



ED REBOA for Exsanguinating Hemorrhage – The UK REBOA Trial

Key Article

- Jansen JO, et al. Emergency department resuscitative endovascular balloon occlusion of the aorta in trauma patients with exsanguinating hemorrhage. The UK-REBOA Randomized Clinical Trial. JAMA. 2023; published online October 12, 2023.

Background

- Hemorrhage is the most common cause of preventable death after trauma.
- Bleeding originating from the torso is particularly challenging because it cannot be controlled without surgery.
- Temporary aortic occlusion can be used to limit hemorrhage and maintain cerebral and coronary perfusion until definitive hemorrhage control is achieved.
- REBOA is a novel technique that has been shown to be effective in animal models.
- The evidence for REBOA in humans, however, has produced divergent results.
- At present, ACEP and the American College of Surgeons recommends REBOA for traumatic life-threatening hemorrhage below the diaphragm in patients with traumatic shock who are unresponsive or transiently responsive to resuscitation, and for patients arriving at the hospital in cardiac arrest from trauma presumed to be from life-threatening hemorrhage below the diaphragm.

Objective

- To examine the effectiveness of REBOA and standard care compared to standard care alone for the management of uncontrolled hemorrhage.

Methods

- Multicenter, open label, Bayesian, group-sequential, registry-enabled, randomized clinical trial.
- 16 major trauma centers in the UK
- Patients
 - Inclusion criteria
 - Adults aged ≥ 16 years
 - Presented to major trauma centers in the UK.
 - Confirmed or suspected life-threatening torso hemorrhage deemed amenable to REBOA.
 - Exclusion criteria
 - Known or thought to be pregnant.
 - Had nonsurvivable injuries.
- Intervention
 - Randomized 1:1 to either REBOA with standard care or standard care alone.
 - REBOA with standard care
 - Clinicians using REBOA were required to complete the trial's training package.
 - Trial did not prescribe or mandate a particular REBOA product.

- Level of occlusion (Zone I or Zone III) left to the judgment of the attending physician.
 - Standard care alone
 - Patients received expected care that is provided at major trauma center – intubation, balanced blood product transfusion, early operative or endovascular hemorrhage control.
 - Could also include open aortic occlusion.
- Primary outcome
 - All-cause mortality at 90 days
- Secondary Outcomes
 - Mortality at 6 months, in-hospital, 24 hours, 6 hours, or 3 hours
 - Need for definitive hemorrhage control procedures.
 - Time to commencement of definitive hemorrhage control procedures
 - Complications
 - Length of stay
 - Blood product use
 - Cause of death

Results

- 90 patients enrolled.
 - REBOA with standard care: 46 patients
 - Standard care: 44 patients
- Baseline characteristics
 - Male: 69%
 - Blunt trauma: 97%
 - 23% required cardiopulmonary resuscitation upon ED arrival.
 - More cases of hypotension among REBOA patients upon ED arrival
 - Higher Abbreviated Injury Scale scores for the head region among REBOA patients
- Treatment Pathways for REBOA
 - 46 patients who received REBOA with standard care.
 - 19 (41%) had REBOA inserted and inflated
 - 17 (37%) responded to other resuscitative efforts and REBOA not needed
 - 2 (4%) deteriorated before arterial access could be established
 - 8 (17%) where arterial access could not be established
 - Zone I inflation: 10 patients (53%)
 - Zone III inflation: 9 patients (47%)
 - Median time from arrival to REBOA inflation: 32 min
 - Median duration of REBOA inflation: 29 min
- **Primary Outcome – All-cause 90-day mortality**
 - REBOA with standard care: 54%
 - Standard care: 42%
 - OR mortality at 90 days for REBOA with standard care: 1.58
- Secondary Outcomes
 - ORs for mortality at 6 months, in-hospital, 24, 6, and 3 hours all increased for REBOA with standard care.
 - More deaths due to bleeding in the REBOA and standard care group – most deaths occurred within 24 hours and most within 3 hours.

- Median time from randomization to definitive hemorrhage control was 19 min longer in the REBOA and standard care group.

Limitations Identified by the Authors

- Trial has an overall small size.
- Trial performed in the UK where blunt trauma predominates – may not be generalizable.
- Low proportion of patients actually had REBOA deployed and inflated.
- Some baseline differences between the groups
- Mortality in the current trial higher than other studies of hemorrhage control interventions

Author conclusions

- REBOA with standard care in trauma patients with exsanguinating hemorrhage did not reduce 90-day all-cause mortality compared with standard care alone.