Canadian Journal of Emergency Medicine
https://doi.org/10.1007/s43678-024-00680-w

NEED TO KNOW: CJEM JOURNAL CLUB

Emergency department resuscitative endovascular balloon occlusion of the aorta in trauma patients with exsanguinating hemorrhage: the UK-REBOA randomized clinical trial

Thariq Badiudeen[1] · **Venkatesh Thiruganasambandamoorthy**[1,2] · **Hans Rosenberg**[1]

Received: 12 December 2023 / Accepted: 17 March 2024

Full Citation: Jansen JO, Hudson J, Cochran C, et al. Emergency Department Resuscitative Endovascular Balloon Occlusion of the Aorta in Trauma Patients With Exsanguinating Hemorrhage: The UK-REBOA Randomized Clinical Trial. *JAMA*. Published online October 12, 2023. https://doi.org/10.1001/jama.2023.20850

Abstract Link: https://jamanetwork.com/journals/jama/article-abstract/2810757

Article Type: Therapy

Ratings: Methods—4/5; Usefulness—3/5

Introduction

Background

Hemorrhage is the primary preventable cause of death in trauma [1]. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a hemorrhage control technique with convincing evidence from animal studies [2], but limited evidence in humans.

Objectives

To investigate the effect of REBOA on 90-day mortality in emergency department (ED) trauma patients with hemorrhage.

Methods

Design

Multi-center pragmatic, Bayesian randomized clinical trial (RCT). Bayesian trials allow prior data to be incorporated with trial data, allowing for updated probability distributions for parameters of interest.

Setting

Sixteen major trauma centers in the UK between October 2017 and March 2022.

Subjects

Patients ≥ 16 years old with confirmed or suspected life-threatening torso hemorrhage.

Intervention

REBOA plus standard trauma care.

Comparator

Standard trauma care alone.

Outcomes

Primary outcome was all-cause mortality at 90 days. Secondary outcomes were mortality at various time points, definitive hemorrhage control procedures and their timing, complications, length of stay, blood product use, and cause of death.

✉ Thariq Badiudeen
Tbadiudeen@toh.ca

[1] Department of Emergency Medicine, University of Ottawa, Ottawa, ON, Canada

[2] Ottawa Hospital Research Institute, Ottawa, ON, Canada

Published online: 25 March 2024

Results

90 patients were included in an intention-to-treat analysis ($n=46$, REBOA plus standard care group; $n=44$, standard care group. One standard group patient withdrew consent, $n=43$. The trial was stopped early due to REBOA plus standard care group safety issues after meeting the stopping rule for harm [>90% probability of odds ratio > 1 for mortality at 90 days during second interim analysis]. The primary outcomes were analyzed using Bayesian logistic regression, meaning prespecified prior distributions were used to obtain posterior distributions after observing the data. Select outcomes are displayed in Table 1. There was an absolute risk reduction of −0.12 (95% CrI −0.33 to 0.08), with a relative risk of 1.29 (CrI 0.84–2.02), a relative risk reduction of −0.29 (95% CrI −1.02 to 0.16), and a number needed to treat of −8.00 (−3.02 to 12.3).

Appraisal

Strengths

- First RCT examining REBOA in traumatic hemorrhage management.
- Simple inclusion criteria.
- Patient-centered primary outcome.
- Standardized REBOA training across sites.

Weaknesses

- Prolonged prehospital time, upwards of 1.5 h from time of injury to ED arrival in both groups.
- Non-standardized REBOA equipment (e.g., manufacturer, lumen, balloon size).
- Low-total REBOA deployments across the 4.5-year long trial period (19 deployments in REBOA plus standard care group, 2 deployments in standard care group); however, the UK, much like Canada sees roughly similar low volumes of penetrating trauma.
- Potential skill deterioration given low frequency of REBOA deployments.

Context

UK-REBOA is the first RCT of REBOA in trauma hemorrhage control.

Study sites had low-frequency REBOA deployments with prolonged prehospital times; most enrolled patients suffered blunt trauma. It is unknown whether centers with higher-frequency REBOA deployment would demonstrate the same lack of benefit and potential harms of REBOA found in UK-REBOA. The same speculation holds for penetrating trauma. Additionally, without detailed descriptions of the REBOA training requirements and non-standardized REBOA devices, the findings should be interpreted carefully [3].

Dr. Jacinthe Lampron, Medical Trauma Director of The Ottawa Hospital, states "the benefits of REBOA in this trial may be outweighed by the time lost. The control group had faster access to definitive hemorrhage control possibly contributing to their improved outcomes. This study should make Canadian trauma providers question the clinical value of using REBOA for trauma patients."

Table 1 Primary and select secondary outcome results

Outcome	REBOA + Standard care ($n=46$)	Standard care alone ($n=44$)	Effect estimate (95% Crl)	Posterior probability of OR > 1, %	Absolute difference (95% CrI), %
Primary outcome					
All-cause mortality at 90 days (%)	54	42	OR, 1.58 (0.72–3.52)	86.9	11.3 (−8.1 to 30.1)
Secondary outcome					
Death within 24 h (%)	37	23	OR, 1.85 (0.79–4.46)	91.8	12.5 (−5.0 to 29.6)
Underwent a definitive hemorrhage control procedure (%)	30	43	OR, 0.60 (0.27–1.37)		−11.5 (−29.6 to 7.1)
Median time from randomization to definitive hemorrhage control procedure, min (IQR)	83 (56–156)	64 (34–83)			

CrI credible interval, *IQR* interquartile range, *OR* odds ratio

Bottom line

REBOA in trauma patients with hemorrhage does not reduce, and may increase, mortality compared to standard care. Future larger studies are needed to accurately address the role of REBOA before discrediting its utility. In Canadian hospitals, REBOA should be deployed on a case-by-case basis and limited to centers familiar with REBOA.

Acknowledgements We would like to thank Dr. Jacinthe Lampron for her expert input.

Declarations

Conflict of interest The authors have no conflicts of interest to declare.

References

1. Jenkins DH, Cioffi WG, Cocanour CS, Davis KA, Fabian TC, Jurkovich GJ, Rozycki GS, Scalea TM, Stassen NA, Stewart RM. Position statement of the Coalition for National Trauma Research on the National Academies of Sciences, Engineering and Medicine report, A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths aft. J Trauma Acute Care Surg. 2016;81:816–8. https://doi.org/10.1097/TA.0000000000001218.
2. White JM, Cannon JW, Stannard A, Markov NP, Spencer JR, Rasmussen TE. Endovascular balloon occlusion of the aorta is superior to resuscitative thoracotomy with aortic clamping in a porcine model of hemorrhagic shock. Surgery. 2011;150:400–9. https://doi.org/10.1016/j.surg.2011.06.010.
3. Tisherman S, Brenner M. Contemporary adjuncts to hemorrhage control. JAMA. 2023;330:E1–3. https://doi.org/10.1001/jama.2023.20850.