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Resuscitative Endovascular Balloon Occlusion of the Aorta in surgical and trauma patients: a systematic review, meta-analysis and practice management guideline from the Eastern Association for the Surgery of Trauma

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ABSTRACT

Background The role of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in the management of patients with subdiaphragmatic bleeding, as well as its utility in traumatic cardiac arrest (TCA), is unknown.

Methods A working group from the Eastern Association for the Surgery of Trauma (EAST) applied the Grading of Recommendations Assessment, Development and Evaluation methodology (GRADE) to perform a systematic review and meta-analysis, assess the level of evidence, and create recommendations pertaining to the use of REBOA in the management of trauma or non-trauma patients, as well as those in TCA (1946 to 2024).

Results Thirty-one studies were included in the meta-analysis. In unstable trauma patients with subdiaphragmatic bleeding, there was no significant difference in mortality among patients who were treated with REBOA vs no REBOA [OR 0.86, 95% CI 0.37, 2.04]. Subgroup analysis for individuals with pelvic fractures demonstrated higher mortality for REBOA vs no REBOA [OR=2.15, CI 1.35, 3.42]. In patients with TCA, pooled analysis demonstrated decreased mortality with REBOA vs resuscitative thoracotomy (OR 0.32, 95% CI 0.15, 0.69). Compared with no REBOA, prophylactic placement of REBOA prior to cesarean section in placenta accreta syndrome (PAS) had lower intra-operative blood loss [−1.06 L, CI −1.57 to −0.56] and red blood cell transfusion [−2.44 units, CI −4.27 to −0.62]. Overall, the level of evidence was assessed by the working group as very low.

Conclusion Considering the risks associated with its use and lack of discernible benefit, the committee conditionally recommends against the use of REBOA in trauma patients who are hemodynamically unstable due to suspected subdiaphragmatic hemorrhage. Further research is needed to identify specific subpopulations who may benefit. For individuals with TCA due to suspected subdiaphragmatic bleeding and for prophylactic placement in PAS, the committee conditionally recommends for the use of REBOA.

Level of Evidence IV

INTRODUCTION

Non-compressible torso hemorrhage (NCTH) is a major cause of preventable deaths due to both traumatic and non-traumatic etiologies.[1 2] Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is a tool to manage NCTH and traumatic cardiac arrest (TCA) in both the hospital and pre-hospital settings. More recently, it has been applied to other diseases, including non-traumatic cardiac arrest, massive gastrointestinal bleeding, and placenta accreta syndrome. Its use remains sporadic, inconsistent, and increasingly controversial. Animal and clinical studies suggest fewer physiological disturbances using endovascular balloon aortic occlusion when compared with open aortic cross-clamping,[3 4] however, clinical studies are conflicting. There are several retrospective studies that have demonstrated improved systolic blood pressure and survival in patients with hemorrhagic shock,[5–7] while others point towards worse outcomes.[8 9] The sole prospective randomized clinical trial evaluating the use of REBOA in comparison to other hemorrhage control techniques in patients with traumatic hemorrhagic shock demonstrated increased mortality with REBOA.[10]

A working group of the Eastern Association for the Surgery for Trauma (EAST) was assembled to conduct a systematic review and develop evidence-based recommendations regarding REBOA use.[11]

OBJECTIVES

The following PICO questions (Population, Intervention, Comparison, Outcomes) were formulated:

PICO 1

In hemodynamically unstable trauma patients with suspected subdiaphragmatic bleeding, should REBOA versus no REBOA be performed, prior to definitive hemostatic procedures, to decrease time

to definitive intervention, blood transfusion requirements and mortality?

PICO 2

In hemodynamically unstable trauma patients with suspected pelvic fractures, should REBOA versus no REBOA be performed, prior to definitive hemostatic procedures, to decrease time to definitive intervention, blood transfusion requirements and mortality?

PICO 3

In trauma patients with cardiac arrest OR impending cardiac arrest due to suspected subdiaphragmatic bleeding, should REBOA versus resuscitative thoracotomy be utilized to increase the rate of return of spontaneous circulation (ROSC), decrease time to aortic occlusion, and decrease mortality?

PICO 4

In trauma patients with cardiac arrest due to suspected subdiaphragmatic bleeding, should REBOA versus resuscitative thoracotomy be utilized to increase the rate ROSC, decrease time to the aortic occlusion, and decrease mortality?

PICO 5

In hemodynamically unstable patients with subdiaphragmatic bleeding of non-traumatic etiology, should REBOA versus no REBOA be performed, prior to definitive hemostatic procedures, to decrease blood transfusion requirements and mortality?

PICO 6

In hemodynamically stable patients with *anticipated* subdiaphragmatic bleeding due to placenta accreta syndrome (PAS), should REBOA vs no REBOA be performed prophylactically, prior to definitive hemostatic procedures, to decrease blood transfusion requirements and blood loss?

SELECTION OF OUTCOME MEASURES

Members of the working group proposed and independently rated (on a scale of 1–9) the clinical outcomes relevant to the use of REBOA in the selected patient populations per PICO question. Only critical outcomes rated 7–9 were considered for inclusion. Outcomes were included as follows: mortality (PICOs 1–5), blood transfusions (PICO 1, 2, 5 & 6), blood loss (PICO 6), time to definitive intervention (PICO 1 & 2), return of spontaneous circulation (ROSC) (PICO 3) and time to aortic occlusion (PICO 3 & 4).

IDENTIFICATION OF REFERENCES

The search strategy, databases and Medical Subject Headings (MeSH) terms used by the librarians are reported in online supplemental appendix 1 (January 1946 to February 2024). The results of the search were uploaded onto covidence.org.[12] Additional queries for manuscripts were made by the lead authors from February to November 2024. Titles and abstracts were screened independently by two working group members, and any conflicts were adjudicated by a third. Similarly, full-text reviews and data extraction were performed independently by two members, and any conflicts were adjudicated by a third. Only studies that matched the patient population and comparative interventions and reported the outcomes of interest were included for each PICO. Among studies with overlapping patient populations, only the ones with the larger cohorts were included. Only studies that included similar patient populations in both groups were included in the meta-analysis. Manuscripts included in both qualitative and quantitative analysis are shown in online supplemental appendix 2; those that made it to the stage of data extraction but were ultimately excluded from the meta-analysis along with their reasoning for exclusion are shown in online supplemental appendix 3. Within each PICO, effort was made to include studies that had the highest level of evidence and most rigorous statistical methods available.

DATA EXTRACTION AND METHODOLOGY

The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) diagram is shown in figure 1. The meta-analyses were performed utilizing Review Manager (RevMan)[13] using a random effects model. Binary outcomes (ROSC and mortality) are reported as odds ratios (OR) with 95% confidence intervals (CI). Time to definitive intervention, time to aortic occlusion, blood transfusion and blood loss were considered continuous outcomes and are reported as a mean difference (MD) with 95% CI. In studies where continuous data were presented as medians and interquartile ranges (IQR), means and SD were calculated according to the Cochrane Database Systematic Review recommendations.[14] The absolute effect (AE) of REBOA per 1000 patients was reported for dichotomous outcomes. The absolute effect was calculated using the GRADEpro Guideline Development Tool.[15]

GRADING OF EVIDENCE

The evidence was assessed according to GRADE methodology[11] considering study design, risk of bias, imprecision, indirectness, and inconsistency. The PRISMA 2020 checklist for systematic reviews was followed.

DEVELOPMENT OF RECOMMENDATIONS

To formulate the recommendations, the working group considered the treatment effect size for each outcome, the risk/benefit ratio of the intervention, and the quality of the evidence available, and all members voted for (strong vs conditional) or against a recommendation for each PICO question. A strong recommendation was made for a PICO only if>70% members voted for a strong recommendation. Voting results for each PICO are shown in online supplemental appendix 5.

RESULTS

PICO 1. REBOA versus no-REBOA for traumatic subdiaphragmatic bleeding

Qualitative synthesis

From the 12 studies included in the qualitative analysis, 1 was a randomized clinical trial (UK-REBOA)[10] and the remainder were retrospective reviews. Data sources included the Japan Trauma Data Bank (JTDB), the American College of Surgeons Trauma Quality Improvement Program database (ACS-TQIP), and retrospective single-institution reviews. The UK-REBOA trial involved 16 trauma centers in the United Kingdom.

REBOA was compared with no REBOA, with individuals receiving open aortic occlusion in some studies. Studies varied in their inclusion criteria, including patients with varying degrees of physiologic exhaustion, mechanism of injury, and resuscitation needs. Some studies conducted different forms of risk adjustment to ensure comparable populations, others did not.

Mortality

The UK-REBOA trial, which randomized trauma patients with suspected torso hemorrhage, found a higher 90-day mortality

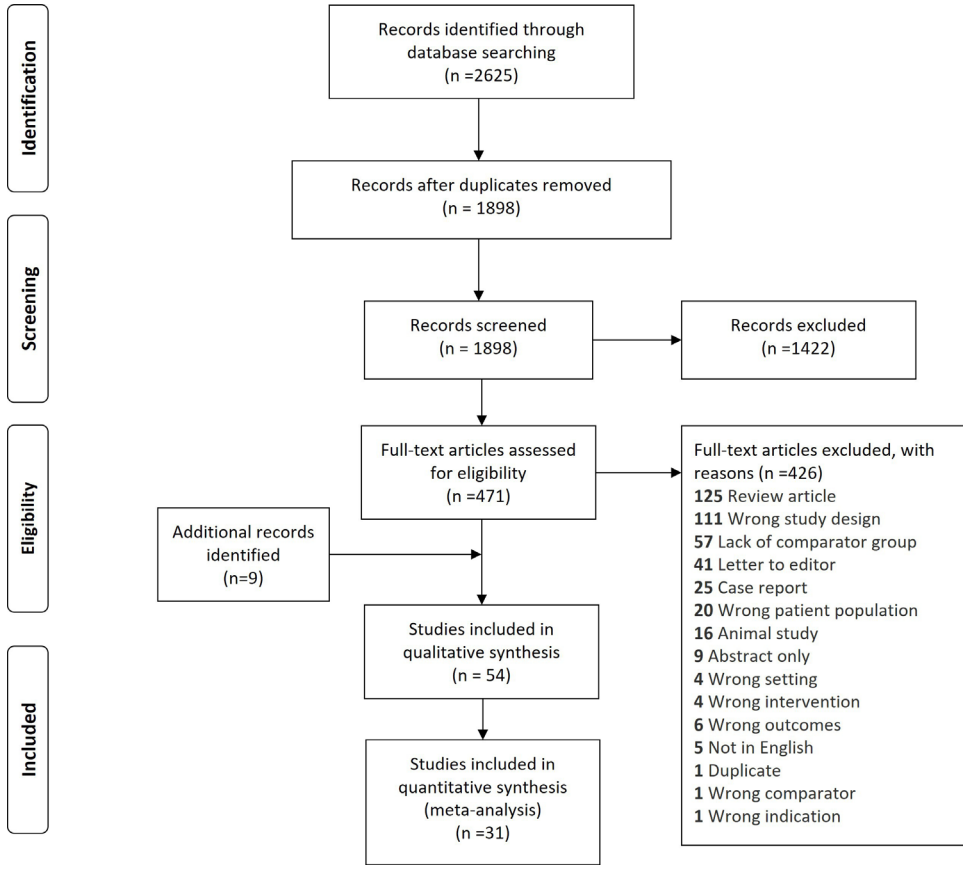


Figure 1 PRISMA diagram demonstrating process of study identification. PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses.

in the REBOA group (posterior probability of increased odds of death with REBOA=86.9%). This difference persisted for other time points (in-hospital, 24-, 6-, and 3 hour). There are limitations to this study, including that only 19 of the 46 individuals randomized to REBOA had the balloon inflated, and the REBOA group had a higher head Abbreviated Injury Scale score and lower median systolic blood pressure. Among the 4 JTDB studies,[6 16–18] two (Norii *et al*. & Inoue *et al*) demonstrated worse outcomes for REBOA. Three of the 4 ACS-TQIP studies, Joseph *et al*.,[8] Linderman *et al*[19] and Wu *et al*,[9] found higher mortality in the REBOA group. Yamamoto *et al*[20] found no mortality difference in those undergoing early hemorrhage-control (<1 hour), whereas REBOA patients who received delayed surgery had lower mortality (61% vs 88%, p<0.001). Among single-center studies, Otsuka *et al*.[21] (Japan) showed higher survival in the REBOA group [OR 7.43 (CI 1.1,51.1)], Harfouche *et al*.[22] (U.S.) found lower mortality for the REBOA (19%) vs historic (45%, p=0.001) and contemporary (35%, p=0.02) no-REBOA groups and Garcia *et al*.[23] (Colombia) demonstrated lower risk for mortality in the REBOA group (OR 0.2, CI 0.05, 0.77).

Transfusion requirements

There was great variability in calculation of transfusion metrics across studies. UK-REBOA[10] found no differences in overall transfusions between groups. Joseph *et al*[8] found no difference in 4- and 24 hours transfusion, whereas Yamamoto *et al*[20] found a higher median packed red blood cell (pRBC) transfusion at 4 and 24 hours for the REBOA group. Otsuka *et al*[21] and Harfouche *et al*[22] demonstrated no difference in transfusion requirements. Garcia *et al*[23] found higher median transfusions for pRBCs, fresh frozen plasma (FFP) and platelets in the REBOA group.

Time to definitive intervention

Time to definitive intervention was variably captured. UK-REBOA found time to hemorrhage control procedures to be longer by 19 minutes in the REBOA group. Inoue *et al*[17] evaluated door to primary surgery time and the REBOA group was 14 minutes faster (CI −25 to −3). Joseph *et al*[8] measured median time from emergency department (ED) to either angioembolization or exploratory laparotomy and found REBOA took longer by 12 (exploratory laparotomy) and 13 minutes (angioembolization) (p=0.04 for both). Yamamoto *et al* found no difference in time to surgery in the delayed group, but the early REBOA group experienced an 8 minute delay (CI 5, 16).

Quantitative synthesis

Eight studies were suitable for meta-analysis evaluating REBOA vs no-REBOA and its effects on mortality, transfusion requirements and time to definitive intervention. Results of the meta-analysis are shown in figure 2A–E. Pooled analysis of five studies demonstrated no statistically significant difference in mortality between the REBOA and no-REBOA groups (OR 0.86, CI 0.37, 2.04). There was significant heterogeneity between studies (p<0.00001) with some studies showing strong evidence of a reduced mortality and some showing strong evidence of an increased mortality among those with REBOA. There was no difference in blood product transfusions or time to definitive intervention between groups.

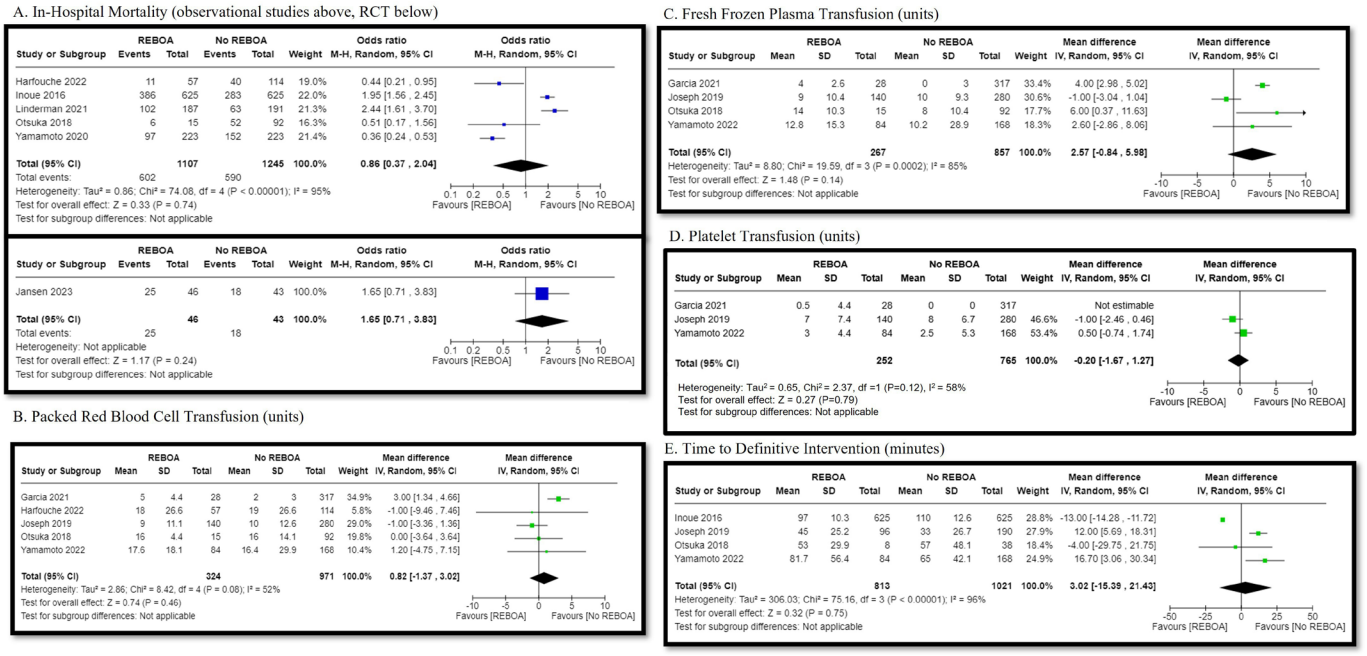


Figure 2 Results of meta-analysis for PICO 1. M-H, Mantel-Haenszel; PICO, Population, Intervention, Comparison, Outcomes; REBOA, resuscitative endovascular balloon occlusion of the aorta; RCT, Randomized Controlled Trial; CI, confidence interval; IV, inverse variance; SD, standard deviation.

Grading the evidence

The level of evidence of the studies included in the quantitative analysis was assessed to be very low (online supplemental appendix 4A). It was lowered for selection bias, inconsistency, heterogeneity between studies, and imprecision due to wide confidence intervals and the low number of included studies.

RECOMMENDATIONS—PICO 1

In hemodynamically unstable trauma patients with suspected subdiaphragmatic bleeding, our analysis showed no mortality benefit for REBOA over no REBOA. The only randomized clinical trial to date addressing this question demonstrated increased mortality for the REBOA group, although with significant limitations as addressed above. Despite the use of adjustment methods, observational studies that included a broad population with varying severity of illness could not completely control for confounding by indication favoring no REBOA. The committee considered these results in the context of known risks associated with catheter balloon occlusion of the aorta (risk of distal limb ischemia and amputation, organ ischemia and the potential for acute kidney injury, and access site complications) and the need for further research to define which subset of these hemodynamically unstable patients, if any, may benefit from REBOA. Given the high risk of bias, however, in the studies evaluated, the committee gave a *conditional* recommendation against using REBOA in this population.

PICO 2. REBOA VERSUS NO-REBOA FOR HEMODYNAMICALLY UNSTABLE PELVIC FRACTURES

Qualitative synthesis

A total of 11 manuscripts were reviewed for the qualitative analysis. All studies were retrospective cohort studies. Four used ACS-TQIP, 1 used the JTDB, 1 was an American Association for the Surgery of Trauma (AAST) multi-institutional trial, 1 used the AAST Aortic Occlusion for Resuscitation in Trauma (AORTA) registry, 3 were small multi-center studies and 1 was a single-center study. Studies varied in their inclusion criteria and risk adjustment process.

Mortality

Among the 4 studies that used ACS-TQIP, Mikdad *et al*[24] found higher mortality in the REBOA vs preperitoneal packing (PPP) group (52% vs 37%, p=0.048) whereas Asmar *et al* found lower mortality in the REBOA alone group (29% vs REBOA+PPP = 54%, PPP alone=44%, p=0.034). Chien *et al*[25] found higher in-hospital mortality in the REBOA group with severe blunt pelvic fractures (32% vs 19% in no-REBOA, p=0.008). Using multivariable regression, Anand *et al*[26] did not find REBOA to be a significantly associated with mortality among individuals with pelvic fractures in hemorrhagic shock.

Matsumoto *et al*[27] conducted a logistic regression analysis using the JTDB to show that patients with severe blunt pelvic fractures treated with REBOA had a higher mortality (OR 4.00, 95% CI 2.87, 5.58). Bini *et al*[28] used AORTA to compare open aortic occlusion (AO) to REBOA in patients who received PPP, external fixation of the pelvis (EF) and/or pelvic AE. Although they found lower mortality in the REBOA group (36% vs 80%, p<0.001), the open AO group was physiologically worse off.

Werner *et al*.[29] (Colorado), Frassini *et al*.[30] (Italy and Maryland) and Kim *et al*.[31] (Korea) were smaller studies that found no difference in mortality between REBOA versus no-REBOA for severe pelvic fractures, whereas Jang *et al*.[32] (Korea) found higher mortality for REBOA (OR 12, CI:2,73) but no effect for hemorrhage-induced mortality.

Quantitative synthesis

Four studies were suitable for meta-analyses evaluating REBOA versus no-REBOA in the setting of pelvic fractures and its effects on mortality, transfusion requirements and time to definitive intervention (figure 3A–E). Pooled analysis showed a detrimental effect of REBOA on mortality when compared with the no-REBOA group (OR 2.15, CI 1.35, 3.42; absolute effect

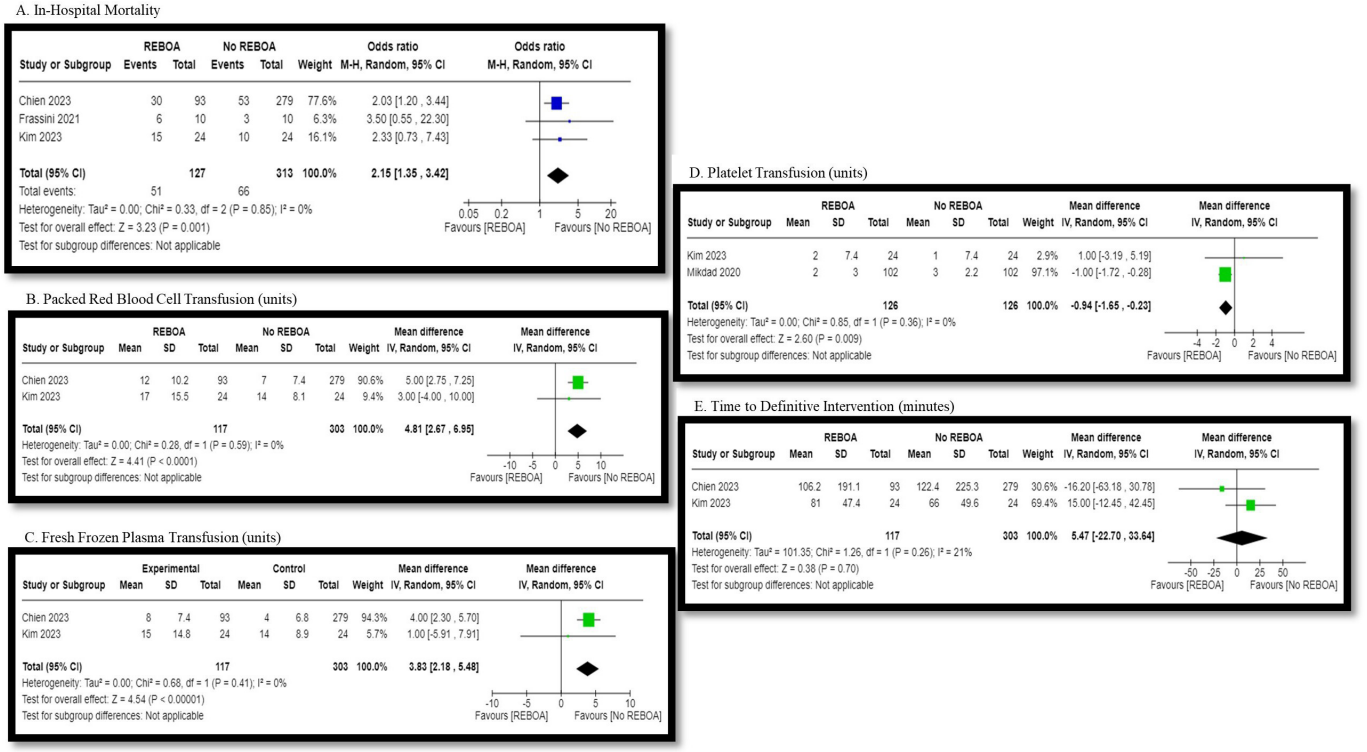


Figure 3 Results of meta-analysis for PICO 2. M-H, Mantel-Haenszel; PICO, Population, Intervention, Comparison, Outcomes; REBOA, resuscitative endovascular balloon occlusion of the aorta; CI, confidence interval; IV, inverse variance; SD, standard deviation.

(AE)=150 more deaths per 1000 patients when compared with no-REBOA, CI 95% from 53 more to 262 more deaths). REBOA was associated with a greater transfusion of units of pRBCs (Mean difference [MD 4.81 units, 95% CI 2.67, 6.95) and FFP (MD 3.83, 95% CI 2.18, 5.48) and lower transfusion of platelets (MD −0.94, CI −1.65–0.23). There was no difference in time to definitive intervention.

Grading the evidence

The level of evidence of the studies included in the quantitative analysis was assessed to be very low (online supplemental appendix 4B). It was lowered for selection bias, inconsistency, and imprecision due to wide confidence intervals and the low number of studies included.

RECOMMENDATIONS—PICO 2

In hemodynamically unstable trauma patients with suspected subdiaphragmatic bleeding due to blunt pelvic fractures, quantitative analysis demonstrated two times greater odds of mortality for the REBOA population. REBOA was associated with higher transfusion of PRBCs and FFP, and no difference in time to definitive intervention. The committee considered these results in the context of known risks associated with REBOA, as well as the likely existence of confounding by indication that favors no REBOA despite risk adjustment. Given the high risk of bias in the studies evaluated, the committee gave a *conditional* recommendation against using REBOA in this population.

PICO 3 REBOA VERSUS RESUSCITATIVE THORACOTOMY IN TCA OR IMPENDING TCA

Qualitative synthesis

Thirteen retrospective studies compared REBOA to resuscitative thoracotomy (RT) in a mixed population of trauma patients who did and did not receive cardiopulmonary resuscitation (CPR). Four were single or two-center studies; 2 used the JTDB; 1 used a Japan national inpatient database; and 6 used the prospective, observational AORTA registry.

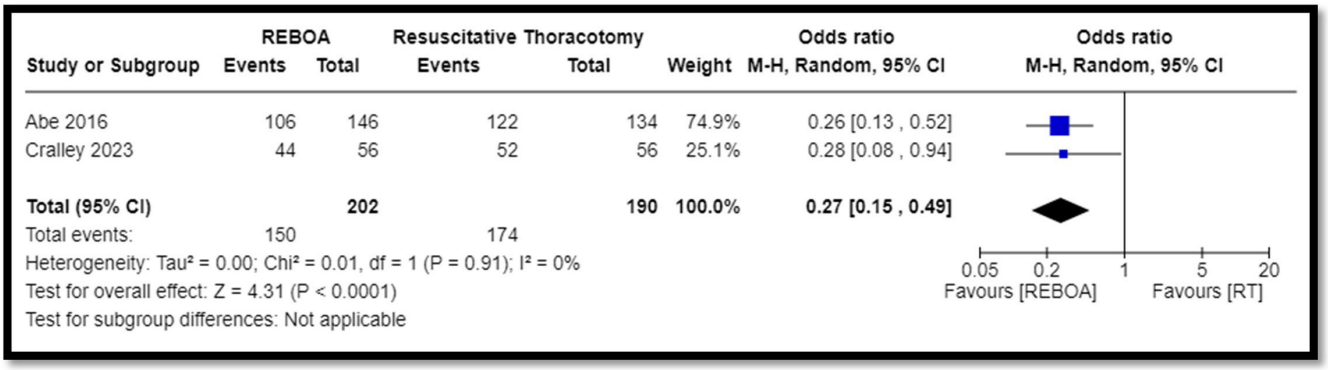
Mortality

Moore *et al*[33] evaluated data from two U.S. trauma centers and found higher survival in the REBOA versus RT group (37.5% vs 9.7%), but a much higher proportion of REBOA patients had vital signs present on admission. Ordonez *et al*.[34] (Colombia) demonstrated lower mortality for REBOA at 24-hours using multivariable regression (OR 0.51, CI 0.13, 2), although both TCA and non-TCA patients were included. Balch *et al*.[35] (Florida) found higher survival in the REBOA group (54% vs 8%), but this group also had a much lower incidence of pre-hospital TCA.

Abe *et al*[36] applied propensity-score matching (PSM) to the JTDB and found lower mortality for REBOA versus RT (OR 0.26, CI 0.13, 0.52). Matsumoto *et al*[37] also used the JTDB and found higher crude mortality rates for RT, but this population was much sicker. Adjusted time-to-death data demonstrated a more rapid onset to death for RT versus REBOA. Aso *et al*[38] conducted a risk-adjusted analysis of data from the Japanese Diagnosis Procedure Combination database and found no difference in in-hospital mortality between groups (Hazard ratio [HR] 0.94, CI 0.6, 1.48).

DuBose *et al*.,[39] Brenner *et al*[5] and Bukur *et al*[40] all found a beneficial effect for REBOA in the AORTA registry, but included mixed populations which highly favored the REBOA versus RT group. In these studies, the REBOA group was inherently less sick than the group that underwent RT, and few, if any, risk adjustments were made to correct these differences. Cralley *et al*[41] demonstrated higher mortality for RT using both PSM (93% vs REBOA: 79%, p=0.03) and multivariable regression

A. In-Hospital Mortality



B. Time to Aortic Occlusion (minutes)

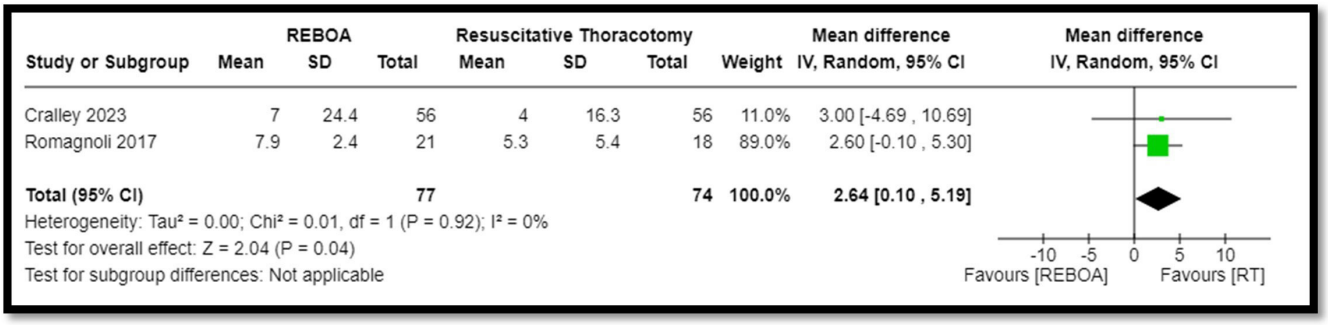


Figure 4 Results of meta-analysis for PICO 3. M-H, Mantel-Haenszel; PICO, Population, Intervention, Comparison, Outcomes; REBOA, resuscitative endovascular balloon occlusion of the aorta; CI, confidence interval; IV, inverse variance; SD, standard deviation; RT, resuscitative thoracotomy.

(adjusted relative risk (aRR) 1.25, CI 1.15,1.36) using AORTA (2013–2021). Brenner *et al*[42] published another study using AORTA (2013–2021), applying multivariate logistic regression and propensity score weighting for risk adjustment, and found higher mortality for RT.

Time to aortic occlusion

Both Romagnoli *et al*[43] and Cralley *et al*[41] found a longer time to first successful aortic occlusion (AO) for REBOA vs RT, although Cralley *et al* did not account for the longer time to attempt first AO in the REBOA group. Dubose *et al*[39] and Brenner *et al*[5] reported similar time from initiation to successful AO for REBOA vs RT, although Brenner *et al* only included individuals who did not require CPR prior to AO for whom it is easier to obtain femoral arterial access.

Return of spontaneous circulation

One single-center study out of Maryland reported on ROSC. Teeter *et al*[44] evaluated patients in cardiac arrest and found a higher rate of ROSC in the REBOA versus RT group (60% vs 33%, p=0.04).

Quantitative synthesis

Studies comparing REBOA to RT included a mixed population with or without cardiac arrest. Given the large differences in patient populations and overlapping datasets, only 3 studies met criteria to be included in the quantitative analysis. Results of the meta-analysis are shown in figure 4A,B. There were an insufficient number of studies to evaluate ROSC. Pooled analysis showed a beneficial effect of REBOA on mortality when compared with RT (OR 0.27, CI 0.15,0.49; absolute effect (AE)=170 fewer deaths per 1000 patients, CI 95% from 74 fewer to 296 fewer deaths). Pooled analysis of time to AO demonstrated that REBOA was associated with longer time to AO by 2.64 min (CI 0.10, 5.19).

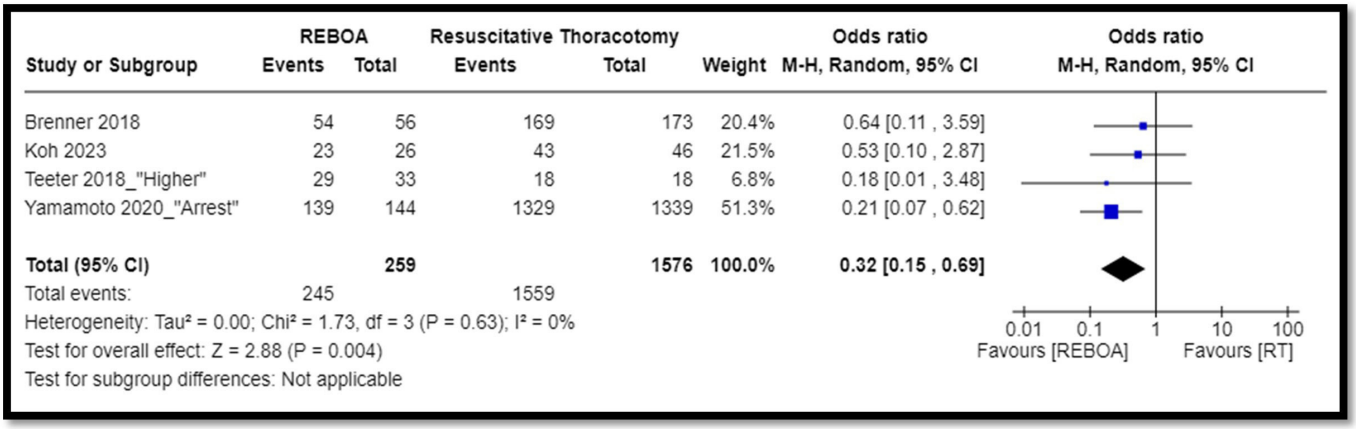
Grading the evidence

The level of evidence of the studies included in the quantitative analysis was assessed to be very low (online supplemental appendix 4C). It was lowered for selection bias, inconsistency, imprecision due to wide confidence intervals and the highly variable inclusion criteria across studies.

RECOMMENDATIONS—PICO 3

In trauma patients with cardiac arrest *or* impending cardiac arrest due to suspected subdiaphragmatic bleeding, quantitative analysis demonstrated nearly four times lower odds of mortality for the REBOA population. Time from initiation to successful AO was slightly longer for REBOA. The committee considered the quality of the evidence as well as the clinical context when deciding on a recommendation. The inclusion of individuals that did not receive CPR in all the studies analyzed added confounding by indication in favor of REBOA that could not be adequately mitigated in a retrospective analysis. In addition, most of the studies reviewed did not define the clinical characteristics of individuals who should undergo AO (either open or endovascular) in the absence of TCA, creating ambiguity regarding the patient population that would fall under this PICO. With these considerations in mind, the committee could not make a recommendation for or against using REBOA in this population.

A. In-Hospital Mortality



B. Time to Aortic Occlusion (minutes)

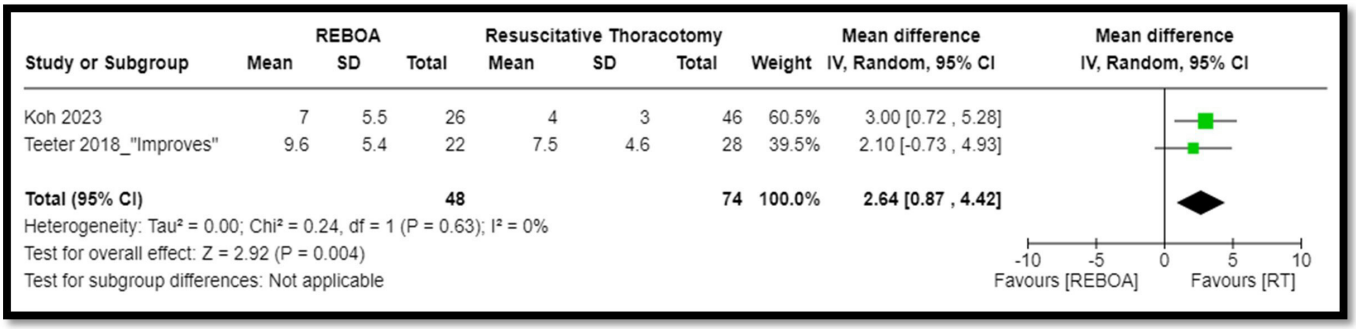


Figure 5 Results of meta-analysis for PICO 4. M-H, Mantel-Haenszel; PICO, Population, Intervention, Comparison, Outcomes; REBOA, resuscitative endovascular balloon occlusion of the aorta; CI, confidence interval; IV, inverse variance; SD, standard deviation; RT, resuscitative thoracotomy.

PICO 4 REBOA VERSUS RESUSCITATIVE THORACOTOMY IN TCA

Qualitative synthesis

There were 7 retrospective cohort studies that provided sufficient data to evaluate only the population in TCA. Two of these studies used AORTA, 2 used the JTDB, 1 was a secondary analysis of a prospective, multicenter database and 2 were single-center studies.

Mortality

Brenner *et al*[5] and Bini *et al*[28] used AORTA to compare unadjusted mortality for individuals undergoing CPR who received REBOA versus RT and found no difference. Norii *et al*[45] compared RT to REBOA using the JTDB, showing higher unadjusted mortality in the RT group (99% vs 95%, p<0.001). Yamamoto *et al*[46] evaluated patients in the JTDB with out-of-hospital TCA. Propensity modeling using inverse probability treatment weight (IPTW) was performed. Results demonstrated 3.7 times higher odds of survival to discharge for the REBOA group (CI 1.9,7.3).

Two separate single-center studies by Teeter *et al*.[44 47]out of Maryland evaluated mortality in trauma patients who received either REBOA or RT in the setting of TCA and found no difference in in-hospital mortality. Koh *et al*[48] conducted a secondary analysis of the multi-center Emergency Truncal Hemorrhage Control observational study. After applying multivariable regression on the IPTW observations, no difference in mortality was seen between groups (RR 0.89 CI: 0.71, 1.12).

Time to aortic occlusion and ROSC

Teeter *et al* and Koh *et al* both evaluated time to AO in patients in TCA who received REBOA versus RT and found a significantly longer time to occlusion in the REBOA group. In Koh's study, this was defined as the time from when the decision was made to when successful AO was achieved, whereas for Teeter's study it was defined as the time from admission to successful AO. A separate single-center study by Teeter *et al*[44] found a higher rate of ROSC among REBOA patients who arrived in TCA versus RT patients (60% vs 33%, p=0.04).

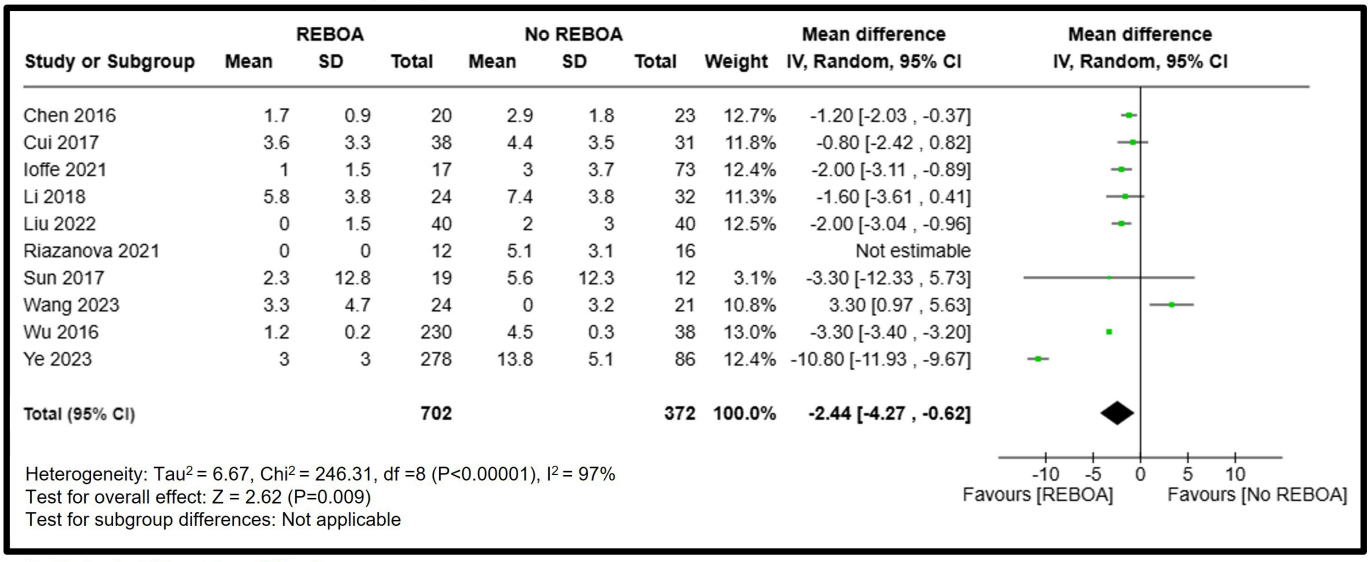
Quantitative synthesis

Four studies were included in the quantitative analysis comparing REBOA to RT for individuals in traumatic cardiac arrest. Results of the meta-analysis are shown in figure 5A,B. Pooled analysis showed a beneficial effect of REBOA on mortality when compared with RT (OR 0.32, CI 0.15,0.69; absolute effect (AE)=22 fewer deaths per 1000 patients, CI 95% from 5 fewer to 57 fewer deaths). Both studies described in the previous section were included in the time to AO analysis, which demonstrated that REBOA was associated with longer time to AO by 2.64 min (CI 0.87, 4.42).

Grading the evidence

The level of evidence of the studies included in the quantitative analysis was assessed to be very low (online supplemental appendix 4D). It was lowered for selection bias, inconsistency, imprecision due

A. Packed Red Blood Cell Transfusion (units)



B. Estimated Blood Loss (liters)

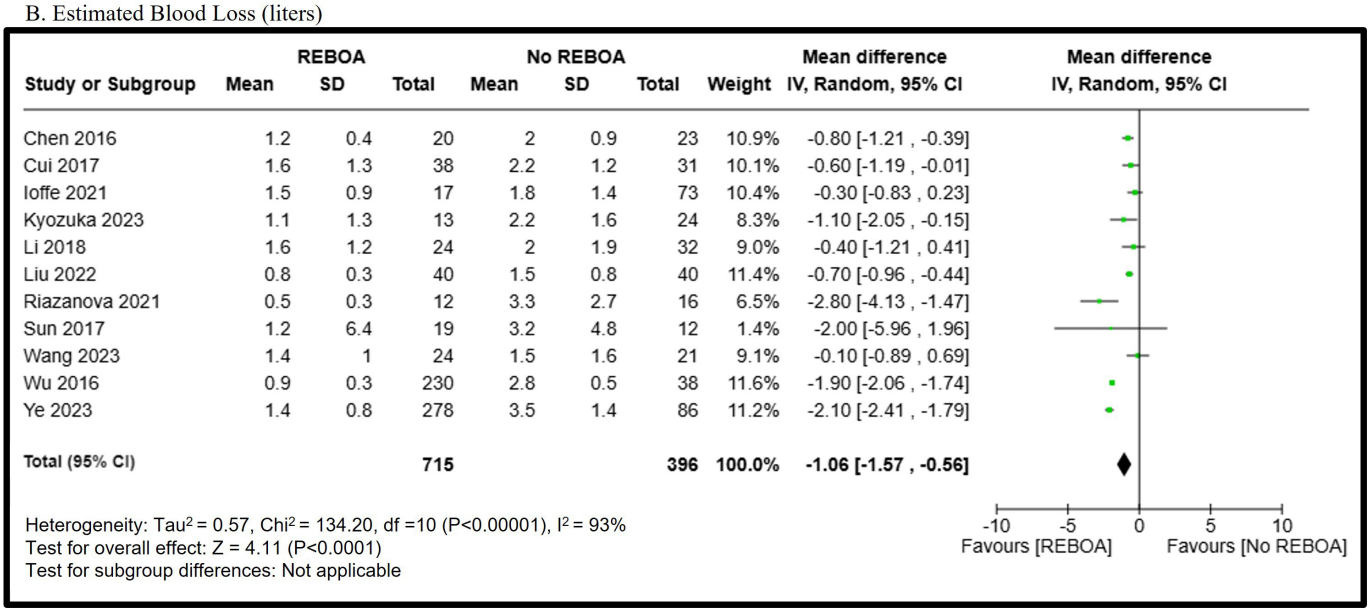


Figure 6 Results of meta-analysis for PICO 6. PICO, Population, Intervention, Comparison, Outcomes; REBOA, resuscitative endovascular balloon occlusion of the aorta; CI, confidence interval; IV, inverse variance; SD, standard deviation.

to wide confidence intervals and low number of studies that were included and the highly variable inclusion criteria across studies.

RECOMMENDATIONS—PICO 4

In trauma patients with cardiac arrest due to suspected subdiaphragmatic bleeding, quantitative analysis demonstrated lower odds of mortality for REBOA by more than half and slightly longer time from initiation to successful AO. The committee considered the quality of the evidence as well as the clinical context when deciding on a recommendation. The morbidity of RT is high as compared with REBOA, which is less invasive. Although the certainty of the evidence among the studies reviewed is very low, limiting the population to TCA alone reduced the confounding by indication. It also reduced the clinical ambiguity as to the target population. With these considerations in mind, the committee made a conditional recommendation for using REBOA in this population.

PICO 5 REBOA in hemorrhagic shock in non-traumatic bleeding

Qualitative synthesis

Only one clinical research study was found that compared REBOA to no-REBOA in non-traumatic bleeding. Deser *et al*[49] conducted a simple, single-center comparison of REBOA versus no REBOA for all patients with ruptured abdominal aortic aneurysms who underwent emergent open aortic surgery, demonstrating higher 24-hour (38% vs 10%, p=0.029) and 30-day (44% vs 14%, p=0.035) mortality and greater pRBC transfusions (5.7 units vs 4.3 units, p=0.01) in the no REBOA group.

Grading the evidence

The level of evidence was extremely low, due to the existence of 1 retrospective study that included a comparison group, the lack of any risk adjustment in the study and the absence of any multicenter or prospective studies.

Table 1 Final committee recommendations for the use of REBOA

Question	Recommendation
PICO 1	In hemodynamically unstable trauma patients with suspected subdiaphragmatic bleeding, we conditionally recommend **against** using REBOA.
PICO 2	In hemodynamically unstable trauma patients with suspected pelvic fractures, we conditionally recommend **against** using REBOA.
PICO 3	In trauma patients with cardiac arrest *OR* impending cardiac arrest due to suspected subdiaphragmatic bleeding, we **cannot make a recommendation for or against** using REBOA over RT.
PICO 4	In trauma patients with cardiac arrest due to suspected subdiaphragmatic bleeding, we conditionally recommend **for** using REBOA over RT.*
PICO 5	In hemodynamically unstable patients with subdiaphragmatic bleeding of non-traumatic etiology, we **cannot make a recommendation for or against** using REBOA.
PICO 6	In hemodynamically stable patients with *anticipated* subdiaphragmatic bleeding due to placenta accreta syndrome, we conditionally recommend **for** the prophylactic use of REBOA.

*In the absence of any other indications for RT.
PICO, Population, Intervention, Comparison, Outcomes; REBOA, resuscitative endovascular balloon occlusion of the aorta; RT, resuscitative thoracotomy.

RECOMMENDATIONS—PICO 5

Lack of research prevented the committee from making a recommendation for or against REBOA in this patient population.

PICO 6 REBOA for prophylactic management of bleeding in placenta accreta spectrum

Qualitative synthesis

Of the 12 studies evaluated, most originated from China, with only a handful from other countries, including the U.S. All studies generally included the diagnosis of PAS by prenatal ultrasound (US) and/or magnetic resonance imaging (MRI) and consent for REBOA was obtained preoperatively. The REBOA catheter was often positioned but not inflated in an infra-renal location prior to cesarean section by an Interventional Radiologist under fluoroscopic guidance in a controlled setting. In Ioffe *et al*,[50] the only U.S.-based study, the REBOA was placed by acute care surgeons and positioned intra-operatively in an infra-renal location by manual palpation. In Riazanova *et al*[51] the REBOA was positioned using US guidance by a vascular surgeon or anesthesiologist. In all cases, the balloon was not inflated until after delivery of the infant. If surgical bleeding control could not be obtained, at some centers angiographic embolization of uterine arteries was performed.

None of the studies included any risk adjustment aside from the inclusion criteria, but the study populations were similar. Several of the studies[50 52–56] found no difference in estimated blood loss (EBL) or transfusion requirements between groups but sample sizes were small, which could explain the ambiguous results. In most studies, there was a trend towards decreased EBL and transfusion volume.

Quantitative synthesis

Eleven studies were included in the quantitative analysis. Results are shown in figure 6A,B. Pooled analysis showed decreased pRBC transfusion (MD −2.44 units, CI −4.27 to –0.62) and less EBL (MD −1.06 liters, CI −1.57 to –0.56) for REBOA versus no REBOA.

Grading the evidence

The level of evidence of the studies included in the quantitative analysis was assessed to be very low (online supplemental appendix 4E). It was lowered for selection bias, inconsistency, imprecision due to wide confidence intervals, and publication bias due to the general positive intervention-outcome relationship reported in most of the studies.

RECOMMENDATIONS—PICO 6

On pooled analysis, prophylactic use of REBOA prior to cesarean section±hysterectomy in patients with PAS led to a reduction of pRBC transfusion by close to 3 units and EBL by 1 L. This included data from over 10 studies that had a relatively homogenous population. An additional benefit of prophylactic over emergent approach to obtaining femoral arterial access is the lower likelihood of access site complications. Given the low certainty of evidence and non-negligible risk associated with REBOA placement, the committee made a conditional recommendation for the use of REBOA in this patient population.

Using these guidelines in clinical practice

This systematic review highlights the best available evidence pertaining to the use of REBOA in hypotensive trauma and non-trauma patients with suspected subdiaphragmatic bleeding. It identifies a unique patient population with PAS that may benefit from prophylactic use of the REBOA catheter prior to cesarean section. There are several limitations to this review. Most of the studies included are retrospective and have a high degree of bias, span a long study period during which practice patterns may have changed, and have heterogenous inclusion criteria that make identifying a target population for REBOA difficult. As such, the committee could only provide conditional rather than strong recommendations for the PICO questions that were evaluated. Each institution should consider these guidelines within their own clinical context and apply them accordingly. REBOA should not be used in isolation but should be part of a protocolized hemorrhage-control strategy. All providers using REBOA should be appropriately trained and comfortable with its use. Resuscitative thoracotomy should still be performed as deemed necessary in individuals in extremis with suspected supradiaphragmatic bleeding.

FUTURE RESEARCH DIRECTIONS

Future studies should evaluate specific clinical scenarios where REBOA may be applied in hemodynamically unstable patients with suspected or confirmed subdiaphragmatic bleeding of traumatic and non-traumatic etiology. Clear inclusion criteria and robust methods to control for bias, and report specific outcome

criteria as defined by a recent expert Delphi consensus panel are critical.[57] As it pertains to PAS, more research should be conducted on the specific grade of PAS that may benefit most from prophylactic REBOA. There is a need for more randomized clinical trials that focus on specific injury patterns for which REBOA may confer the greatest benefit to risk ratio, such as Zone III REBOA use in pelvic fracture hemorrhage and Zone I REBOA in cardiac arrest. REBOARREST is one example of such a trial and is currently underway in Norway.[58]

CONCLUSION

Our recommendations are stated in table 1. Due to the paucity or inconsistencies of the data available, we could not provide a recommendation for the emergency use of REBOA in non-traumatic hemorrhage nor in impending traumatic cardiac arrest. There is a need for better quality research that defines the target population of patients with impending arrest. In all cases, REBOA must be used as part of a coordinated hemorrhage-control strategy and not in isolation, with clear institutional protocols, robust quality control and adequate user training.

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