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Delays in Surgical Intervention and Temporary Hemostasis Using Resuscitative Endovascular Balloon Occlusion of the aorta (REBOA): Influence of Time to Operating Room on Mortality

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ABSTRACT

Background: The optimal candidates for resuscitative endovascular balloon occlusion of the aorta (REBOA) remain unclear. We hypothesized that patients who experience delays in surgical intervention would benefit from REBOA.

Methods: Using the Japan Trauma Databank (2014–2019), patients transferred to the operating room (OR) within 3 h were identified. Patients treated with REBOA were matched with those without REBOA using propensity scores, and further divided based on the transfer time to OR: ≤ 1 h (early), 1–2 h (delayed), and >2 h (significantly-delayed). Survival to discharge was compared.

Results: Among 5258 patients, 310 underwent REBOA. In 223 matched pairs, patients treated with REBOA had improved survival (56.5% vs. 31.8%; $p < 0.01$), although in-hospital mortality was reduced by REBOA only in the delayed and significantly-delayed subgroups (HR = 0.43 [0.28–0.65] and 0.42 [0.25–0.71]).

Conclusions: REBOA-treated trauma patients who experience delays in surgical intervention (>1 h) have improved survival.

Introduction

Trauma is a major cause of morbidity and mortality across the world, and over 50% of potentially preventable trauma deaths are caused by massive hemorrhage.[1–3] Although various adjuncts to timely surgical intervention for hemorrhage are available including resuscitative thoracotomy (RT), massive transfusion, and whole blood administration,[4–6] resuscitative endovascular balloon occlusion of the aorta (REBOA) has been developed as an additional technique for temporary control of arterial hemorrhage.[7–10] Since this is a relatively less invasive method for acute hemorrhage control with potential clinical benefits, REBOA has been used in various regions and countries with increasing popularity, particularly in the management of trauma patients.[1,7,8,11]

As the number of published trauma-related REBOA studies continues to increase, considerable debate has been generated regarding the benefits of REBOA in severely injured trauma patients, mainly due to conflicting clinical results.[12–16] A 2018 prospective analysis using the American Association for the Surgery of Trauma (AAST) Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery (AORTA) database revealed a survival benefit in hypotensive patients not requiring cardiopulmonary resuscitation who underwent REBOA compared with RT.[12] Similarly, another retrospective analysis in 2019, using the Japan nationwide trauma database, also reported improved survival in trauma patients treated with REBOA compared to propensity-matched controls.[13] Conversely, a case-control study analyzing the American College of Surgeons Trauma Quality Improvement Program (ACS TQIP) dataset reported that REBOA was associated with increased mortality,[1] and two other studies performing similar analyses on the Japanese trauma database found a higher mortality with REBOA use as well.[14,15]

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There are several potential reasons for the contradictory findings in the aforementioned studies. First, as REBOA is typically used in the management of severely injured trauma patients with massive hemorrhage, REBOA use by itself could be considered a surrogate marker for injury severity in retrospective studies.[17] Second, in studies where propensity score matching is applied, differences in covariates for propensity score calculation, as well as match-caliper for matching, could result in conflicting results.[18] Thirdly, studies using decades-old data could also limit the appropriate interpretation of study results.[5] Furthermore, as REBOA was designed to temporize hemorrhage until definitive surgical control is achieved,[10,17] studies performed in clinical settings without adequate resources for definitive hemostasis, or where operating rooms are not immediately available, could negatively affect the study results due to prolonged time to surgical control of bleeding.[19,20]

Therefore, a careful and methodological selection of inclusion criteria to identify the appropriate study population, along with a rational algorithm for defining a similar control population, should be applied in studies evaluating REBOA outcomes.[13,18] Accordingly, in an effort to identify the optimal candidates for REBOA, we examined outcomes in patients treated with REBOA compared with a similar propensity-matched cohort of patients treated without REBOA, evaluating three preoperative time periods based on the transfer time to OR after hospital arrival. Using a large nationwide database with recent data reflecting current standards of care, we hypothesized that REBOA use would improve survival in severely injured trauma patients who experience delays in surgical intervention, compared to those who do not.

Material and methods

Study design and setting

We conducted a retrospective cohort study using data from the Japan Trauma Data Bank (JTDB). The JTDB was established as a Japanese nationwide trauma registry in 2003 and has been maintained by the Japanese Association for the Surgery of Trauma and the Japanese Association for Acute Medicine, comprised of over 200 participating hospitals and tertiary care centers. JTDB data is collected prospectively and entered by treating physicians or volunteer registrars designated by each hospital into an online data collection portal.[13] Prior to study initiation, all collaborating hospitals obtained individual local Institutional Review Board approval for the Conduct of Human Research.

In hemodynamically unstable trauma patients without immediate access to surgical intervention, current practice in Japan recommends placement of a REBOA catheter in Zone 1 (between left subclavian artery and celiac artery) through the femoral artery with fluoroscopy and/or ultrasound. The insertion of REBOA in our study population was performed by both trauma surgeons and emergency physicians, as in Japan trauma surgeons are not always present in the hospital at time of patient arrival and delays to definitive care are therefore somewhat common, frequently resulting in REBOA placement by emergency physicians. As a result, REBOA is recognized as a standard life-saving procedure throughout Japan and performed at most of the JTDB participating hospitals. Ten-Fr REBOA catheters were used until 2013, until 7-Fr options became clinically available.[13]

Study population

We retrospectively reviewed data from the JTDB between January 2014 and March 2019. Inclusion criteria consisted of trauma patients greater than 15 years of age who arrived with a palpable pulse, were eventually transferred to the OR, and received a transfusion of any blood product type within 24 h after arrival. Patients with missing or invalid data regarding prehospital information, vital signs on arrival, time of arrival, time of surgery, or in-hospital survival were excluded. Patients who were transferred to the OR more than 3 h after hospital arrival were also excluded.

Data collection and definitions

Available data in the database included age, sex, mechanism of injury, prehospital vital signs, vital signs on arrival, imaging tests performed during resuscitation, any surgical procedures or angiography, transfusion within 24 h after arrival, any other additional procedures (tube thoracotomy, endotracheal intubation, RT, and REBOA), Abbreviated Injury Scale (AIS) score, Injury Severity Score (ISS), hospital length of stay, and survival status at discharge. REBOA catheter size, position of REBOA placement, duration of REBOA inflation, and complications related to REBOA were not available in the database. The amount of transfusion was also not available in the database.

The transfer time to OR after hospital arrival was defined as the time between hospital arrival and initiation of surgery in the OR, or angiography in the radiology suite. Conflicting and/or ambiguous data on time elements were coded as invalid data.

Outcome measures

Primary outcome was survival to discharge. Secondary outcomes included survival at 28 days and hospital-free days to day 90, defined as the number of days alive and out of the hospital between day of hospital arrival and 90 days later.

Statistical analysis

Patient data were divided between REBOA and non-REBOA groups. The REBOA group consisted of patients who underwent REBOA catheter placement, while the non-REBOA group consisted of those who were treated without REBOA. To select a similar cohort of control patients from the non-REBOA group, propensity score matching was performed.[21] The propensity score was developed using logistic regression to estimate the probability of being assigned to the REBOA group compared with the non-REBOA group. Relevant covariates were carefully selected from known or possible survival predictors in trauma patients including injury variables, vital signs on presentation, severity of injuries, and presence of intraabdominal hemorrhage,[7,8,12,13,16,22–25] and these were subsequently entered into the propensity model.[26] Patients with missing covariates were excluded from propensity score calculation. One to one propensity score matching was then performed using a greedy matching algorithm without replacement, where a caliper width of less than 0.01 of the standard deviation of logit-transformed propensity score was applied. The inter-group comparison of primary and secondary outcome after propensity score matching was performed using Chi-square tests or linear regression analysis, as appropriate.[26,27]

Matched patients in both REBOA and non-REBOA groups were further divided into three subgroups based on the transfer time to the OR after hospital arrival: the early subgroup included patients with transfer times less than 1 h, the delayed subgroup with transfer times between one and 2 h, and the significantly-delayed subgroup with transfer times between two and 3 h. Survival to discharge was then compared between the REBOA and the non-groups, and hazard ratios were calculated using proportional hazard model in each subgroup. Kaplan-Meier plots of survival curves up to 90 days after hospital arrival were also drawn in each subgroup. Furthermore, another subgroup analysis was performed in patients who did not undergo thoracotomy that preceded other

surgical interventions.

A sensitivity analysis was performed to confirm that these results were not dependent on the method of matching and the subgroup analyses.[18] In order to exclusively select patients who experienced inappropriate delays in surgical intervention before the matching procedure, we defined the population to only include patients who were transferred to the OR later than 30 min after hospital arrival. Then, propensity score matching analyses were repeated on the selected population, where propensity scores were calculated with the same variables and the same matching algorithm was applied. Survival to discharge was compared between the REBOA and non-REBOA groups without dividing patients into subgroups.

Missing data analyses on transfer times to OR and survival data were performed with Missing Completely at Random test. Descriptive analyses on unmatched patients in the REBOA group were also performed to characterize patients who were excluded before and during propensity score matching.

Descriptive statistics are presented as means ± SD or number (%). Results were compared using unpaired t tests, Mann-Whitney U tests, Chi-square tests, or Fisher's exact tests, as appropriate. For testing of all hypotheses, a two-sided α threshold of 0.05 was considered statistically significant. All statistical analyses were conducted using SPSS, version 25.0 (IBM, Armonk, NY, USA) and Microsoft Excel (Microsoft, Redmond, WA, USA).

Results

After the screening process, a total of 187,059 trauma patients who presented to JTDB collaborating hospitals during the study period were identified. Among them, 10,601 patients were aged <15 years, 14,047 arrived without a pulse, and 84,409 did not undergo surgical intervention. Although 71,782 patients satisfied all inclusion criteria, 32,082 were excluded due to missing or unknown data in terms of prehospital information, vital signs on arrival, or transfer times, and 153 were excluded due to missing survival data. A total of 34,289 patients were transferred to the OR later than 3 h after hospital arrival and excluded from analyses. The patient flow diagram is summarized in Fig. 1.

Of the 5258 patients eligible for this study, 310 (5.6%) were treated with REBOA and 4948 (94.1%) were not. Patient characteristics are summarized in Table 1. Patients in the REBOA group had significantly lower Glasgow Coma Scale (GCS) and lower systolic blood pressures (sBP) on arrival compared with those in the non-REBOA group (9 ± 5 vs. 11 ± 4 and 87 ± 36 vs. 120 ± 41, respectively), as well as higher ISS (36 ± 16 vs. 26 ± 14) and lower Revised Trauma Score (RTS) (5.42 ± 1.86 vs. 6.44 ± 1.50). Furthermore, significantly more patients in the REBOA group, compared with the non-REBOA group, underwent thoracotomy that preceded other surgical interventions (48 [15%] vs. 275 [6%]), and required angiography (139 [45%] vs. 1517 [31%]). The transfer time to OR after hospital arrival was comparable between the two groups (1.4 ± 0.8 h vs. 1.7 ± 0.7 h).

Considering these non-negligible biased distributions in known survival predictors of trauma patients, propensity score matching was performed to select similar cohorts of patients from both groups. The final propensity model predicting allocation to the REBOA group included the following covariates: age, vital signs on arrival (GCS, respiratory rate, heart rate, and sBP), mechanism of injury (blunt or penetrating), result of Focused Assessment with Sonography in Trauma (FAST) exam (positive, negative, or not performed), and ISS.

Among the 310 patients in the REBOA group, 223 patients were matched with controls in the non-REBOA group. Patient characteristics after matching are summarized in Table 1 (standardized difference of covariates before and after matching are shown in Table S1 and hemostatic procedures among the matched pairs are shown in Table S2 in the Supplementary Appendix). Propensity score matching analysis revealed that survival to discharge was significantly higher among patients treated with REBOA compared to those treated without REBOA (126 [56.5%] vs. 71 [31.8%]; odds ratio [OR] = 2.78; 95% confidence interval [CI] = 1.89–4.09; $p < 0.001$; Table 2). Survival at 28 days was also significantly higher in patients in the REBOA group compared to those in the non-REBOA group (132 [59.2%] vs. 79 [35.4%]; OR = 2.64; 95% CI = 1.80–3.88; p < 0.001; Table 2). Furthermore, hospital-free days to day 90 were longer in patients in the REBOA group than in those in the non-REBOA group (24 ± 30 days vs. 15 ± 35 days; p < 0.001; Table 2).

Mean transfer times to the OR after hospital arrival were comparable between the two groups after matching (1.5 ± 0.8 h vs. 1.4 ± 0.8 h), and 143, 191, and 112 patients were allocated to the early (within 1 h), delayed (one to 2 h), and significantly-delayed (two to 3 h) subgroups, respectively. Survival to discharge was significantly higher among patients treated with REBOA than among those treated without REBOA in the delayed and significantly-delayed subgroups (66 [66.6%] vs. 30 [33.0%]; p < 0.001 and 34 [59.6%] vs. 15 [27.3%]; p = 0.001, respectively; Table 3), whereas there were no significant differences in the early subgroups (26 [39.4%] vs. 26 [33.8%]; p = 0.49; Table 3). Kaplan-Meier plots of survival curves for patients treated with REBOA and without REBOA in each subgroup are shown in Fig. 2. REBOA use was significantly associated with reduced mortality in the delayed and significantly-delayed subgroups (HR = 0.43; 95% CI = 0.28–0.65 and 0.42; 95% CI = 0.25–0.71, respectively), although the HR was not significant in the early subgroup (HR = 0.92; 95% CI = 0.60–1.40). The subgroup analysis on patients who did not undergo thoracotomy that preceded other surgical interventions similarly identified higher survival to discharge among patients treated with REBOA, compared with patients treated without REBOA (121/191 [63.4%] vs. 65/184 [35.3%]; p < 0.001).

A sensitivity analysis was performed to validate that the primary results were not dependent on the statistical methods of subgroup analyses. Patients who were transferred to the OR more than 30 min after hospital arrival were selected (261 in the REBOA group and 4664 in the non-REBOA group), and propensity score calculation and matching procedures were repeated. Two hundred and four matched pairs (408 patients) were selected from both groups, and propensity score matching analysis similarly identified that survival to discharge was significantly higher among patients treated with REBOA than among those treated without REBOA (118 [57.8%] vs. 82 [40.2%]; OR = 2.04; 95% CI = 1.38–3.03; $p < 0.001$; Table S3 in the Supplementary Appendix). Kaplan-Meier plots of survival curves were also drawn in the selected population, and significant HR of 0.72 was detected (Fig. S1 in the Supplementary Appendix).

Missing data analyses using the transfer time to OR and survival data revealed that missing data was completely random without statistical significance. Descriptive analyses on unmatched patients in the REBOA group found that they had a lower ISS (27 ± 14 vs. 33 ± 15) and higher RTS (6.41 ± 1.52 vs. 5.75 ± 1.83), compared those who were matched.

Discussion

In our study evaluating severely injured patients, REBOA use was associated with improved overall survival. In particular, REBOA use in patients who experienced transfer times to the OR between one and 3 h after arrival exhibited improved survival, but this benefit did not extend to patients transferred to the OR within 1 h.

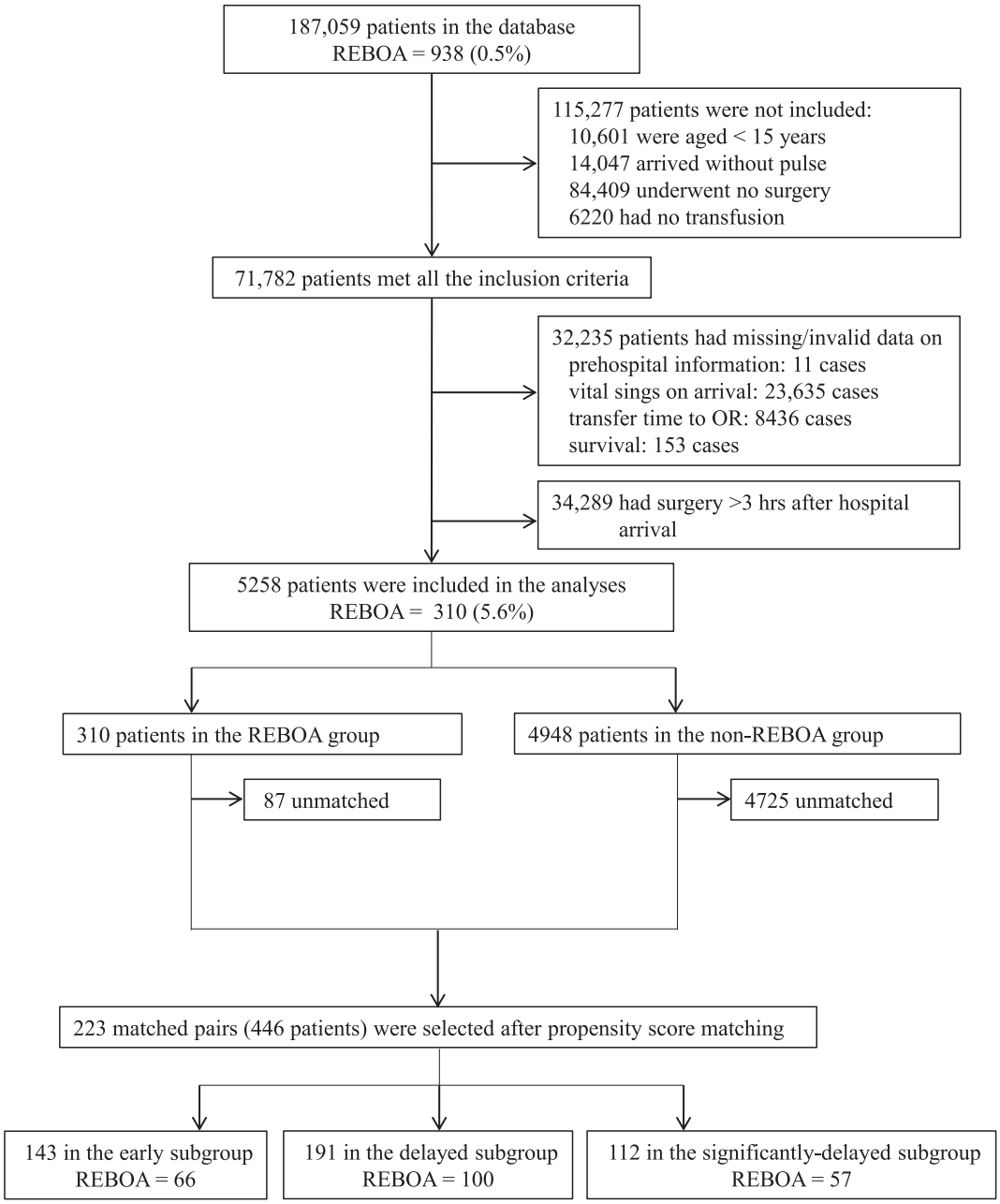

Fig. 1. Study Flow Diagram. We identified 187,059 trauma patients who presented to collaborating centers during study period. A total of 5258 patients were eligible for this study, among whom 310 (5.6%) were treated with REBOA. After propensity score matching, 223 pairs (446 patients) were selected. The matched patients were further divided into the early (143 patients), the delayed (191 patients), and the significantly-delayed (112 patients) subgroups. Abbreviations: REBOA = resuscitative endovascular balloon occlusion of the aorta, OR = operating room.

Although current literature in the use of REBOA is inconclusive and occasionally conflicting in terms of benefits, there are several differences between our study and other recent retrospective case-control publications suggesting potential harmful effects of REBOA.[1,12–15] First, in an attempt to capture severely injured patients with significant hemorrhage in our cohort, we only included patients who underwent surgical intervention or angiography within 3 h and required transfusion within 24 h after hospital arrival. This approach is supported by and similar to the prospective AAST AORTA study which identified a survival benefit using REBOA only among hypotensive patients with massive hemorrhage.[12] Second, we strictly matched patients by a narrower match-caliper than typical standards,[13,18,27] resulting in a more appropriate selection of severely injured patients from the non-REBOA groups. To support this approach, the mean ISS of our control population was 36, higher than the control cohort's ISS in a recent ACS TQIP study.[1] Third, in an attempt to identify the effects of REBOA in relation to the time of surgical intervention, we divided the matched population into three different subgroups based on the transfer time to OR. To the best of our knowledge, this is the first study to define population according to delays in surgical intervention as it relates to REBOA utilization.

Temporary normalization of blood pressure as a physiologic effect of REBOA use has been reported in various studies,

Table 1
Characteristics of patients treated with or without REBOA.

	REBOA		non-REBOA		P value	REBOA		non-REBOA	
	Before matching					After matching			
Case	310		4948			223		223	
Age(y/o)	55 ± 21		60 ± 21		0.001	56 ± 21		58 ± 22	
Male Sex	198	(64%)	3191	(64%)	0.83	146	(65%)	135	(61%)
Vital Signs on Arrival									
GCS	9 ± 5		11 ± 4		<0.001	10 ± 5		9 ± 5	
Respiratory Rate (/min)	25 ± 8		23 ± 9		<0.001	24 ± 8		25 ± 8	
Heart Rate (/min)	110 ± 28		96 ± 26		<0.001	105 ± 28		107 ± 29	
BP systolic (mmHg)	87 ± 36		120 ± 41		<0.001	95 ± 37		93 ± 36	
BP diastolic (mmHg)	59 ± 26		74 ± 25		<0.001	65 ± 32		63 ± 30	
Mechanism of Injury					0.19				
Blunt	283	(91%)	4338	(88%)		198	(89%)	213	(96%)
Penetrating	22	(7%)	549	(11%)		20	(9%)	8	(4%)
unknown mechanism	5	(2%)	61	(1%)		5	(2%)	2	(1%)
FAST					<0.001				
Positive	166	(54%)	1054	(21%)		99	(44%)	79	(35%)
not performed	19	(6%)	845	(17%)		16	(7%)	22	(10%)
missing data	11	(4%)	271	(5%)					
AIS									
Head	1 ± 2		2 ± 2		<0.001	2 ± 2		2 ± 2	
Chest	3 ± 2		2 ± 2		<0.001	3 ± 2		3 ± 2	
Abdomen	3 ± 2		1 ± 2		<0.001	2 ± 2		2 ± 2	
ISS	36 ± 16		26 ± 14		<0.001	33 ± 15		36 ± 16	
missing data	1	(0.3%)	51	(1%)					
RTS	5.42 ± 1.86		6.44 ± 1.50		<0.001	5.75 ± 1.83		5.33 ± 1.68	
Transfer time to OR (hrs)	1.4 ± 0.8		1.7 ± 0.7		<0.001	1.5 ± 0.8		1.4 ± 0.8	
Thoracotomy preceding*	48	(15%)	275	(6%)	<0.001	32	(14%)	39	(17%)
Angiography	139	(45%)	1517	(31%)	<0.001	99	(44%)	92	(41%)

GCS = Glasgow Coma Scale, BP = blood pressure, FAST = Focused Assessment with Sonography in Trauma, AIS = Abbreviated Injury Scale, ISS = Injury Severity Score, RTS = Revised Trauma Score, OR = operating room, * = thoracotomy included emergency department thoracotomy.

potentially allowing trauma victims to reach the next level of care, particularly in resource restricted environments.[28–31] A study of 20 combat casualties with noncompressible torso hemorrhage who underwent REBOA reported that REBOA placement during mass casualty events allowed time for the surgeon to stabilize the initial set of patients who required operative intervention.[28] Another study of patients injured in a combat setting also revealed that REBOA use resulted in immediate normalization of blood pressure and enabled successful attainment of surgical hemostasis in an austere location, 2 h away from the next level of care.[29] Similarly, our study identified the beneficial effects of REBOA only in patients who experienced delays in surgical intervention, which reflects the setting where trauma surgeons are not immediately available and delays to definitive surgical care may be common. It should be also noted that the other study on combat casualties recommended REBOA use when surgery is likely to be delayed or where the single operating room (OR) is occupied by another case.[31]

There would be several reasons for the result that a survival benefit was not detected among patients treated with REBOA who were transferred to the OR within 1 h after arrival. As we only included patients who were transferred to the OR, those with exsanguination who might be candidates for REBOA but could not reach to the OR were not contained in our results. Another possible reason might be that trauma patients who undergo immediate surgical hemostasis might not need the temporally hemostasis by REBOA, which suggested that the majority of trauma patients who have essentially immediate access to ORs might not be candidates for REBOA. Furthermore, it would be suggested that patients transferred to the OR within 1 h after arrival were too sick to survive regardless of REBOA placement in this study setting. Although our results might not be applicable outside Japan, as the number of trauma patients who are ideal candidates for REBOA use in civilian settings in the US has been reported to be limited,[32] selection criteria of candidates and algorithms should be rigorously evaluated.

The results of this study must be interpreted in the context of our study design, as it has several limitations. We analyzed JTDB data, which unfortunately does not record the indication for the use of REBOA. Our results may have therefore been affected if the indication for REBOA use was an unmeasured strong outcome predictor, such as insufficient blood product storage or a necessity to transfer the patient, which would be somewhat specific to Japan. However, as we carefully selected patients who were suspected of hemorrhage and subsequently performed strict matching, our results would still reflect the effectiveness of REBOA in patients who experienced delays in surgical intervention. It should also be noted that sensitivity analyses revealed similar results, and these analyses also validated that our findings were not dependent on statistical methods of subgroup analyses.

Table 2
Impact of REBOA on survival to discharge and secondary outcomes.

	REBOA	non-REBOA	P value	OR	95% CI
Survival to discharge	126(56.5%)	71(31.8%)	<0.001	2.78	1.89–4.09
- Discharged to home	53(23.8%)	21(9.4%)			
- Discharged to other health care facility	71(31.8%)	48(21.5%)			
Survival at 28 days	132(59.2%)	79(35.4%)	<0.001	2.64	1.80–3.88
Hospital-free days to day 90 (days)	24 ± 30	15 ± 35	<0.001		

Table 3
Transfer time to OR and effectiveness of REBOA.

	REBOA	no REBOA	P value	OR	95% CI
Early: within 1 h					
Survival to discharge	26(39.4%)	26(33.8%)	0.49	1.28	0.64–2.53
Survival at 28 days	27(40.9%)	29(37.7%)	0.69	1.15	0.58–2.25
Hospital-free days to day 90 (days)	17 ± 28	15 ± 26	0.40		
Delayed: 1–2 h					
Survival to discharge	66(66.0%)	30(33.0%)	<0.001	3.95	2.16–7.21
Survival at 28 days	68(68.0%)	30(33.0%)	<0.001	4.32	2.36–7.92
Hospital-free days to day 90 (days)	29 ± 30	13 ± 24	<0.001		
Significantly-delayed: greater than 2 h					
Survival to discharge	34(59.6%)	15(27.3%)	0.001	3.94	1.78–8.73
Survival at 28 days	37(64.9)	20(36.4%)	0.003	3.24	1.49–7.01
Hospital-free days to day 90 (days)	25 ± 30	17 ± 55	0.02		

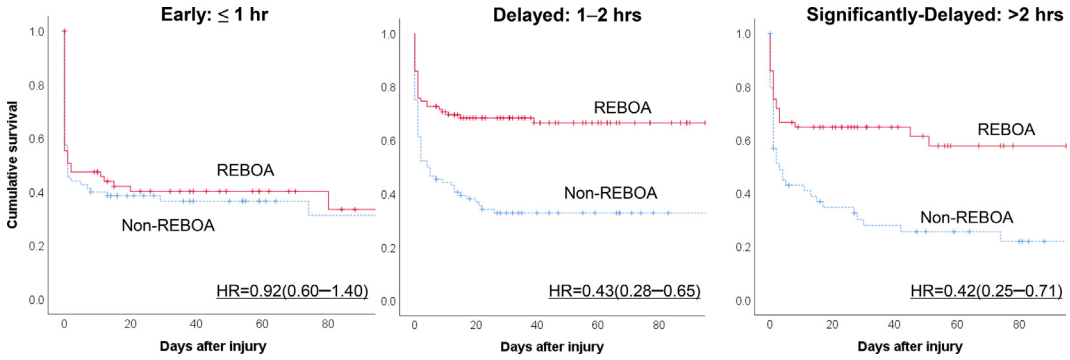

Fig. 2. Kaplan-Meier plots of survival curves for patients treated with REBOA and without REBOA in each subgroup. REBOA use was significantly associated with reduced mortality in the delayed and significantly-delayed subgroups (HR = 0.43; 95% CI = 0.28–0.65 and 0.42; 95% CI = 0.25–0.71, respectively), although HR was not significant in the early subgroup (HR = 0.92; 95% CI = 0.60–1.40).

Another limitation of our study relates to the fact that variables related to REBOA placement, including the size of the REBOA catheter, position of placement, duration of inflation, procedural complications, and postprocedural response were not available in the database. As potential complications such as limb ischemia due to prolonged occlusion of the aorta would exist, duration of inflation should be cautioned particularly when REBOA catheter is placed for prolonged OR wait times. Although diversity of procedures would limit interpreting our results, we believe our results might have merits for further studies regarding the delays in definitive hemostasis as an indication for REBOA use.

Finally, because this is a retrospective study, our results are not conclusive. Although we report a higher survival to discharge in patients treated with REBOA compared to those treated without REBOA, particularly when surgical delays were encountered, residual confounding and unmeasured survival predictors exist as impediments to confirming the efficacy of REBOA. Additional clinical investigations, such as a well-designed prospective study are needed to validate our results.

Conclusions

In severely injured patients, the use of REBOA was associated with improved survival. Patients who experienced delays in transfer to the OR greater than 1 h after arrival benefited from improved survival after REBOA, whereas those who underwent surgical intervention without delay did not. Use of REBOA should therefore be considered in severely injured patients when preoperative delays or prolonged OR wait times are expected.

Data statement

The data of this study are available from the Japanese Association for Trauma Surgery and the Japanese Association for Acute Medicine, but restrictions apply to the availability of these data. Data are however available from the authors upon reasonable request and with permission of the Japanese Association for Trauma Surgery and the Japanese Association for Acute Medicine.

Declaration of competing interest

The authors have no conflict of interest to report.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2020.07.017.

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