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CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

Resuscitative Endovascular Balloon Occlusion of the Aorta for Control of Non-Compressible Truncal Hemorrhage: A Review of Clinical Effectiveness and Guidelines

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Context and Policy Issues

Truncal hemorrhage is one of the leading causes of death following traumatic injury in Canada among both military[1] and civilian populations.[2] A study of all Canadian Forces members who died in Afghanistan over a two year period found that torso hemorrhage accounted for 33% of deaths,[1] and a study of all deaths occurring over a five year period at a level one trauma center in Toronto, Canada found that 15% of all deaths were due to hemorrhage, primarily from the torso.[2]

Hemorrhage is broadly classified as compressible and non-compressible. Compressible hemorrhages are due to injuries to the extremities and can be managed with direct pressure or tourniquets, whereas non-compressible hemorrhage cannot be controlled by direct pressure and involves vascular disruption in the thoracic cavity, solid abdominal organs, named axial torso vessel, or pelvic fracture with ring disruption.[3] Mortality rates among patients with non-compressible truncal hemorrhaging (NCTH) are very high, with estimates ranging from 18% to 86%,[4,5] and among military populations approximately 75% of NCTH deaths occur before hospital admission.[5] Death can occur quickly due to severe blood loss, and quickly addressing blood loss has the potential to greatly improve survival rates; studies from wars in Iraq and Afghanistan indicate that among potentially survivable injuries, 50% to 80% of deaths were due to severe blood loss.[6,7]

One strategy to quickly address blood loss due to NCTH is to administer pre-hospital treatment.[8] However, standard pre-hospital treatment options are extremely limited, and include rapid transport to a care facility and administration of blood products.[1] Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a promising new treatment for addressing NCTH blood loss in the pre-hospital setting.[8] REBOA is achieved with a balloon catheter that occludes large vessels to reduce blood loss, and the balloon can be inflated in different locations within the thoracic cavity depending on the location of the injury.[8,9] However, the efficacy and safety of this device compared to usual treatment is not well known.[9]

The purpose of this report is to examine the comparative clinical effectiveness and safety of REBOA versus usual treatment (e.g., rapid evacuation, administration of blood product) in pre-hospital settings, and to examine clinical guidelines regarding the use of REBOA in pre-hospital settings.

Research Questions

1. What is the clinical effectiveness of resuscitative endovascular balloon occlusion of the aorta for control of non-compressible truncal hemorrhage in the pre-hospital environment?
2. What are the evidence-based guidelines regarding the use of resuscitative endovascular balloon occlusion of the aorta for the management of non-compressible truncal hemorrhage in the pre-hospital environment?

Key Findings

No relevant clinical effectiveness evidence or evidence-based guidelines regarding the use of resuscitative endovascular balloon occlusion of the aorta for the management of non-compressible truncal hemorrhage in the pre-hospital environment were identified.

Methods

Literature Search Methods

A limited literature search was conducted on key resources including Ovid Medline, PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases and a focused Internet search. No methodological filters were applied to limit retrieval by publication type. The search was limited to English language documents published between January 1, 2013 and February 6, 2018.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults with non-compressible truncal hemorrhage (e.g., in the chest, abdomen, or pelvis) in the pre-hospital setting
Intervention	Resuscitative endovascular balloon occlusion of the aorta (REBOA)
Comparator	Usual treatment (e.g., management of any compressible hemorrhage, provision of blood product, rapid evacuation)
Outcomes	Q1: Clinical effectiveness and safety (e.g., temporary hemorrhage control, blood pressure control/improvement, prevention of death due to blood loss, transfusion requirement) Q2: Evidence-based guidelines
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2013. Additionally, clinical practice guidelines with unclear methodology were excluded.

Summary of Evidence

Quantity of Research Available

A total of 295 citations were identified in the literature search. Following screening of titles and abstracts, 269 citations were excluded and 26 potentially relevant reports from the electronic search were retrieved for full-text review. Sixteen potentially relevant publications were retrieved from the grey literature search. Of these potentially relevant articles, 42

publications were excluded for various reasons, while no publications met the criteria for inclusion in this report. Appendix 1 describes the PRISMA flowchart of the study selection. References of potential interest are provided in Appendix 2.

Summary of Findings

No relevant clinical effectiveness or guidelines were identified; therefore, a summary of findings cannot be provided.

Conclusions and Implications for Decision or Policy Making

This review did not identify any studies evaluating the comparative effectiveness of REBOA versus usual care in the pre-hospital setting, or any evidence-based clinical guidelines. Given the lack of identified evidence, the effectiveness of REBOA versus usual care and guidelines for the use of REBOA in pre-hospital settings remains unclear.

A few case studies of REBOA in the pre-hospital setting indicate it may be a promising treatment. A case series of four patients injured during wartime found that pre-hospital use of REBOA resulted in immediate normalization of blood pressure, and all four patients survived transfer to the next level of care.[10] Two other case reports indicate favorable outcomes (i.e., survival) for civilians in the pre-hospital setting,[11,12] although long-term complications due to use of REBOA included leg amputation.[12] Although these case reports provide some preliminary evidence of the clinical effectiveness of REBOA, a much stronger research base is needed to make any conclusion about the effectiveness of REBOA and guidelines for its use. Future research comparing REBOA with usual treatment in pre-hospital settings may help reduce uncertainty.

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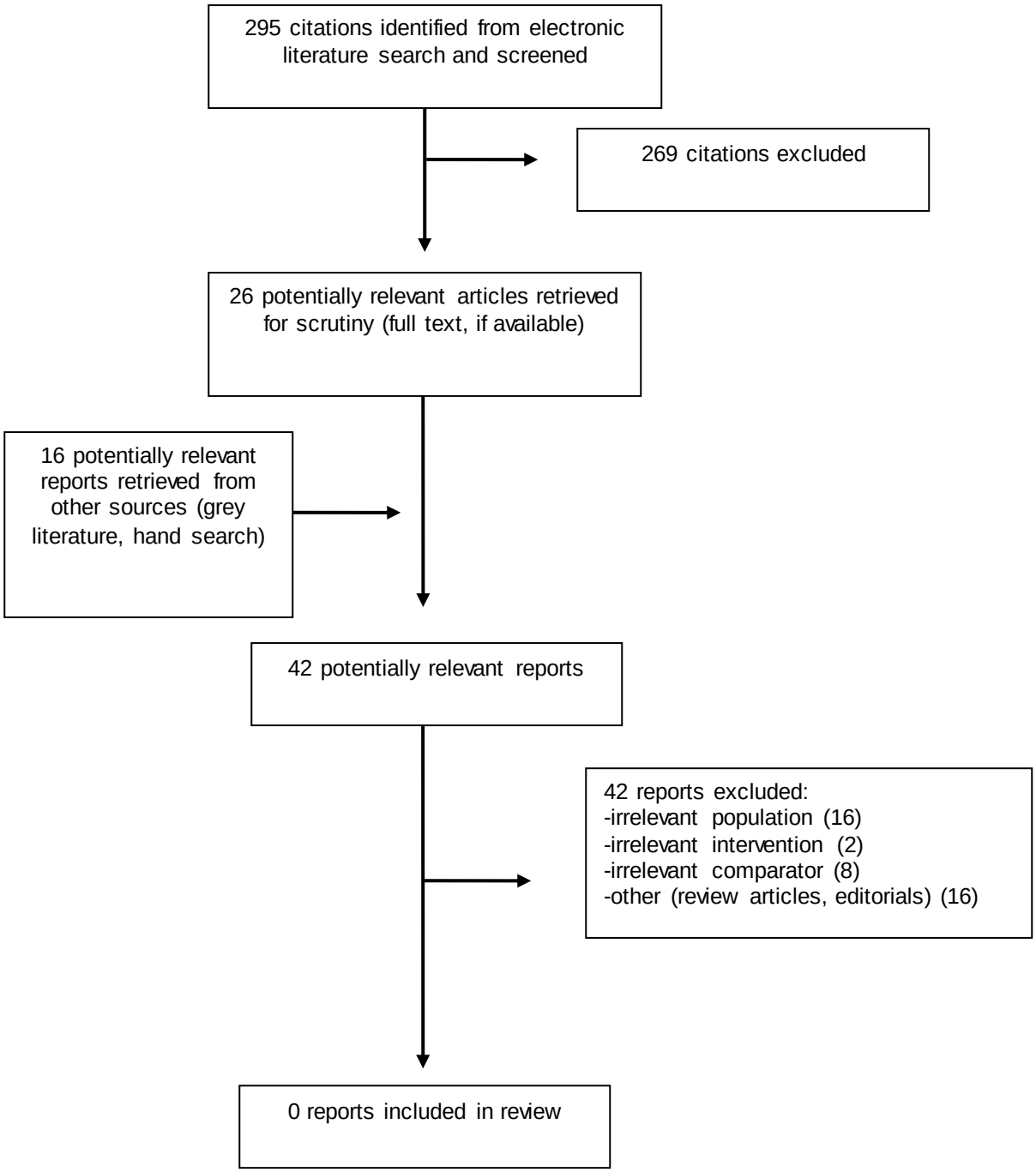
Appendix 1: Selection of Included Studies



Appendix 2: References of Potential Interest

Clinical Practice Guidelines – no systematic methodology

Resuscitative endovascular balloon occlusion of the aorta (REBOA) for hemorrhagic shock [Internet]. Houston (TX): United States Army Institute of Surgical Research; 2017 [cited 2018 Mar 7] (Joint trauma system cloinical practice guideline; no. JTS CPG 38). Available from:
http://www.usaisr.amedd.army.mil/cpgs/REBOA_%2006Jul2017CORRECTED.pdf

Feasibility of teaching REBOA to nonsurgical medical specialists in pre-hospital setting – simulated (non-human) study

Teeter W, Romagnoli A, Glaser J, Fisher AD, Pasley J, Scheele B, et al. Resuscitative endovascular balloon occlusion of the aorta: pushing care forward. J Spec Oper Med. 2017;17(1):17-21.

Review Article – complications and mitigating strategies for REBOA

Davidson AJ, Russo RM, Reva VA, Brenner ML, Moore LJ, Ball C, et al. The pitfalls of REBOA: risk factors and mitigation strategies. J Trauma Acute Care Surg. Oct 4;2017

Review Articles – feasibility in pre-hospital military settings

Knight RM. A perspective on the potential for battlefield resuscitative endovascular balloon occlusion of the aorta. J Spec Oper Med. 2017;17(1):72-5.

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