EVMS EM JC CRITICAL REVIEW FORM:

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Citation:

Gorman, E. et.al., **High resuscitative endovascular balloon occlusion of the aorta procedural volume is associated with improved outcomes: An analysis of the aorta registry.** Journal of Trauma and Acute Care Surgery, 91(5), 781–789. (2021)

Background:

REBOA or Resuscitative Endovascular Balloon Occlusion of the Aorta is a method of hemorrhage control initially described in military casualties with non-compressible torso hemorrhage. It has gained increased popularity in trauma settings where it can serve as a bridge to open surgical control of hemorrhage in patients at risk for imminent cardiovascular collapse from hemorrhagic shock. That stated, the use of REBOA remains controversial as there is no high-grade evidence regarding patient-centered outcomes and potential harms can be significant including arterial dissection, thromboembolism as well as extremity and spinal cord ischemia.

Current guidelines from the ACS Committee on Trauma and ACEP include the following recommendations:

REBOA is less invasive than resuscitative thoracotomy and in skilled hands may be more rapidly applied as compared with resuscitative thoracotomy.

REBOA is indicated for traumatic life-threatening hemorrhage below the diaphragm in patients in hemorrhagic shock who are unresponsive or transiently responsive to resuscitation.

The major rate-limiting step to REBOA is the ability to safely and efficiently cannulate the common femoral artery (CFA) in a hypovolemic patient

An acute care surgeon must be immediately available to definitively address the specific cause of hemorrhage to avert the dire complications of truncal and or spinal cord ischemia from prolonged aortic occlusion.

Any institution performing REBOA should enroll patients in the American Association for the Surgery of Trauma, multi-institutional Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery registry which was the source of the study we are reviewing here.

Study Hypothesis: REBOA outcomes are improved in centers with high REBOA utilization.

Primary outcome: to compare the mortality rate between high and low volume REBOA centers. The secondary outcome was to compare REBOA-related complication rates.

Study Methodology:

This was a 5-year retrospective analysis of the prospective observational American Association for the Surgery of Trauma Multicenter Trials Committee AORTA registry. The analysis

was between January 1, 2014, and November 6, 2018. The patients eligible to be included were 18 years and older undergoing aortic occlusion (AO) in the acute phases after injury.

Primary endpoint: in-hospital mortality stratified by the volume of REBOA deployments.

Secondary endpoint: complications stratified by volume group and type of device over the duration of the study period.

The optimal cutpoint was to include a minimum of 50 patients in each cohort from at least five different centers for comparison. **Low volume centers** were centers submitting less than 10 REBOA cases, **Average volume centers** were with 11 to 30 REBOA cases, and **High volume centers** reported more than 30 REBOA cases.

What were the results

Total of 495 patients underwent REBOA with a mean age of 43 years and males represented 75% of enrolled patients

Blunt trauma was the most common mechanism of injury at 80%

REBOA was more likely to be performed in the ED in high and average volume centers

CPR during initiation of REBOA was more likely to occur in the high-volume group

Vessel cannulation by ultrasound or direct cutdown was more likely in high-volume centers

Zone 1 deployments were more likely to occur in high-volume centers.

Improvement in post-occlusion hemodynamics was more likely to occur in patients undergoing REBOA at high-/average volume institutions (76.5 vs. 70%)

High-volume REBOA centers median time from admission to start of REBOA was 15 minutes; vs. average, 27 minutes vs. low, 35 minutes

There was NO difference in unadjusted mortality between High (57%), Average (60%) and Low (67%) p= 0.35

Multivariate modeling was performed to assess factors associated with lower mortality and included:

1. Signs of life at time of REBOA placement
2. Hemodynamic stability after REBOA placement
3. Zone III placement
4. High volume REBOA centers

Factors associated with lower risk of complications included use of smaller #7 French introducer sheathe and CPR at the time of REBOA. The most common complications were distal embolism (4.2%) followed by extremity ischemia (4.0%)

The REBOA volume group was not associated with decrease in complication rate

A multilevel linear model with mortality as outcome and number of REBOA placements as predictor was created, using number of REBOA procedures as a predictor of mortality. The findings were a fixed effect regression, demonstrating 8% lower risk of death with an increasing

number of REBOA procedures. When using the Youden index once again to find a new optimal cutpoint defined as 26 cases per center or greater, the high-volume centers **had 44% lower mortality** when comparing high to low settings (AOR, 0.56; 95% CI, 0.32–0.98)

Applicability to my patient care

Sentara Norfolk General Hospital is a Level 1 trauma center. We are more likely to see patients with higher injury burden and require life-sustaining treatments. And we are more likely to fall into the average to high volume center category from this study. Thus, having a higher rate of utilization, we are more likely to place REBOA in the emergency department and if this data is accurate, may translate into lower mortality rates, and less complications.

Strengths

The strengths of this research paper include the size of the study population, with at least 50 patients in each cohort. Also, the statistical analyses used, including stratified analysis and multivariate analysis, which controlled for more than one confounder (SBP, location of REBOA placement, REBOA volume group, etc).

Weaknesses/Bias

This study analyzed patients from a voluntarily submitted national database which could have missed many patients. The significance of this is that the associations between REBOA volume and outcome can only be inferred, not proven. There were missing variables such as the experience/training of the operator placing the REBOA, cause of death, indications for AO, or reasoning for zone placement.

The processes and protocols of high versus low volume institutions vary. This was not evaluated in this retrospective study, therefore, the better REBOA outcomes and proficiency may be due to the institution itself. The high-volume centers may have better processes for trauma than a low volume center, thus proficiency explaining the difference in results rather than the procedure itself.

There was a selection bias. Only successfully placed REBOA were reported, there were no failed REBOA placements reported.

There were more Level 1 trauma centers reporting data than low volume centers, thus the data may not be generalized to the community setting.

No report on patient-centered outcomes such as time to discharge, quality of life measures

Some of the authors of this paper (Fox and Spalding) have a financial relationship or are employed by Prytime Medical, the manufacturer of one of the most common REBOA catheters on the market, giving them a substantial financial conflict of interest.

My Clinical Bottom Line

Although this study demonstrates lower mortality rates, less complications, and improved survival in the high-volume institutions, there are several other variables that need to be addressed/studied (including operator experience and comparison to patient population that did not have REBOA placement, etc.).