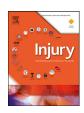
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Pre-peritoneal pelvic packing for early hemorrhage control reduces mortality compared to resuscitative endovascular balloon occlusion of the aorta in severe blunt pelvic trauma patients: A nationwide analysis 🕸



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ABSTRACT

Background: Early hemorrhage control after severe blunt pelvic trauma is life-saving. The aim of this study is to compare the efficacy and outcomes of pre-peritoneal packing (PPP) and Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) with a subsequent hemorrhage control procedure to control life-threatening pelvic hemorrhage in trauma patients.

Methods: A 3-year (2015-2017) retrospective analysis of the Trauma Quality Improvement Program (TQIP) was performed. All blunt trauma patients (aged ≥15 years) who underwent PPP or Zone 3 REBOA placement were included while deaths on arrival and transfers were excluded. Patients were matched on clinical characteristics using propensity score matching (PSM). Univariate analysis was performed to compare mortality, time to procedure, time in ED, transfusion requirements, complications rates, and ICU and hospital length of stay (LOS) amongst patient groups.

Results: Of 420 trauma patients, 307 underwent PPP and 113 REBOA. Patients had similar hemodynamics and ISS upon presentation, but PPP patients had a higher GCS (P = 0.037) and more blunt kidney injuries (P = 0.015). After PSM, 206 trauma patients were included in the analysis. There were no significant differences in blood transfusion, LOS, or major complications. Time to REBOA was shorter than time to PPP (52 vs 77.5 min; P < 0.001) with longer time in ED (65 vs 51 min; p = 0.023). The 24-hour (32.4 vs 17.7%; P = 0.23) and in-hospital mortality (52.0 vs 37.3%; P = 0.048) were higher after REBOA.

Conclusion: PPP is associated with improved survival compared to REBOA placement. Delay in definitive hemorrhage control may provide a potential explanation, but causation remains unresolved. This data suggests that early PPP may offer a benefit over REBOA in the setting of hemorrhage after blunt pelvic trauma. Further, large, multi-institutional studies are warranted to support these findings.

Level of Evidence: Prognostic study, level III.

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Introduction

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Patients presenting with severe traumatic pelvic fractures are at high risk for mortality and significant morbidity. In some series, mortality rates still exceed 30% despite well-coordinated team approaches and advances in damage control resuscitation [1]. Common maneuvers for hemorrhage control for pelvic hemorrhage span from simple temporizing applications such as pelvic binders to aggressive operative interventions.

Originating from Europe, pre-peritoneal packing (PPP) is now used throughout the United States for the hemodynamically unstaRecently, Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) has emerged as a promising technique for hemorrhage control in severely injured trauma patients [8]. Some studies have demonstrated a survival benefit with REBOA [9–11]. However, there are two national, multi-institutional studies that suggest RE-BOA may be associated with increased mortality, acute kidney injury, and limb amputation [12,13].

The American Association for the Surgery of Trauma (AAST) Pelvic Fracture Study Group demonstrated a significant variability across institutions with respect for the use of REBOA for early hemorrhage control after pelvic bleeding [10]. As it currently stands, there are no clear guidelines in regard to best practices for expedient pelvic hemorrhage control that results in optimal outcomes. The aim of this study was to compare the efficacy and outcomes of PPP and REBOA to control life-threatening pelvic hemorrhage in trauma patients. We hypothesized that REBOA in conjunction with standard trauma resuscitation would minimize delays to intervention and result in improved in-hospital survival when compared to PPP.

Methods

Study design and setting

This study was reported on adhering to the RECORD STROBE guideline [14]. We conducted a retrospective analysis of the 2015–2017 American College of Surgeons Trauma Quality Improvement Program (ACS-TQIP) database. No data linkage was performed. The Institutional Review Board (IRB) granted this study exemption from approval due to deidentified data.

Study population

All patients (\geq 15 years of age) with blunt pelvic fractures who received either PPP or abdominal aorta REBOA (non-zone 1) were included. Patients receiving PPP as a second hemorrhage control procedure after initially undergoing REBOA were considered to be in the REBOA group. Exclusion criteria included patients who were dead on arrival, transferred from an outside hospital, had a penetrating mechanism, did not have pelvic fractures, or had PPP or REBOA after 4 h. Patients who had external fixation or angioembolization before PPP or REBOA were also excluded. REBOA patients were identified using the following 'Internal Statistical Classification of Diseases and Related Health Problems (ICD)'-10 procedure codes: "04L03DZ", "04L03DJ" and "04L04DZ" to exclude patients who received REBOA in zone 1. Patients receiving PPP were identified using the following ICD procedure codes "2W03×5Z", "2W03×6Z", "2W13×6Z', "2W43×5Z", "2W53×5Z" and 2W53×6Z". To control for correct coding, patients with these ICD procedure codes were only included if they had a second exploratory laparotomy indicating removal of packing within 72 h or if they died within 72 h with no ability to go back to the operating room to remove packing. Available data included demographics (age, sex), injury parameters (mechanism of injury, injury severity score (ISS) and Abbreviated Injury Scale (AIS) score for each body region), vital signs on arrival (systolic blood pressure (SBP), heart rate (HR) and Glasgow Coma Scale (GCS) score), transfusion requirements within 4 and 24 h after arrival (packing red blood cells (RBCs), platelets (PLT) and fresh frozen plasma (FFP)), interventional angiography, hospital- and Intensive Care Unit (ICU) length of stay (LOS), in-hospital complications and mortality.

Outcomes

The primary outcome of interest was mortality, including 24 hmortality and overall in-hospital mortality comparing PPP and RE-BOA. Secondary outcomes included transfusion requirements, time to procedures, time in the Emergency Department (ED), hospital and ICU LOS, and complication rates (including acute kidney injury (AKI), sepsis, surgical site infections (SSI), limb amputation, venous thromboembolism (VTE) and extremity compartment syndrome).

Statistical analysis

Patients were divided between those treated with REBOA in conjunction with a definitive procedure for hemorrhage control (REBOA-group) and those who received PPP as primary procedure (PPP-group). Propensity Score Matching (PSM) was used to correct for confounders that affect mortality such as ISS and vital signs at presentation to the ED. Patients were matched on a 1:1 ratio using logistic regression to estimate the probability of being assigned to the REBOA group compared to the PPP group. The patients were matched based on significantly different variables between the groups including vital signs in the ED, injury parameters (ISS and AIS) and intra-abdominal, solid organ injuries and propensity scores were matched. Conflicting data elements were coded as missing data or interpreted with clinical judgement. Continuous parametric data are reported as a medians and interguartile ranges (IQR) (25-75) and categorical data as frequencies and percentages. The inter-group comparison after PSM was performed using univariate analysis with the Mann-Whitney test for continuous variables and χ^2 test for categorical variables. For testing of all hypotheses, a two-sided p-value threshold of 0.05 was considered statistically significant. All statistical analyses were performed using STATA, version 15.1.

Results

A total of 67,846 eligible patients with blunt pelvic fractures were identified during the study period. Among them, 307 patients received PPP and 113 received REBOA. Fig. 1 presents a flow diagram of the patient selection. Before matching, patients in the PPP group had a higher GCS (GCS \leq 8, 133 [43.3%] vs 62 [54.9%]; P = 0.037) but were more likely to have a blunt kidney injury (75 [24.4%] vs 15 [13.3%]; P = 0.015). The demographics and injury characteristics are summarized in Table 1.

Considering the non-negligible biased differences in survival predictors between the two groups, propensity score matching was performed. Of the 67,846 patients, 204 patients were matched and included in the final analysis (PPP-group 102 patients, REBOAgroup 102 patients). The demographics and injury characteristics of the matched cohort of blunt pelvic fracture trauma patients are demonstrated in Table 2. After matching, there were no differences between the PPP-group and REBOA-group regarding mean age (45.0 \pm 17.6 vs 45.6 \pm 18.1; *P* = 0.811), gender (female; 35.3% vs 34.3%; P = 1.000), SBP < 90 mm Hg (32.4% vs 37.3%; P = 0.557), pulse > 100 bpm (59.8% vs 58.8%; P = 1.000) and GCS \leq 8 (51.0% vs 51.0%; P = 1.000). Furthermore, there were no significant differences in median ISS (34 [IQR, 27-45] vs 34 [IQR, 27–43]; P = 0.828), AIS head \geq 3 (27.5% vs 32.4%; P = 0.541), AIS thorax \geq 3 (46.1% vs 50.0%; P = 0.674), liver injuries (35.3%) vs 38.3%; P = 0.772), splenic injuries (31.4% vs 30.4%; P = 1.000), kidney injuries (12.8% vs 13.7%; P = 1.000), lower extremity fractures (57.8% vs 53.9%; P = 0.672), and vascular injuries (18.6% vs 22.6%; P = 0.604). Of the 102 patients receiving REBOA, 38 (37.3%)

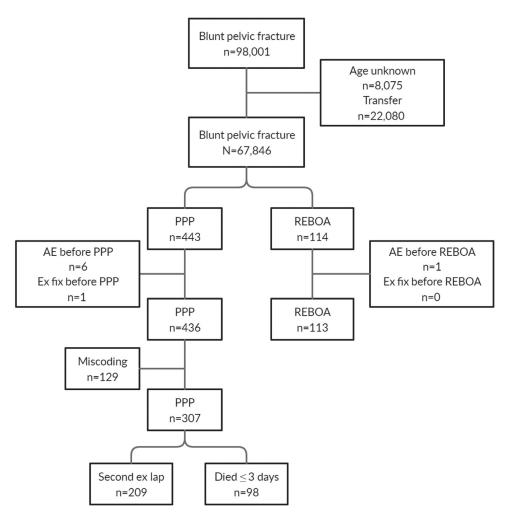


Fig. 1. Patient selection flow diagram.

Table 1

Demographics and injury characteristics before propensity score matching.

	PPP $(n = 307)$	REBOA ($n = 113$)	P-value
Age \pm mean (SD), y	42.7 ± 18.8	45.2 ± 18.0	0.157
Female	102 (33.2%)	40 (35.4%)	1
Vital signs in ED			
SBP < 90 mm Hg	95 (31.0%)	43 (38.1%)	0.197
HR > 100 bpm	204 (66.5%)	69 (61.1%)	0.356
type="Other"GCS ≤ 8	133 (43.3%)	62 (54.9%)	0.037
Injury parameters			
ISS, median (IQR)	36 [29-48]	34 [27-43]	0.223
Head AIS > 3	87 (28.3%)	37 (32.7%)	0.4
Thorax AIS > 3	144 (46.9%)	57 (50.4%)	0.582
Pelvic fractures	307 (100.0%)	113 (100.0%)	1
With intact posterior arch	110 (35.8%)	46 (40.7%)	
Incompletely disrupted posterior arch	122 (39.7%)	34 (30.1%)	
Completely disrupted posterior arch	55 (17.9%)	32 (28.3%)	
Liver Injuries	123 (40.1%)	45 (39.8%)	0.631
Splenic Injuries	108 (35.2%)	36 (31.9%)	0.563
Kidney Injuries	75 (24.4%)	15 (13.3%)	0.015
Lower extremity fractures, total	142 (46.3%)	66 (58.4%)	0.028
Femur	86 (28.0%)	39 (34.5%)	
Tibia	81 (26.4%)	32 (28.3%)	
Fibula	80 (26.1%)	27 (23.9%)	
Vascular injuries	54 (17.6%)	24 (21.2%)	0.398
Iliac	36 (11.7%)	18 (15.9%)	
Lower extremity	21 (6.8%)	7 (6.2%)	

Abbreviations: SD = standard deviation, ED = emergency department, SBP = systolic blood pressure, HR = heart rate, GCS = Glasgow Coma Scale, ISS = Injury Severity Score, IQR = interquartile range, AIS = Abbreviated Injury Scale, PPP = preperitoneal pelvic packing, RE-BOA = Resuscitative Endovascular Balloon Occlusion of the Aorta.

Table	2
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Demographics and injury characteristics after propensity score matching.

	PPP $(n = 102)$	REBOA ($n = 102$)	P-value
Age \pm mean (SD), y	45.0 ± 17.6	45.6 ± 18.1	0.811
Female	36 (35.3%)	35 (34.3%)	1
Vital signs in ED			
SBP < 90 mm Hg	33 (32.4%)	38 (37.3%)	0.557
HR > 100 bpm	61 (59.8%)	60 (58.8%)	1
$GCS \leq 8$	52 (51.0%)	52 (51.0%)	1
Injury parameters			
ISS, median (IQR)	34 [27-45]	34 [27–43]	0.828
Head AIS > 3	28 (27.5%)	33 (32.4%)	0.541
Thorax AIS > 3	47 (46.1%)	51 (50.0%)	0.674
Pelvic fractures	102 (100.0%)	102 (100.0%)	1
With intact posterior arch	39 (38.3%)	41 (40.2%)	
Incompletely disrupted posterior arch	45 (44.1%)	31 (30.4%)	
Completely disrupted posterior arch	16 (15.7%)	31 (30.4%)	
Liver Injuries	36 (35.3%)	39 (38.3%)	0.772
Splenic Injuries	32 (31.4%)	31 (30.4%)	1
Kidney Injuries	13 (12.8%)	14 (13.7%)	1
Lower extremity fractures, total	59 (57.8%)	55 (53.9%)	0.672
Femur	34 (33.3%)	35 (34.3%)	
Tibia	34 (33.3%)	26 (25.5%)	
Fibula	33 (32.4%)	22 (21.6%)	
Vascular injuries	19 (18.6%)	23 (22.6%)	0.604
Iliac	8 (7.8%)	17 (16.7%)	
Lower extremity	11 (10.8%)	7 (6.9%)	

Abbreviations: SD = standard deviation, ED = emergency department, SBP = systolic blood pressure, HR = heart rate, GCS = Glasgow Coma Scale, ISS = Injury Severity Score, IQR = interquartile range, AIS = Abbreviated Injury Scale, PPP = preperitoneal pelvic packing, RE-BOA = Resuscitative Endovascular Balloon Occlusion of the Aorta.

Table 3Hemorrhage control procedures after PPP and REBOA .

	PPP $(n = 102)$	REBOA ($n = 102$)
Angioembolization	32 (31.4%)	38 (37.3%)
PPP	-	70 (68.6%)
External fixation	7 (6.9%)	11 (10.8%)

Abbreviations: PPP = preperitoneal pelvic packing, RE-BOA = Resuscitative Endovascular Balloon Occlusion of the Aorta.

received angioembolization, 70 (68.6%) received PPP and 11 (10.8%) received external fixation as second procedure after REBOA, with some patients receiving PPP and external fixation simultaneously. Of the 102 patients receiving PPP, 32 (31.4%) received angioembolization, and 7 (6.9%) received external fixation as second procedure after PPP (Table 3). The number of exploratory laparotomies in the PPP group was higher than in the REBOA group (94.1% vs 68.6%; P<0.001), including the number of liver injuries which were managed operatively (52.8% vs 15.4%; P = 0.001). There were no differences in the rates of operative versus non-operative management of kidney and splenic injuries between the PPP and RE-BOA groups (splenectomy: 55.6%, PPP vs 44.0%, REBOA; P = 0.58; nephrectomy: 20.0%, PPP vs 14.3%, REBOA; P = 1.00). Thoracotomies were performed similarly across both groups (9.8% vs 6.9%; P = 0.61) (Table 4).

Propensity score matching analysis revealed that in-hospital mortality was significantly higher in patients receiving REBOA compared to PPP (52.0% vs 37.3%; P = 0.048). A Kaplan-Meier plot of survival curves for both of patients treated with PPP and RE-BOA is shown in Fig. 2. Mortality after 24 h was also significantly higher in the REBOA-group compared to the PPP-group (32.4% vs 17.7%; P = 0.023) and analysis showed a trend towards a higher mortality rate in the ED (6.9% vs 1.0%; P = 0.065).

Table 5 summarizes the outcomes of the PPP and REBOA groups. No differences were found between the groups in units pRBC transfusion required at 4 h (13 [7–22] vs 11 [6–19]; P = 0.170) or 24 h (16 [9–27] vs 14 [7–22]; P = 0.262),

Table 4

	Operative j	procedures	after	PPP	and	REBOA
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	PPP $(n = 102)$	REBOA ($n = 102$)	p-value
Exploratory laparotomy	96 (94.1%)	70 (68.6%)	< 0.001
Thoracotomy	10 (9.8%)	7 (6.9%)	0.61
Management of solid organ in	njury		
Spleen	32	31	
Embolization	0 (0%)	2 (6.5%)	0.14
Splenectomy	18 (56.3%)	14 (45.2%)	0.38
Non-operative management	14 (43.8%)	17 (54.8%)	
Liver	36	39	
Embolization	3 (8.3%)	3 (7.7%)	0.92
Surgical management*	19 (52.8%)	6 (15.4%)	0.001
Non-operative management	17 (47.2%)	33 (84.6%)	
Kidney AIS>2	10	7	
Nephrectomy	2 (20.0%)	1 (14.3%)	1.00
Non-operative management	8 (80.0%)	6 (85.7%)	

Abbreviations: PPP = preperitoneal pelvic packing, REBOA = Resuscitative Endovascular Balloon Occlusion of the Aorta *Includes hepatectomy and liver repair.

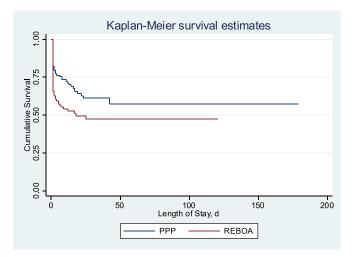


Fig. 2. Kaplan-Meier survival analysis.

	PPP $(n = 102)$	REBOA ($n = 102$)	P-value
Mortality			
In-hospital mortality	38 (37.3%)	53 (52.0%)	0.048
24-hour mortality	18 (17.7%)	33 (32.4%)	0.023
ED mortality	1 (1.0%)	7 (6.9%)	0.065
Transfusion, median (IQR), units			
pRBC 4 h	13 [7-22]	11 [<mark>6</mark> -19]	0.170
pRBC 24 h	16 [<mark>9</mark> -27]	14 [7-22]	0.262
FFP 4 h	8 [3-12]	7 [4-13]	0.921
FFP 24 h	9 [5-16]	10 [4-16]	0.838
PLT 4 h	2 [2-3]	2 [1-3]	0.721
PLT 24 h	3 [2-5]	2 [1-5]	0.369
Complications			
AKI	11 (10.8%)	10 (9.8%)	1.000
Sepsis	6 (5.9%)	3 (2.9%)	0.498
Surgical Site Infection	5 (4.9%)	2 (2.0%)	0.445
Lower limb amputation	7 (6.9%)	4 (3.9%)	0.537
VTE	13 (12.8%)	10 (9.8%)	0.659
Extremity Compartment Syndrome	2 (2.0%)	1 (1.0%)	1.000
Fasciotomy	5 (4.9%)	2 (2.0%)	0.445
Hospital disposition			0.226
Home	14 (22.6%)	11 (22.9%)	
Rehabilitation	30 (48.4%)	17 (35.4%)	
Skilled Nursing Facility	16 (25.8%)	14 (29.2%)	
Other	2 (3.2%)	6 (12.5%)	
Length of stay, median (IQR), d			
Hospital	26 [16-38]	17 [<mark>10</mark> -29]	0.02
Intensive Care Unit	15 [<mark>9</mark> -22]	8 [4-16]	< 0.001
Time to Procedure, median (IQR) mins	77.5 [52–109]	52 [23-92]	< 0.001
Time in ED, median (IQR), mins	51 [32-80]	65 [39–129]	0.023

Table 5

Outcomes after propensity score matching.

Abbreviations: ED = emergency department, IOR = interguartile range, pRBC = packed redblood cells, FFP = fresh frozen plasma, PLT = platelets, AKI = acute kidney injury, VTE = venous thromboembolism, PPP = preperitoneal pelvic packing, REBOA = Resuscitative Endovascular Balloon Occlusion of the Aorta.

units plasma transfusion required at 4 h (8 [3-12] vs 7 [4-13]; P = 0.921) or 24 h (9 [5-16] vs 10 [4-16]; P = 0.838) and units platelets transfusion required at 4 h (2 [2–3] vs 2 [1–3]; P = 0.721) or 24 h (3 [2–5] vs 2 [1–5]; P = 0.369). Moreover, complication rates between the groups were similar at final analysis; AKI (10.8% vs 9.8%; P = 1.000), amputation (6.9% vs 3.9%; P = 0.537), extremity compartment syndrome (2.0% vs 1.0%; P = 1.000), VTE (12.8% vs 9.8%; P = 0.659), SSI (4.9% vs 2.0%; P = 0.445) and sepsis (5.9% vs. 2.9%; P = 0.498). Fasciotomy was performed in 5 patients (4.9%) in the PPP-group and in 2 patients (2.0%) in the REBOA-group (P = 0.445). Hospital disposition was not significantly different between the two groups; discharged home (22.6% vs 22.9%), to rehabilitation (48.4% vs 35.4%) and to a skilled nursing facility (25.8% vs 29.2%).

The time to a definitive hemorrhage control procedure was longer for PPP (77.5 mins [52-109] vs 52 [23-92]; P<0.001). However, PPP resulted in significantly less time spent in the ED (51 mins [IQR, 32-80] vs 65 mins [IQR, 39-129]; P = 0.023). In the patients that survived hospitalization, patients undergoing PPP had a significantly longer ICU length of stay (15 days [IQR, 9-22] vs 8 days [4-16]; P<0.001) and hospital length of stay (26 days [IQR, 16–38] vs 17 days [10–29]; P = 0.02).

Of all 102 patients receiving REBOA, 70 patients received RE-BOA in the ED with a median timing to procedure of 34 mins [IQR, 17-62]. Thirty-two patients received REBOA in the operating room with a median timing to procedure of 100 mins [IQR, 76-155.5].

Discussion

To our knowledge, this is the first national study to compare PPP and REBOA in patients with blunt pelvic fractures. Propensity score matching of the ACS-TQIP database showed that PPP was independently associated with a decrease in 24-hourand in-hospital mortality. Notably, there were no differences in transfusion requirements nor complications between the two groups.

Currently, the World Society of Emergency Surgery (WSES) and the Joint Statement regarding REBOA from the American College of Surgeons & American College of Emergency Physicians conditionally recommend the use of REBOA as a bridge to definitive treatment in the hemodynamically unstable patient with suspected pelvic bleeding [15,16]. Prior studies evaluating REBOA have mostly included distal thoracic aorta (Zone 1) occlusion, and most of these studies have shown promising results especially in the setting of traumatic arrest with a lower than expected mortality [9-11]. We wanted to evaluate the outcomes of REBOA specifically used for the control of pelvic hemorrhage by identifying patients with balloon occlusion isolated at the abdominal aorta. As placement of REBOA in Zone 2, from the celiac artery to the renal artery, is considered to be a no-occlusion zone, the included patients in the RE-BOA group most likely had the device deployed in Zone 3. Interestingly, our findings echo similar results from the Japanese Trauma Data Bank which suggested that REBOA was not necessarily associated with improved mortality when compared to standard of care [13]. Some of the controversy around the Japanese study reflect the inexperience and learning-curve associated with REBOA placement as well as questions concerning patient selection as REBOA is often considered as a last-ditch effort. Recently, Joseph et al. compared REBOA patients to non-REBOA patients with similar clinical characteristics [12]. These investigators also found similar results as the Japanese study, in which transfusion requirements and hospital length of stay were not different, but REBOA (mostly Zone 1) was associated notably with a higher 24-hour and in-hospital mortality in the REBOA group as well as other REBOA-specific complications such as profound limb ischemia and acute kidney injury [12]. Nevertheless, Burlew et al. considers REBOA a valuable

adjunct in reducing mortality in pelvic trauma patients especially when patients present in extremis [5].

In this study, there were several important clinical characteristics that differed between our groups early into the hospital stay and were likely not trivial in regard to patient outcomes. Time to procedure was significantly shorter in the REBOA group compared to the PPP group, but this was also associated with the significantly longer time spend in the ED. In addition, not every REBOA patient underwent placement within the ED, but instead one-third of RE-BOA patients had placement outside of the trauma bay which often included the operating room. REBOA placement in the OR resulted in a significantly longer time to intervention compared to patients that underwent REBOA in the ED, and this likely contributed to the higher than expected median time to REBOA overall.

Mortality within 24 h after trauma is frequently the result of hemorrhagic shock or devastating traumatic brain injury [17]. Before PSM, REBOA patients were noted to have more severe head injuries when compared to their PPP counterparts. After matching, head injury severity was evenly distributed between the groups. Despite this, transfusion requirements remained similar between groups, but the likelihood of death remained significantly higher in the REBOA group.

This study did not find a difference in AKI, limb amputation, or other complications, which contrasts from previous studies [12]. Nevertheless, prior studies focused mainly on patients with balloon occlusion at the distal thoracic aorta which likely resulted in a higher burden of visceral ischemia and reperfusion injury [18].

The results of our study must be interpreted in the context of the study design. Due to the retrospective nature of the database, we were only able to use the initial systolic blood pressure upon presentation in the ED. Therefore, we do not have access to the details surrounding the clinical judgement and indications to proceed with PPP versus REBOA. For example, we cannot expand on why certain locations were preferred for REBOA placement such as the OR versus the ED. The database also fails to capture cause of death which leaves this currently unanswerable. Despite our best efforts to match patients on potential confounders, the number of variables included in the dataset is limited, rendering the study liable to bias due to residual confounding variables, such as the type and the size of catheter used and the duration of occlusion of the aorta. A multi-institutional, prospective study by the AAST-AORTA study group is currently ongoing and will hopefully elaborate on these questions.

Conclusions

REBOA for hemorrhage control after blunt pelvic trauma is associated with higher mortality when compared to PPP. Causality remains unclear, but it is likely multifactorial. Clinical factors such as abrupt changes in hemodynamics, or prolonged ED time resulting in a delay to definitive hemorrhage control may contribute to the results of this study. Further, large, multi-institutional studies are warranted to support these findings.

Authorship

S.M., I.E. and A.M. designed this study. S.M., I.E. and M.E. performed the data analysis/interpretation. S.M., I.E. and M.E. performed the statistical analysis. S.M., I.E. and A.M. performed the literature search S.M., I.E., M.E., J.F., N.S., D.K., G.V., H.K., A.M. contributed to the writing and critical revisions.

Declaration of Competing Interest

The authors declare no conflicts of interest. No specific funding was received for this study.

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