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**To cite:** Kuo L-W, Liao C-H, Cheng C-T, *et al. Trauma Surg Acute Care Open* 2024;**9**:e001460. Analysis of the current usage of resuscitative endovascular balloon occlusion of the aorta (REBOA) in pediatric trauma patients: a retrospective observational study from the American College of Surgeons—Trauma Quality Improvement Program databases

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## ABSTRACT

**Background** Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been an established life-saving procedure for adult trauma patients, but the evidence for its use in pediatric patients is still under question. The purpose of this study was to examine the outcome of REBOA in pediatric patients.

**Methods** We retrospectively analyzed observational cohort data from the American College of Surgeons– Trauma Quality Improvement Program from 2017 to 2019. We analyzed 183 506 trauma patients aged 7–18, and 111 patients were matched by propensity score analysis. Basic demographics, injury severity, trauma type, and clinical outcomes of the patients receiving REBOA and those not receiving REBOA were compared. In the REBOA patients, a subgroup analysis was performed to evaluate the potential influence of age and body weight on the outcomes of REBOA.

**Results** After the pretreatment factors were balanced for the REBOA and no-REBOA groups, the patients in the REBOA group had more transfused packed red blood cells within the first 4 hours (3250 mL vs. 600 mL, p<0.001), and the mortality rate was higher in the REBOA group, but it did not reach statistical significance (56.8% vs. 36.5%, p=0.067). No significant difference was detected regarding in-hospital complications. In the subgroup analysis of the patients who received REBOA, we discovered no significant difference in mortality and complications between the subgroups when compared by age (>15 years old/≤15 years old) or weight (>58 kg or  $\leq$ 58 kg).

**Conclusions** Pediatric trauma patients who received REBOA were not significantly associated with an increased risk of mortality when compared with no-REBOA patients with matched basic demographics and pretreatment factors. Younger age and lighter body weight did not seem to influence the outcomes of REBOA regarding survival and complications. **Level of evidence** Level III

## BACKGROUND

Trauma is one of the leading causes of death for the pediatric population worldwide,<sup>12</sup> and bleeding

## WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been an established lifesaving procedure for adult trauma patients.WHAT THIS STUDY ADDS
- ⇒ No significant difference in mortality risk was observed in the pediatric REBOA patients compared with no-REBOA patients. Younger age and lighter body weight did not influence the outcomes of REBOA in terms of survival and complications.

# HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ REBOA did not improve the chances of survival for pediatric trauma patients, but the results should not be interpreted as a dismissal for pediatric use. When considering REBOA for pediatric patients, younger age and lighter body weight should not be viewed as contraindications.

is a fundamental factor contributing to mortality.<sup>3</sup> Furthermore, the mortality among injured children with life-threatening bleeding was approximately two to three times that reported in adult populations.<sup>4</sup> Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been a widely accepted life-saving procedure for adult trauma patients. However, in the pediatric population, only a few studies have discussed the use of REBOA, and most of these studies focused on adolescent patients.<sup>5 6</sup> To the best of our knowledge, only one study from Japan has published the outcomes of patients younger than 16 years old who received REBOA.<sup>7</sup>

Due to the scarce evidence supporting its benefit in pediatric patients, the use of REBOA has not yet gained prevalence in this age group. However, the need for a bridging procedure for life-threatening hemorrhage still exists. In a study in 2021, Theodorou *et al* estimated that nearly 20% of severely injured pediatric patients could benefit from REBOA as a temporary hemorrhage control procedure.<sup>8</sup> However, there is still no consensus on the exact indication, contraindication, or age limitation for the use of REBOA.

The main goal of this study is to examine the use of REBOA in pediatric patients in the USA by analyzing the American College of Surgeons–Trauma Quality Improvement Program (ACS-TQIP) databank for all patients under 18 years of age who received REBOA placement, and this study can provide a better understanding of its potential risks and benefits.

#### **METHODS**

## **Study population**

All patients retrieved from the ACS-TQIP between 2017 and 2019 were eligible for inclusion. The exclusion criteria were as follows: age greater than or equal to 18 years old or unknown age, trauma type that did not belong to blunt or penetrating categories, no signs of life or unknown signs of life on emergency department (ED) arrival, transferal to another hospital from the ED or ED discharge disposition labeled as not known/ not recorded (NK/NR), and received resuscitative thoracotomy. We defined resuscitative thoracotomy as thoracotomy during ED as a hemorrhagic control surgery. Patients whose hemorrhage control surgery was labeled as NK/NR, patients undergoing thoracotomy as a hemorrhage control surgery without a time to surgery, and patients without a time between ED arrival and ED discharge were also excluded because these patients' thoracotomy information could not be confirmed. Hemorrhage control procedures after REBOA (International Classification of Diseases-10th Revision procedure codes: 04L03DJ, 02LW3DJ, 04L03DZ, and 04L04DZ; online supplemental table 1), such as transcatheter arterial embolization (TAE) and laparotomy, were included in our analysis (see the Covariate selection section). Therefore, we excluded patients who underwent TAE or laparotomy before REBOA or patients with non-verifiable time sequences of REBOA and hemorrhage control procedures. 14 target outcomes were evaluated, including 12 primary outcomes and 2 secondary outcomes. (see the Covariate selection section). Patients with missing data for these 12 primary outcomes were excluded rather than using single expectation-maximization imputation (see the Missing values section). All the 12 primary outcomes had missing values <1.3%. The patients were then divided into two groups based on REBOA. Finally, the youngest patient who received REBOA was 7 years old. As a result, patients aged <7 years were excluded. Figure 1 shows the patient enrollment procedure.

## **Covariate selection**

Several categories of patients' basic demographics were collected. We have collected patients' basic information, including age, sex, and body weight (BW). The physiological presentation of the patients in the ED was gathered from the database, including systolic blood pressure, body temperature, pulse rate, respiratory rate, pulse oximetry, and Glasgow Coma Scale score. Information regarding trauma, such as the Injury Severity Score (ISS) and trauma type, was also collected. The diagnosis and severity of the injuries were determined using Abbreviated Injury Scale (AIS) codes. In ACS-TQIP, AIS 9 represents 'not possible to assign' and was thus labeled as missing values. Associated injuries, including hepatic (AIS: 5418XX; online supplemental table 2), splenic (AIS: 5442XX; online supplemental table 3), renal (AIS: 5416XX; online supplemental table 4), and pelvic fracture (8526XX for AIS 98 version, and 8561XX for AIS 05 and 15 versions; online supplemental table 5), lower extremity

#### 3,138,896 patients from the ACS-TQIP between 2017-2019

- Excluded 2,788,176 patients aged ≥18 years old or unknown age
- Excluded 25,455 patients with non-blunt/non-penetrating trauma or unknown mechanism
- Excluded 1,648 patients arrived at ED with no signs of life or unknown signs of life
- Excluded 28,311 patients transferred to another hospital from the ED or without information of ED discharge disposition
- Excluded resuscitative thoracotomy:
  - Excluded 18,898 patients' hemorrhagic control surgery labeled NK/NR
  - Excluded 24 patients underwent hemorrhagic control surgery without time to procedure
  - Excluded 36 patients underwent thoracotomy as a hemorrhagic control surgery without a time between ED arrival and ED discharge
  - Excluded 85 patient underwent resuscitative thoracotomy
- Excluded 48 patients' angiography labeled NK/NR
- Excluded 12 patients underwent REBOA, angiography, or lower extremity amputation without time to procedure
- Excluded 6 patients underwent TAE, laparotomy, or lower extremity amputation before REBOA
- Excluded 4790 patients with missing target outcomes



**Figure 1** Patient enrollment procedure. ACS-TQIP, American College of Surgeons–Trauma Quality Improvement Program; ED, emergency department; NK/NR, not known/not recorded; REBOA, resuscitative endovascular balloon occlusion of the aorta; TAE, transarterial embolization.

fracture (femur (8518XX for AIS 98 version, and 853XXX for AIS 05 and 15 versions; online supplemental table 6), tibia (853404-853422 for AIS 98 version, and 8540XX-8543XX for AIS 05 and 15 versions; online supplemental table 7), and fibula (851605-851614 for AIS 98 version, and 8544XX for AIS 05 and 15 versions; online supplemental table 8)), vascular injuries (iliac vascular (AIS: 5206XX-5210XX; online supplemental table 9) and lower extremity vascular injuries (AIS: 82XXXX; online supplemental table 10)), were collected. 12 primary outcomes were evaluated, including TAE, laparotomy, or lower extremity amputation (International Classification of Diseases-10th Revision procedure code: online supplemental table 11) after REBOA, volume of transfused packed red blood cells within the first 4 hours (4-hour PRBC), length of stay, mortality rate, and six hospital events (deep vein thrombosis, pulmonary embolism (PE), stroke/cerebrovascular accident (CVA), acute kidney injury, myocardial infarction, and extremity compartment syndrome). For patients who underwent TAE or laparotomy, we analyzed their time to TAE and time to laparotomy as secondary outcomes.

The single expectation-maximization imputation method was applied for the covariates with missing values (except for the 12 primary outcomes; see the *Study population* section). Imputation was used for the following missing data: sex, BW, systolic blood pressure, body temperature, pulse rate, respiratory rate, pulse oximetry, Glasgow Coma Scale score, ISS, and vascular injury of the lower extremity. All variables reported missing values of less than 9.2%. The final dataset was checked for the rationality of the input data.

## **Statistical analysis**

We first compared the REBOA and no-REBOA groups with the original data after single expectation-maximization imputation. The continuous variables were evaluated using the Mann-Whitney U test, and the categorical variables were analyzed using the  $\chi^2$  test with continuity correction for 2×2 tables. In some instances, there are cells in the tables where the expected values under the null hypothesis were less than 5. If appropriate, we employed Fisher's exact test instead of the  $\chi^2$  test in such situations. Fisher-Freeman-Halton test was used for larger tables than  $2 \times 2$ . Several statistically significant differences in the pretreatment factors were observed. To overcome this bias, 2:1 propensity score matching (PSM) was used to balance all pretreatment factors. After PSM, all target outcomes were compared. Finally, we conducted a subgroup analysis on the REBOA patients to investigate the potential influence of age and BW on the outcomes of the REBOA patients, and the subgroups were divided by the 25th percentile of age (15 years old) and BW (58 kg). Statistical significance was set at p<0.05. All statistical analyses were performed using R software (V.2022.12.0+353).

#### RESULTS

We analyzed 183494 pediatric trauma patients, of whom 37 received REBOA. The patient characteristics and patterns of injuries before PSM are summarized in table 1. In general, the patients who received REBOA were older and had poorer vital signs when presented to the ED. The REBOA patients had more severe injuries (median ISS: 32.0 vs. 4.0, p<0.001) and were more likely to sustain severe injuries to the liver, spleen, kidney, and pelvis. The ratio of penetrating injuries was also higher in the REBOA group (32.4% vs. 10.4%, p<0.001). The patients who received REBOA were more likely to receive TAE (16.2% vs. 0.2%, p<0.001) and undergo a laparotomy (62.2% vs. 0.7%, p<0.001) for hemorrhage control, and they had more 4-hour PRBC transfusion than those who did not receive REBOA (3250 mL vs. 0 mL, p<0.001). The REBOA patients had more in-hospital complications, including PE (2.7% vs. 0.0%, p<0.001), stroke/CVA (5.4% vs. 0.0%, p<0.001), and acute kidney injury (8.1% vs. 0.1%, p<0.001). More patients in the REBOA group had to receive lower extremity amputation (2.7% vs. 0.1%, p=0.022), and the mortality rate was 56.8%, which was significantly higher than that of the no-REBOA patients (0.9%, p<0.001).

Of the 183 494 pediatric trauma patients, 111 were matched, with 37 patients from the REBOA group and 74 from the no-REBOA group. Subsequently, we verified the creation of a new pair of well-balanced cohorts by ensuring that the standardized mean difference for all pretreatment factors was <0.2 (online supplemental table 12), which is generally considered small.<sup>9</sup> The 14 target outcomes are presented in table 2. Compared with the no-REBOA group, the patients in the REBOA group had a higher likelihood of undergoing laparotomy

(62.2% vs. 32.4%, p=0.005) and had more 4-hour PRBC transfusion requirements (3250.0 mL vs. 600.0 mL, p<0.001). There was no significant difference regarding length of stay (2.0 days vs. 6.5 days, p=0.439), deep vein thrombosis (2.7% vs. 2.7%, p>0.999), PE (2.7% vs. 2.7%, p>0.999), stroke/CVA (5.7% vs. 0%, p=0.109), acute kidney injury (8.1 vs. 2.7, p>0.331), and lower limb amputations (2.7% vs. 1.4%, p>0.999). The mortality rate was higher in the REBOA group but did not reach statistical significance (56.8% vs. 36.5%, p=0.067).

In the subgroup analysis, we divided the REBOA group by the 25th age percentile (15 years old, see table 3). The patients who were 15 years old or younger (n=10) were compared with their counterparts who were older than 15 years old (n=27). The sex ratio (male 70.0% vs. 70.4%, p>0.999) was similar between the two groups. No significant difference was presented in the overall severity, trauma types, and severity of each specific organ among the groups, and the proportions of patients receiving TAE (30.0% vs. 11.1%, p=0.313) and laparotomy (50.0% vs. 66.7%, p=0.454) were also similar. The younger REBOA patients received significantly less 4-hour PRBC transfusion (1520.0 mL vs. 4800.0 mL, p=0.017), but there were no significant differences regarding in-hospital complications and mortality (50.0% vs. 59.3%, p=0.716). Subgrouping of BW was also performed by dividing at the 25th percentile (58 kg). The patients who weighed no more than 58 kg (n=11) were compared with the heavier group. Likewise, there was no significant difference in target outcomes (table 4) between the different BW groups.

## DISCUSSION

This article is the first nationwide study to compare the results of REBOA to no-REBOA in a pediatric trauma population in the USA. 37 REBOA patients were identified from 2017 to 2019, which was much more than the 11-patient study published by Theodorou *et al* in 2020.<sup>6</sup> The data by Theodorou *et al* were based on the American Association for the Surgery of Trauma Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry, and they only included patients from certain contributing hospitals.<sup>10</sup> Our current study is based on the ACS-TQIP database, which essentially included more trauma centers and patients in the USA, resulting in more patients being collected. The AORTA Registry contained more specific details regarding aortic occlusion, but the ACS-TQIP database included more patients, so we chose the latter to have a more general outline of REBOA use in the pediatric population.

Our current study revealed that the median age of REBOA use was 16 years of age. Approximately one-quarter of the REBOA patients were  $\leq 15$  years old, and the youngest patient who received REBOA was 7 years old. The distribution was similar to the Japanese study by Norii and colleagues in 2017, where 15 of their 54 REBOA patients (27%) were under 16.<sup>7</sup> However, they did not specify the age of the youngest REBOA patient. We disclosed a survival rate of 43.2%, which was slightly better than the 30% reported by Theodorou *et al*<sup>6</sup> and the 28.6% in the article by Smith *et al*<sup>8</sup> in 2020, but similar to the 42.6% in Norii *et al*<sup>2</sup>s study.<sup>7</sup> Our results indicated that REBOA can be a viable option as a bridging maneuver for pediatric patients who present with shock and severe trauma.

We discovered that the REBOA group had a higher laparotomy rate after REBOA and a significantly larger 4-hour PRBC transfusion requirement than the no-REBOA group, even after PSM balanced all the demographics, vital signs, and associated injuries. The mortality rate was higher in the REBOA group but did not reach statistical significance (56.8% vs. 36.5%, p=0.067). In

Table 1         Demographics of all patients with/without resuscitative endovascular balloon occlusion of the aorta (REBOA)					
Variables	All patients (n=183494)	REBOA (-) (n=183 457)	REBOA (+) (n=37)	P value†	
Age (year)	13.0 (10.0, 16.0)	13.0 (10.0, 16.0)	16.0 (15.0, 17.0)	<0.001*‡	
Sex					
Male	125 081 (68.2)	125 055 (68.2)	26 (70.3)	0.922§	
Female	58 413 (31.8)	58 402 (31.8)	11 (29.7)		
Weight (kg)	55.3 (38.0, 70.0)	55.3 (38.0, 70.0)	72.0 (58.0, 80.0)	<0.001*‡	
Conditions at the ED					
Systolic blood pressure (mm Hg)	124.0 (114.0, 135.0)	124.0 (114.0, 135.0)	93.0 (78.0, 109.0)	<0.001*‡	
Body temperature (°C)	36.8 (36.6, 37.1)	36.8 (36.6, 37.1)	36.4 (36.0, 36.7)	<0.001*‡	
Pulse rate (/min)	93.0 (80.0, 107.0)	93.0 (80.0, 107.0)	110.0 (95.0, 133.0)	<0.001*‡	
Respiratory rate (/min)	20.0 (18.0, 22.0)	20.0 (18.0, 22.0)	18.0 (16.0, 24.0)	0.525‡	
Blood oxygen saturation (%)	99.0 (98.0, 100.0)	99.0 (98.0, 100.0)	97.0 (83.0, 100.0)	<0.001*‡	
Glasgow Coma Scale	15.0 (15.0, 15.0)	15.0 (15.0, 15.0)	6.0 (3.0, 14.0)	<0.001*±	
	40(40,90)	40(40.90)	32 0 (22 0 43 0)	<0.001*±	
Trauma type	4.6 (4.6, 5.6)	4.0 (4.0, 5.0)	52.0 (22.0, 45.0)	(0.001 1	
Blunt	164 364 (89 6)	16/ 339 (89 6)	25 (67 6)	<0.001* **	
Penetroting	10120 (10.4)	10118 (10.4)	12 (22 4)	<0.001	
Associated honotic injury	13130 (10.4)	19110 (10.4)	12 (32.4)		
Associated nepatic injury	177541 (06.9)	177526 (06.0)	1E (40 E)	-0.001*5	
	177 541 (90.8) 4630 (2.5)	177 520 (90.8)	15 (40.5)	<0.001 9	
AIS≤3	4620 (2.3)	4610 (2.5)	10 (27.0)		
AIS≥4	1333 (0.7)	1321 (0.7)	12 (32.4)		
Associated splenic injury			27 (72 0)	0.001*0	
Nil	177110 (96.5)	177 083 (96.5)	27 (73.0)	<0.001*§	
AIS≤3	4811 (2.6)	4806 (2.6)	5 (13.5)		
AIS≥4	1573 (0.9)	1568 (0.9)	5 (13.5)		
Associated renal injury					
Nil	179670 (97.9)	179 644 (97.9)	26 (70.3)	<0.001*§	
AIS≤3	2825 (1.5)	2818 (1.5)	7 (18.9)		
AIS≥4	999 (0.5)	995 (0.5)	4 (10.8)		
Associated pelvic fracture					
Nil	175 990 (95.9)	175 964 (95.9)	26 (70.3)	<0.001*§	
AIS≤3	6793 (3.7)	6786 (3.7)	7 (18.9)		
AIS≥4	711 (0.4)	707 (0.4)	4 (10.8)		
Lower limb fractures, total					
Femur	13859 (7.6)	13 854 (7.6)	5 (13.5)	0.199**	
Tibia	17510 (9.5)	17 507 (9.5)	3 (8.1)	>0.999**	
Fibula	11 901 (6.5)	11 899 (6.5)	2 (5.4)	>0.999**	
Vascular injury					
Iliac	221 (0.1)	217 (0.1)	4 (10.8)	<0.001* **	
Lower extremity	906 (0.5)	905 (0.5)	1 (2.7)	0.167**	
TAE after REBOA	324 (0.2)	318 (0.2)	6 (16.2)	<0.001* **	
Time to TAE (h)¶	2.5 (1.2, 4.4)	2.5 (1.2, 4.4)	2.5 (1.4, 3.6)	0.879‡	
Laparotomy after REBOA	1259 (0.7)	1236 (0.7)	23 (62.2)	<0.001* **	
Time to laparotomy (h)¶	1.1 (0.6, 2.0)	1.1 (0.6, 2.0)	0.8 (0.6. 1.4)	0.203‡	
4 h PRBC transfusion (mL)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	3250.0 (1400.0. 6250.0)	<0.001*‡	
Length of stay (day)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	2.0 (1.0, 25.0)	0.141‡	
Hospital complication	210 (210) 510)	210 (210) 510)	2.0 (1.0, 2010)		
Deep vein thrombosis	268 (0 1)	267 (0 1)	1 (2 7)	0.053**	
Pulmonary embolism	79 (0.0)	78 (0 0)	1 (2 7)	0.016* **	
Stroko/corobrovascular accident	85 (0.0)	83 (0.0)	2 (5 1)	<0.011* **	
	0.00	05 (0.0)	2 (0.4)	<0.001* **	
Acate Kiuney injury	(0.1)	127 (0.1) C (0.0)	2 (0.1) 0 (0.0)	<0.001	
iviyocardiai intarction	0 (0.0)	0 (0.0)	0 (0.0)	>0.999**	
Extremity compartment syndrome	197 (0.1)	197 (0.1)	0 (0.0)	>0.999^^	
Lower extremity amputation	108 (0.1)	107 (0.1)	1 (2.7)	0.022* **	
Mortality	1724 (0.9)	1703 (0.9)	21 (56.8)	<0.001* **	

Continuous variables: median (first and third quartiles); categorical variables: numbers (percentages). \*Statistical significance (p<0.05). \*Comparisons among patients with/without REBOA. #Mann-Whitney U test. §X<sup>2</sup> test with continuity correction. ¶Only patients who underwent the procedure were included. \*\*Fisher's exact test. AIS, Abbreviated Injury Scale; ED, emergency department; PRBC, packed red blood cells; TAE, transcatheter arterial embolization.

(REBUA)			
Variables	REBOA (-) (n=74)	REBOA (+) (n=37)	P value
TAE after REBOA	8 (10.8)	6 (16.2)	0.545†
Time to TAE (h)‡	3.9 (2.4, 4.5)	2.5 (1.4, 3.6)	0.192§
Laparotomy after REBOA	24 (32.4)	23 (62.2)	0.005*¶
Time to laparotomy (h)‡	0.7 (0.5, 1.2)	0.8 (0.6, 1.4)	0.279§
4 h PRBC transfusion (mL)	600.0 (0.0, 2307.8)	3250.0 (1400.0, 6250.0)	<0.001*§
Length of stay (day)	6.5 (2.0, 19.8)	2.0 (1.0, 25.0)	0.439§
Hospital complication			
Deep vein thrombosis	2 (2.7)	1 (2.7)	>0.999†
Pulmonary embolism	2 (2.7)	1 (2.7)	>0.999†
Stroke/cerebrovascular accident	0 (0.0)	2 (5.4)	0.109†
Acute kidney injury	2 (2.7)	3 (8.1)	0.331†
Myocardial infarction	0 (0.0)	0 (0.0)	NaN
Extremity compartment syndrome	0 (0.0)	0 (0.0)	NaN
Lower extremity amputation	1 (1.4)	1 (2.7)	>0.999†
Mortality	27 (36.5)	21 (56.8)	0.067¶

 Table 2
 Outcomes after 2:1 propensity score matching between patients with/without resuscitative endovascular balloon occlusion of the aorta (REROA)

Continuous variables: median (first and third quartiles); categorical variables: numbers (percentages).

\*Statistical significance (p<0.05).

†Fisher's exact test.

‡Only patients who underwent the procedure were included.

§Mann-Whitney U test.

 $\mathbb{R}^2$  test with continuity correction.

NaN, not a number; PRBC, packed red blood cells; TAE, transcatheter arterial embolization.

the adult population, similar findings were presented by Joseph *et al.*<sup>11</sup> In the study by Joseph *et al*, placement of REBOA in severely injured trauma patients was associated with a higher mortality rate. The time to angioembolization and the time to laparotomy were both significantly higher in the REBOA group, indicating that a possible delay to definite hemorrhagic control might be the cause of the inferior outcomes since every 3-minute delay to definite hemorrhagic control would increase the probability of death by 1%.<sup>12</sup> However, there was no significant difference in the time to TAE and the time to laparotomy between the two groups in our study; therefore, the worse outcome in the REBOA group could not be attributed to the timing of definite hemorrhage control.

Despite the survival difference not reaching statistical significance in our study, the mortality rate was still 20% higher in the REBOA group, which is hard to unsee. One might conclude that our study results indicate that REBOA was associated with an increased risk of death in pediatric patients, just as the UK-REBOA trial suggested that REBOA may increase the risk of mortality when compared with standard care.13 However, we could not draw such a firm conclusion. A crucial reason is that no matter how delicate the study design is, it is difficult to have the two balanced arms in such critical patients for comparison. The UK-REBOA trial is a prospective randomized controlled trial, yet considerable heterogenicity exists between the REBOA group and the standard treatment group, including the initial blood pressure and the proportion of head injuries.<sup>14 15</sup> Hence, it might be too bold to state that REBOA is not beneficial to patients.

Another study proposed by Chien and colleagues also demonstrated the difficulty of truly balancing the two arms.<sup>16</sup> In their retrospective study, 93 patients with severe pelvic fractures who received REBOA were matched with those who did not receive REBOA. Factors including age, sex, injury severity, vital signs, and trauma type were balanced, but the REBOA group had worse survival. Chien's REBOA cohort also had significantly more blood transfusion requirements than the no-REBOA group. Their theory was that REBOA patients were in more critical condition than no-REBOA patients in a way that was not depictable by meticulous matching for injury severity, physiological condition at admission, and comorbid conditions. Therefore, they needed more blood transfusions, and they had worse survival rates. Similar findings were also presented in our current study. In our study cohort, the REBOA group had significantly more 4-hour PRBC transfusion than the no-REBOA group. We agree with Chien's hypothesis and believe that these results should not dismiss the use of REBOA on pediatric patients. More detailed research in the future is needed to understand this phenomenon better and recognize specific indications and contraindications in this population.

In the subgroup analysis, we attempted to discuss whether age or BW could influence survival and complications. We hypothesized that with a relatively smaller artery size, the pediatric population might be more vulnerable to device-related complications, similar to the fact that larger profile devices were associated with the risk of arterial access-related limb ischemic complications.<sup>17</sup> We chose the 25th percentile of age in the REBOA patients to separate the age groups. However, we did not find significant differences in outcomes between the younger and older REBOA patients. In addition to age, we analyzed the possible impact of BW because age might not represent body size perfectly in adolescent populations since the variation in body size among the same age group might be significant.<sup>18</sup> Similar to the standard of age categorization, we chose the 25th percentile of BW as the cut point to divide our patients into smaller and larger groups. Nevertheless, we found no differences in the outcomes between these two groups. Therefore, we could not suggest an age limitation for REBOA use in adolescents. Currently, the smallest available REBOA device approved by the Food and Drug Administration is the COBRA-OS (Control Of Bleeding, Resuscitation, Arterial Occlusion System).<sup>19</sup> With its 4-French caliber, it might be the suitable device of choice for pediatric trauma patients with smaller body sizes.

Table 3         Subgroup analysis for patients with resuscitative endovascular balloon occlusion of the aorta (REBOA), based on age				
Variables	Age ≤15 years old (n=10)	Age >15 years old (n=27)	P value	
Age	13.5 (11.0, 14.8)	17.0 (16.0, 17.0)	<0.001*†	
Sex				
Male	7 (70.0)	19 (70.4)	>0.999‡	
Female	3 (30.0)	8 (29.6)		
Weight (kg)	57.5 (46.0, 72.4)	72.1 (64.1, 80.8)	0.055†	
Conditions at the ED				
Systolic blood pressure (mm Hg)	94.0 (86.2, 103.2)	84.0 (75.5, 117.5)	0.811†	
Body temperature (°C)	36.9 (36.4, 37.1)	36.3 (35.4, 36.7)	0.006*†	
Pulse rate (/min)	107.5 (86.5, 131.2)	111.0 (95.0, 142.5)	0.516†	
Respiratory rate (/min)	20.5 (16.0, 32.0)	18.0 (16.0, 21.0)	0.416†	
Blood oxygen saturation (%)	96.5 (93.8, 100.0)	97.0 (81.5, 99.0)	0.545†	
Glasgow Coma Scale	11.0 (5.2, 15.0)	3.0 (3.0, 13.0)	0.088†	
Injury Severity Score	26.0 (20.0, 37.2)	33.0 (23.5, 46.5)	0.451†	
Trauma type				
Blunt	8 (80.0)	17 (63.0)	0.445‡	
Penetrating	2 (20.0)	10 (37.0)		
Associated hepatic injury				
Nil	4 (40.0)	11 (40.7)	0.897§	
AIS≤3	2 (20.0)	8 (29.6)		
AIS≥4	4 (40.0)	8 (29.6)		
Associated splenic injury				
Nil	8 (80.0)	19 (70.4)	>0.999§	
AIS≤3	1 (10.0)	4 (14.8)		
AIS≥4	1 (10.0)	4 (14.8)		
Associated renal injury				
Nil	8 (80.0)	18 (66.7)	0.716§	
AIS≤3	2 (20.0)	5 (18.5)		
AIS≥4	0 (0.0)	4 (14.8)		
Associated pelvic fracture				
Nil	7 (70.0)	19 (70.4)	0.366§	
AIS≤3	3 (30.0)	4 (14.8)		
AIS≥4	0 (0.0)	4 (14.8)		
Lower limb fractures, total				
Femur	0 (0.0)	5 (18.5)	0.295‡	
Tibia	1 (10.0)	2 (7.4)	>0.999‡	
Fibula	0 (0.0)	2 (7.4)	>0.999‡	
Vascular injury	. (	- (		
lliac		3 (11.1)	>0.999‡	
Lower extremity	0 (0.0)	l (3./)	>0.999‡	
TAE after REBOA	3 (30.0)	3 (11.1)	0.313‡	
lime to IAE (h)¶	3.6 (2.5, 3.6)	1.4 (1.1, 3.3)	0.188†	
	5 (50.0)	18 (66.7)	0.454‡	
Time to taparotomy (n)1	1.2 (1.1, 2.1)	0.8 (0.6, 1.3)	0.0175	
4 n PRBC transfusion (mL)	1520.0 (712.5, 2690.5)	4800.0 (2275.0, 6825.0)	0.01/bt	
Length of stay (day)	7.0 (2.0, 30.2)	2.0 (1.0, 21.0)	0.3117	
Doop usin thromhosic	1 (10.0)	0 (0 0)	0.270+	
		1 (3 7)	0.270+ >0.000+	
runnondry emporism Stroko/corobrouscular accident	1 (10.0)	1 (3.7)	>0.333+	
	1 (10.0)	2 (7 4)	1 000+	
Acute Kulley Injury		2 (7.4)	NaN	
	0 (0.0)	0 (0.0)	NaN	
	0 (0.0)	1 (3 7)	\0 999t	
Mortality	5 (5.0)	16 (59 3)	0.716±	
wortunity	5 (50.0)	(6.56)	0.710+	

Continuous variables: median (first and third quartiles); categorical variables: numbers (percentages). \*Statistical significance (p<0.05). †Mann-Whitney U test.

TMann-Wintiey or test. #Fisher's exact test. §Fisher-Freeman-Halton test. ¶Only patients who underwent the procedure were included. AIS, Abbreviated Injury Scale; ED, emergency department; NaN, not a number; PRBC, packed red blood cells; TAE, transcatheter arterial embolization.

Table 4         Subgroup analysis of patients with resuscitative endovascular balloon occlusion of the aorta (REBOA), based on body weight				
Variables	Body weight ≤58 kg (n=11)	Body weight >58 kg (n=26)	P value	
Age	15.0 (12.5, 17.0)	16.0 (16.0, 17.0)	0.122†	
Sex				
Male	6 (54.5)	20 (76.9)	0.244‡	
Female	5 (45.5)	6 (23.1)		
Weight (kg)	52.0 (47.0, 56.8)	76.0 (70.7, 81.6)	<0.001†	
Conditions at the ED				
Systolic blood pressure (mm Hg)	83.0 (75.0, 93.0)	104.5 (80.0, 121.8)	0.046†	
Body temperature (°C)	36.4 (36.3, 37.0)	36.4 (35.2, 36.7)	0.257†	
Pulse rate (/min)	110.0 (104.5, 136.0)	109.0 (86.8, 132.8)	0.539†	
Respiratory rate (/min)	20.0 (16.0, 33.5)	18.0 (16.0, 21.5)	0.232†	
Blood oxygen saturation (%)	96.0 (81.5, 98.5)	98.0 (84.8, 99.8)	0.556†	
Glasgow Coma Scale	11.0 (3.0, 14.0)	3.5 (3.0, 14.0)	0.459†	
Injury Severity Score	35.0 (22.0, 46.5)	30.5 (22.8, 42.8)	0.868†	
Trauma type				
Blunt	7 (63.6)	18 (69.2)	>0.999‡	
Penetrating	4 (36.4)	8 (30.8)		
Associated hepatic injury				
Nil	2 (18.2)	13 (50.0)	0.106§	
AIS≤3	3 (27.3)	7 (26.9)		
AIS≥4	6 (54.5)	6 (23.1)		
Associated splenic injury				
Nil	6 (54.5)	21 (80.8)	0.187§	
AIS≤3	3 (27.3)	2 (7.7)		
AIS≥4	2 (18.2)	3 (11.5)		
Associated renal injury				
Nil	7 (63.6)	19 (73.1)	0.636§	
AIS≤3	2 (18.2)	5 (19.2)		
AIS≥4	2 (18.2)	2 (7.7)		
Associated pelvic fracture				
Nil	9 (81.8)	17 (65.4)	0.540§	
AIS≤3	2 (18.2)	5 (19.2)		
AIS≥4	0 (0.0)	4 (15.4)		
Lower limb fractures, total				
Femur	1 (9.1)	4 (15.4)	>0.999‡	
Tibia	0 (0.0)	3 (11.5)	0.540‡	
Fibula	0 (0.0)	2 (7.7)	>0.999‡	
Vascular injury				
Iliac	0 (0.0)	4 (15.4)	0.296‡	
Lower extremity	0 (0.0)	1 (3.8)	>0.999‡	
TAE after REBOA	1 (9.1)	5 (19.2)	0.646‡	
Time to TAE (h)¶	1.7 (1.1, 3.2)	3.1 (1.5, 3.6)	0.440†	
Laparotomy after REBOA	7 (63.6)	16 (61.5)	>0.999‡	
Time to laparotomy (h)¶	1.1 (0.7, 1.6)	0.8 (0.6, 1.2)	0.539†	
4 h PRBC transfusion (mL)	2764.0 (725.0, 5162.5)	3625.0 (1837.5, 6912.5)	0.311†	
Length of stay (day)	1.0 (1.0, 25.5)	2.5 (2.0, 21.5)	0.530†	
Hospital complication				
Deep vein thrombosis	1 (9.1)	0 (0.0)	0.297‡	
Pulmonary embolism	0 (0.0)	1 (3.8)	>0.999‡	
Stroke/cerebrovascular accident	1 (9.1)	1 (3.8)	0.512‡	
Acute kidney injury	1 (9.1)	2 (7.7)	>0.999‡	
Myocardial infarction	0 (0.0)	0 (0.0)	NaN	
Extremity compartment syndrome	0 (0.0)	0 (0.0)	NaN	
Lower extremity amputation	0 (0.0)	1 (3.8)	>0.999‡	
Mortality	6 (54.5)	15 (57.7)	>0.999‡	

Continuous variables: median (first and third quartiles); categorical variables: numbers (percentages). \*Statistical significance (p<0.05). †Mann-Whitney U test.

TMann-Wintiey or test. #Fisher's exact test. §Fisher-Freeman-Halton test. ¶Only patients who underwent the procedure were included. AIS, Abbreviated Injury Scale; ED, emergency department; NaN, not a number; PRBC, packed red blood cells; TAE, transcatheter arterial embolization.

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Our study has several limitations. The nature of the study design might carry selection bias. For example, the interhospital transfer patients were excluded, leaving only the patients who received the whole treatment in one hospital in our study. This selection might rule out patients treated in a less capable hospital; therefore, the accurate results for all pediatric REBOA patients might be worse than we presented. The small sample size could also mask the potential difference in statistical analysis, making us unable to detect meaningful findings. Last, we chose the ACS-TQIP database rather than the AORTA Registry to include more patients, but the downside of this selection is that the ACS-TQIP database did not include details regarding the procedure, such as the device type, arterial access technique, duration of the procedure, and patients' response after occlusion. These elements might help us further define the use of **REBOA** in pediatric patients.

## **CONCLUSIONS**

The use of REBOA was associated with a higher mortality risk among pediatric patients compared with no-REBOA patients, but the difference did not reach statistical significance. The actual cause of this phenomenon is still unknown and requires more detailed and thorough investigations. We do not discourage the use of REBOA in pediatric trauma patients. REBOA is not a panacea; it is simply an adjunct in the advanced resuscitation of patients with traumatic hemodynamic shock.<sup>15</sup> Before more convincing evidence emerges, we should not rule out such a useful tool, especially when the clinical situation is critical. Younger age and lighter BW did not seem to influence the outcomes of REBOA regarding survival and complications. A larger scale study is essential to clarify whether there is an age or body size limitation for pediatric REBOA use.

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