TP, YBS, and AB contributed to the project idea and the conceptual design of the protocol. OB, AE, and AB supervised the research protocol. OB, TP, YBS conducted the literature review and the search strategy. OB drafted the protocol. AE, JG, DD, PF, kk, and TR contributed to editing and supervising of the search design. All authors approved the final manuscript. AB and TR are the guarantors of the review.

#### Acknowledgment of additional contribution:

The authors would like to acknowledge the assistance of Mrs. Tara Landry - Librarian at MUHC for her remarkable help in the acquisition of the research material and to recognize the great support of the Montreal General Hospital Foundation, the McGill University Health Centre Emergency Medicine and Adult Trauma Programs. <u>Funding</u>

#### <u>Statement:</u>

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

#### **Competing / Conflicts of interest statement:**

The research has no competing interest or any conflicts of interest to disclose.

Word Count: 1530

#### Table 1. Search Strategy developed for MEDLINE using PICO 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.

#### Table 2. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Studies describing the implementation of	Studies describing the outcomes of
REBOA at the facility level	REBOA use in non-trauma cases such as orthopedic and post-partum hemorrhage
Studies reviewing the outcomes of REBOA see in trauma care including	Studies describing the use of REBOA in the setting of limb amputation or solely for orthopedic indications
Studies describing REBOA use in trauma and emergency medicine	Pediatric studies
Studies reporting complications of REBOA usage	Animal studies
Studies reporting junctional bleeding at the groin level	Elective procedures
Studies reporting REBOA insertion in zones one and three	
Studies describing REBOA use in non- compressive hemorrhage	

#### Table 3. Draft Charting form

Study Characteristics	First Author last name Publication year
	Country

	Торіс
	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
	lime of sheath removal
	Location of sheath removal
	CFA repair
	CFA imaging
Mechanism and severity	Mechanism
, second s	ISS – Injury Severity Score
	Injury location
	Type of injury
	Subsequent surgical procedure
	Operation Performed
Maior Outcome	Blood and blood product use
	Follow Up
	Complications
	Incidence of complications
	Type of complications
	Mortality
	Cause of death

## **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 Hemorrhage

Journal:	BMJ Open
Manuscript ID	bmjopen-2018-027572.R1
Article Type:	Protocol
Date Submitted by the Author:	17-Dec-2018
Complete List of Authors:	Bekdache, Omar; McGill University Health Centre, Surgery Paradis, Tiffany; McGill University Faculty of Medicine Shen, Yu Bai; McGill University Faculty of Medicine Elbahrawy, Aly; McGill University Health Centre Grushka, Jeremy; McGill University Health Centre Deckelbaum, Dan; McGill University Faculty of Medicine, Khwaja, Kosar; McGill University Health Centre Fata, Paola; McGill University Health Centre Razek, Tarek; McGill University Health Centre Beckett, Andrew; McGill University Health Centre
<b>Primary Subject Heading</b> :	Surgery
Secondary Subject Heading:	Emergency medicine, Intensive care, Surgery
Keywords:	TRAUMA MANAGEMENT, ACCIDENT & EMERGENCY MEDICINE, Resuscitative Endovascular Balloon Occlusion of the Aorta, Damage control measures in trauma, therapeutic aortic occlusion, Trauma resuscitation
	·

#### SCHOLARONE<sup>™</sup> Manuscripts

**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 Hemorrhage

Omar Bekdache<sup>1</sup> MD; Tiffany Paradis<sup>2</sup> BSc.; Yu Bai He Shen<sup>2</sup> BSc.; Aly Elbahrawy<sup>1,3</sup> MD; Jeremy Grushka<sup>1</sup> MD, MSc; Dan L. Deckelbaum<sup>1</sup> MD, MPH; Kosar Khwaja<sup>1</sup> MD, MSc; Paola Fata<sup>1</sup> MD; Tarek Razek<sup>1</sup> MD, FRCSC, FACS and Andrew Beckett<sup>1,4</sup> MD, FRCSC, MSc.

- (1) Department of Trauma and Acute Surgical Care, MUHC
- <sup>(2)</sup> McGill University. Faculty of Medicine
- <sup>(3)</sup> Medical Research Institute, Alexandria University, Egypt
- <sup>(4)</sup> Royal Canadian Medical Services

Omar Bekdache: <u>omar.bekdache@mail.mcgill.ca</u> Tiffany Paradis: <u>tiffany.paradis@mail.mcgill.ca</u> Yu bai He Shen: <u>yu.b.shen@mail.mcgill.ca</u> Aly Elbahrawy: <u>aly.elbahrawy@mail.mcgill.ca</u> Jeremy Grushka: jeremy.grushka@mcgill.ca Dan Deckelbaum: <u>dan.deckelbaum@mcgill.ca</u> Kosar Khwaja: <u>dr.k.khwaja@mcgill.ca</u> Rosar Khwaja: <u>dr.k.khwaja@mcgill.ca</u> Paola Fata: <u>paola.fata@mcgill.ca</u> Tarek Razek: <u>tarek.razek@mcgill.ca</u> Andrew Beckett: <u>andrew.beckett@mcgill.ca</u>

> Correspondence to be sent to: Omar Bekdache MD 1650 Cedar Avenue. Montreal General Hospital. H3G1A4 McGill University Health Center. Montreal. Canada. (omar.bekdache@mail.mcgill.ca)

#### Abstract:

#### Introduction:

Hemorrhage 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 analyze 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

1	
2	
3 4	studies related to the topic of REBOA. For a comprehensive search, we will explore
5	
6	organizational websites, key journals, and hand-search reference lists of key studies.
7	
8	Data will be charted and sorted using a descriptive analytical approach.
9 10	
10	Ethics and Dissemination:
12	Tables summered is not assessed as the data and callested from antibility socilable
13	Etnics approval is not necessary as the data are collected from publicly available
14	The market will be an example time where The market will be discussioned at
15	sources and there will be no consultative phase. The results will be disseminated
16 17	the second second states at least section of a line of an elicit state time section section second
17	through presentations at local, national, clinical and medical education conferences
19	and through multipotion in a near reviewed in small
20	and through publication in a peer-reviewed journal.
21	
22	Keywords: Balloon occlusion of the Aorta – REBOA – therapeutic aortic occlusion -
23	
24 25	Damage control measures in trauma – Trauma resuscitation
26	
27	
28	
29	
30	
31	
33	
34	
35	
36	
37	
38	
40	
41	
42	
43	
44	
45 46	
40	
48	
49	
50	
51	
52 53	
54	
55	
56	
57	
58	
59 60	
00	

#### **Article Summary**

#### 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 REBOA.
- Findings will have implications on researchers for recognizing 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
- Contacts of researchers and experts for additional complementary information will be limited

#### **Introduction**

Mortality resulting from hemorrhage remains the leading cause of preventable death. In the case of an abdominal trauma with exsanguinating - life-threatening - injuries, laparotomy followed by rapid abdominal aortic clamping has been an important initial step to prevent hemorrhagic death. Recently, there has been a movement towards less invasive techniques to manage non-compressible hemorrhage, such as resuscitative endovascular balloon occlusion of the aorta (REBOA). The actual concept of endovascular aortic occlusion for transient hemorrhagic 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 amongst the REBOA group <sup>2</sup>. However, it is important to note that REBOA is not a permanent solution; rather it is a temporary hemodynamic stabilization 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 minutes. This study also draws attention to the fact that most studies report on mortality outcomes with little information on the occlusion zone and complications  $^{3}$ .

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 peered reviewed and Grey literature. Additionally, this scoping review will contribute to defining the challenges of implementation, as well as the clear setup 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 Reviews and Meta-Analysis for Protocols (PRISMA-P) guidelines <sup>7</sup>. This method includes the following five steps: (1) identifying the research question; (2) identifying an iterative team approach; (4) charting the data; and (5) collating, summarizing 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:

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

#### BMJ Open

• <u>Benefits of REBOA –</u> What are the clear indications, pitfalls, and advantages
of its use compared to other available modalities?
• <u>Application of REBOA –</u> Which selective population will benefit the most
from its application through comprehensively designed algorithms?
• <u>Implementation of REBOA –</u> What are the challenges of the adoption of the
technique into the armamentarium of advanced trauma centers? 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 programs
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 hypothesized that the current literature could be categorized 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 (MeSH) 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 (Table 1). Second, we identified relevant related terms and keywords ("balloon occlusion", "embolization, therapeutic", "therapeutic occlusion", "aorta", "aorta occlusion", or "artificial embolization", combined with "resuscitation", as well as "REBOA"). The quest will be supplemented by a vast grey literature search through Google Scholar, organizational websites of various relevant organizations, 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 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 program (EndNote<sup>R</sup> 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 (PRISMA) statement <sup>9</sup>.

#### **Stage 3- Study Selection:**

Two independent reviewers (TP & 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 skepticism of the first reviewers about inclusion eligibility of specific titles and abstracts. A sample of the retrieved articles (i.e., 20 percent) 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 (PICO)' framework - recommended by Schardt, C et al. to improve searching PubMed for clinical questions <sup>10</sup>.

#### **Exclusion criteria:**

The following were excluded:

- 1. Cadaveric studies
- 2. Animal studies

Inclusions and exclusions criteria are summarized in table 2.

#### **Stage 4- Data Charting**

The research team will develop a data-charting form (Table 3). 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.

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 organized in data charting form using Microsoft Excel database. Three reviewers (TP,

YB & OB) will pilot the data extraction form to answer the relevant research question.

#### **Stage 5- Synthesizing**

The fifth stage described by Arksey and O'Malley framework<sup>8</sup> for collating and summarizing data will involve a descriptive numerical summary. We will summarize the quantitative data in a table outlining the overall number of studies, countries, topics, type, year of publication, and study designs. Next, we will organize, stratify and analyze 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 centers. 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.

#### **References**

- Hughes LCCW. Use of an Intra-Aortic Balloon Catheter Tamponade for Controlling Intra-Abdominal Hemorrhage in Man. *Surgery*. 1954;36(65).
- Moore LJ, Brenner M, Kozar RA, et al. Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage. *J Trauma Acute Care Surg.* 2015;79(4):523-530; discussion 530-522.
- Gamberini E, Coccolini F, Tamagnini B, et al. Resuscitative Endovascular Balloon Occlusion of the Aorta in trauma: a systematic review of the literature. *World J Emerg Surg.* 2017;12:42.
- Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005; 8:19–32.
- 5. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. Implement Sci 2010; 5:69.
- The Joanna Briggs Institute. Joanna briggs institute reviewers'manual 2015.
   2015 https:// joannabriggs. org/ assets/ docs/ sumari/Reviewers- Manual\_ Methodology- for- JBI- Scoping- Reviews\_ 2015\_v2.pdf
- Moher D, Liberati A, Tetzlaff J, *et al.* Preferred reporting items for systematic reviews and meta-analyses: the PRISMA Statement. Open Med 2009; 3:e123– 30.
- McGowan J, Sampson M, Salzwedel DM, et al. PRESS peer review of electronic search strategies: 2015 guideline statement. J Clin Epidemiol 2016;75:40–6. 29.
- 9. Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for

systematic review and meta-analysis protocols (PRISMA-P) 2015:elaboration and explanation. BMJ 2015; 349:g7647–g7647.

 Schardt, C., Adams, M.B., Owens, T. et al. Utilization of the PICO framework to improve searching PubMed for clinical questions. BMC Medical informatics and Decision Making. 2007, 7:16. 1186/1472-6947.

#### **Authors' Contribution - Author Statement:**

OB, TP, YBS, and AB contributed to the project idea and the conceptual design of the protocol. OB, AE, and AB supervised the research protocol. OB, TP, YBS conducted the literature review and the search strategy. OB drafted the protocol. AE, JG, DD, PF, kk, and TR contributed to editing and supervising of the search design. All authors approved the final manuscript. AB and TR are the guarantors of the review.

#### Acknowledgment of additional contribution:

The authors would like to acknowledge the assistance of Mrs. Tara Landry -Librarian at MUHC for her remarkable help in the acquisition of the research material and to recognize the great support of the Montreal General Hospital Foundation, the McGill University Health Centre Emergency Medicine and Adult Trauma Programs.

#### **Funding Statement:**

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

#### **Competing / Conflicts of interest statement:**

The research has no competing interest or any conflicts of interest to disclose.

#### **Word Count:** 1605

#### **Table 1. Search Strategy developed for MEDLINE using PICO Frame**

Identify key concepts and provide synonyms of the following:

<u>Population:</u> 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.

# Table 2. 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 hemorrhage	

#### Table 3. 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 vs. peer training Credentials of performer
Mechanism and severity	Mechanism ISS – 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

to peer terien ony