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Resuscitative endovascular balloon occlusion of the aorta (REBOA) is associated with improved survival in severely injured patients: A propensity score matching analysis

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ABSTRACT

Background: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a technique for temporary control of arterial hemorrhage. However, its effectiveness and clinical outcomes are unclear.
Methods: Using a nationwide database (2004–2016) in Japan, trauma patients with survival data were identified. Patients were divided between REBOA and non-REBOA groups, and a propensity score was developed using multivariate logistic regression. Survival to discharge was compared between the groups after propensity score matching.
Results: Among 82,371 patients included in this study, 385 were treated with REBOA. After propensity score matching, 117 pairs were selected. Survival to discharge was significantly higher among patients treated with REBOA than among those treated without REBOA (53 [45.3%] vs. 38 [32.5%]; odds ratio = 1.72; 95% CI = 1.01–2.93; p = 0.04).
Conclusions: REBOA use was associated with improved survival to discharge and should therefore be considered during the management of severely injured trauma patients.

Introduction

Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a technique for temporary control of arterial hemorrhage which maintains cerebral and coronary perfusion while improving hemodynamic stability in trauma victims.[1–4] This relatively less invasive method has developed to broad applications including traumatic arrest,[5] subdiaphragmatic hemorrhage,[6] combat casualties,[7,8] and prehospital management[9,10] since the first report in 1954.[11] While various investigators have challenged the optimal situation where REBOA can be applied as an effective treatment,[1,3,5,12–14] recent literature suggests that REBOA may be indicated as an alternative to cross-clamping the proximal aorta via resuscitative thoracotomy (RT), or an adjunct for life-threatening hemorrhage below the diaphragm.[1,15]

Despite the improvement of technology and increasing popularity in REBOA,[2–14,16] there is considerable debate regarding improved clinical outcomes for severely injured patients managed by REBOA.[1–3,12,17,18] An analysis in 2015 using the American Association for the Surgery of Trauma (AAST) Aortic Occlusion in Resuscitation for Trauma and Acute Care Surgery (AORTA) database revealed no difference in survival between REBOA and RT groups,[12] and other database analyses demonstrated that REBOA treatment was associated with higher in-hospital mortality compared with patients treated without REBOA.[17,18] Although a more recent study using the AAST AORTA database found a survival benefit of REBOA compared with RT in hypotensive patients not requiring cardiopulmonary resuscitation (CPR), these results may not be universally applicable since the majority of REBOA cases enrolled in the study

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were treated at only two institutions.[1]

Furthermore, given that REBOA provides only temporary hemostasis and definitive therapy always needs to follow, some limitations should be considered in determining the optimal study design that can validate the efficacy of REBOA. First, comparing REBOA with cross-clamping the aorta through RT is not ideal since definitive hemostasis can be achieved with simultaneous procedures, such as cardiorrhaphy, aortorrhaphy, and pulmonary resection in patients with RT, but not with REBOA. Second, in retrospective or observational studies, the clinical outcome of death after trauma might be significantly modified by factors other than REBOA, including physiological signs, severity of injuries, procedures for definitive hemostasis, and even the fact that the REBOA catheter can be placed prior to other surgical procedures. Third, although some studies may support the superiority of REBOA over RT, the possibility that equal or better outcomes could be obtained without REBOA or RT must be considered and not all studies evaluate this possibility.

Accordingly, in an effort to verify the efficacy of REBOA on severely injured patients, we examined outcomes in patients treated with REBOA compared with those treated without REBOA, using propensity score matching analysis that offered the most reliable method in a retrospective study for reducing the effects of confounding factors. We hypothesized that REBOA would improve in-hospital survival in trauma victims, applied in conjunction with other standard trauma resuscitation and hemostasis procedures.

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, in which more than 200 major hospitals including tertiary care centers participate currently. Data were collected prospectively and entered by treating physicians or volunteer registrars designated by each hospital into the online data collection portal. All collaborating hospitals obtained individual local Institutional Review Board approval for the Conduct of Human Research before the study was initiated.

In Japan, REBOA is usually placed at Zone 1 (between left subclavian artery and celiac artery) by emergency physicians or trauma surgeons through the femoral artery with or without fluoroscopy in the setting of uncontrolled hemorrhagic shock. REBOA is recognized as a standard procedure and performed at most of participating hospitals. 10Fr REBOA catheters had been used until 2013 when 7Fr ones became clinically available.

Study population

We retrospectively reviewed data from the JTDB and included trauma patients who arrived at each participating center from 2004 to 2016. Patients with missing or unknown survival data were excluded.

Available data included age, sex, mechanism of injury, prehospital vital signs, vital signs on arrival, imaging tests performed during resuscitation, any surgical procedures or angiography, unplanned second surgical procedures or interventional angiography provided within 48 h after the initial hemostatic operation, 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. Conflicting and/or ambiguous data elements were coded as missing data. The duration of REBOA inflation and complications related to REBOA, type of hospital (academic or community), were not available in the database.

Outcomes

Primary outcome was survival to discharge, recorded as discharge to home or other healthcare facility in the database. Secondary outcomes included survival at 28 days and hospital-free days to day 90, a composite of in-hospital death and hospital length of stay defined as the number of days alive and out of the hospital between the hospital arrival and 90 days later. Patients who died during the index hospitalization and those hospitalized for more than 90 days were classified as having zero hospital-free days. For patients discharged alive before day 90, hospital-free days were calculated as 90 minus length of stay.

Statistical analysis

Patient data were divided between REBOA and non-REBOA groups. The REBOA group consisted of patients who were treated with REBOA in conjunction with other standard resuscitation and hemostasis procedures in the ED, while the non-REBOA group consisted of those who were treated with standard care without REBOA.

Because many cofounders can affect survival to discharge, such as vital signs on presentation, severity of injuries, and procedures for definitive hemostasis, propensity score matching was performed to compare the primary outcome between both groups, as well as to assess secondary outcomes.[19] A 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 victims,[1–3,12,20–25] and were entered into the propensity model, regardless of their relevance to REBOA device placement, to ensure high-fidelity propensity scores.[26] Patients with missing covariates were excluded from propensity score calculation. The precision of discrimination and propensity score calibration were analyzed with the *c*-statistic and Hosmer–Lemeshow goodness-of-fit test. One to one propensity score matching was then performed using a greedy matching algorithm without replacement, where a caliper width of less than 0.03 in the logit-transformed propensity score was applied. The inter-group comparison of primary outcome after propensity score matching was performed using linear regression analysis.

In addition to comparing survival at 28 days between the REBOA and non-REBOA groups, Kaplan-Meier plots of survival curves up to 28 days for each group were drawn. Hazard ratios were calculated for 1 day to 2 days after injury and more than 2 days after injury, using proportional hazard model.

Several subgroup analyses were also performed to evaluate the heterogeneity of the treatment effect of REBOA. Given that subdiaphragmatic hemorrhage was suggested as one of the optimal indications for REBOA,[15] one of the subgroups selected included patients with isolated abdominal injury or pelvis/lower extremity injury, defined as patients who had AIS of 3 or greater in abdomen or pelvis/lower extremity with AIS of 2 or lower in other regions. Primary and secondary outcomes were compared between the REBOA and non-REBOA groups in the selected patients after propensity score matching.

Furthermore, missing data analyses on survival data with Missing Completely at Random test, as well as descriptive analyses on unmatched patients in the REBOA group, were 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 24.0 (IBM, Armonk, NY, USA) and Microsoft Excel (Microsoft, Redmond, WA, USA).

Results

After the screening process, a total of 88,701 trauma patients who presented to collaborating hospitals during the study period were identified and included in the study. Among them, 417 (0.5%) patients underwent REBOA treatment in conjunction with other standard resuscitation. Six thousand three hundred and thirty patients were excluded due to missing or unknown survival data. The patient flow diagram is summarized in Fig. 1.

A total of 82,371 patients were eligible for this study, among whom 385 (0.5%) were treated with REBOA and 81,986 (99.5%) were not treated with REBOA. 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 (8 ± 5 vs. 13 ± 3 and 71 ± 48 vs. 133 ± 40, respectively), as well as higher ISS (35 ± 15 vs. 15 ± 11), lower Revised Trauma Score (RTS) (4.29 ± 2.61 vs. 7.16 ± 1.69), and lower Trauma and Injury Severity Score (TRISS) calculated probability of survival (Ps) (0.40 ± 0.35 vs. 0.88 ± 0.23). Furthermore, more patients in the REBOA group, compared with the non-REBOA group, required surgery, angiography, an unplanned second surgical procedure or interventional angiography within 48 h after the initial hemostatic operation, and transfusion within 24 h after arrival.

Considering these non-negligible biased distributions in known survival predictors of trauma patients, propensity score matching was performed. The final propensity model predicting the allocation to the REBOA group included as covariates age, vital signs on arrival (GCS, respiratory rate, heart rate, and sBP), mechanism of injury (blunt or penetrating, self-inflicted or not, and alcohol-related or not), result of Focused Assessment with Sonography in Trauma (FAST) exam (positive or negative), hemostatic procedure (surgery and angiography), unplanned second surgical procedure or interventional angiography within 48 h after the initial hemostatic operation, transfusion within 24 h after arrival, ISS, RTS, and TRISS calculated Ps. This model was validated to have high decimation and calibration for the probability of being assigned to the REBOA group (*c*-statistic = 0.972 and Hosmer-Lemeshow goodness-of-fit $p = 0.821$).

Among the 385 patients in the REBOA group, 117 patients matched with those 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 in the Supplementary Appendix). Propensity score matching analysis revealed that survival to discharge was significantly higher among patients treated with REBOA than among those treated without REBOA (53 [45.3%] vs. 38 [32.5%]; odds ratio [OR] = 1.72; 95% confidence interval [CI] = 1.01–2.93; $p = 0.04$; Table 2).

Survival at 28 days was also significantly higher in patients in the REBOA group compared to those in the non-REBOA group (55 [47.0%] vs. 38 [32.5%]; OR = 1.84; 95% CI = 1.08–3.13; $p = 0.04$;

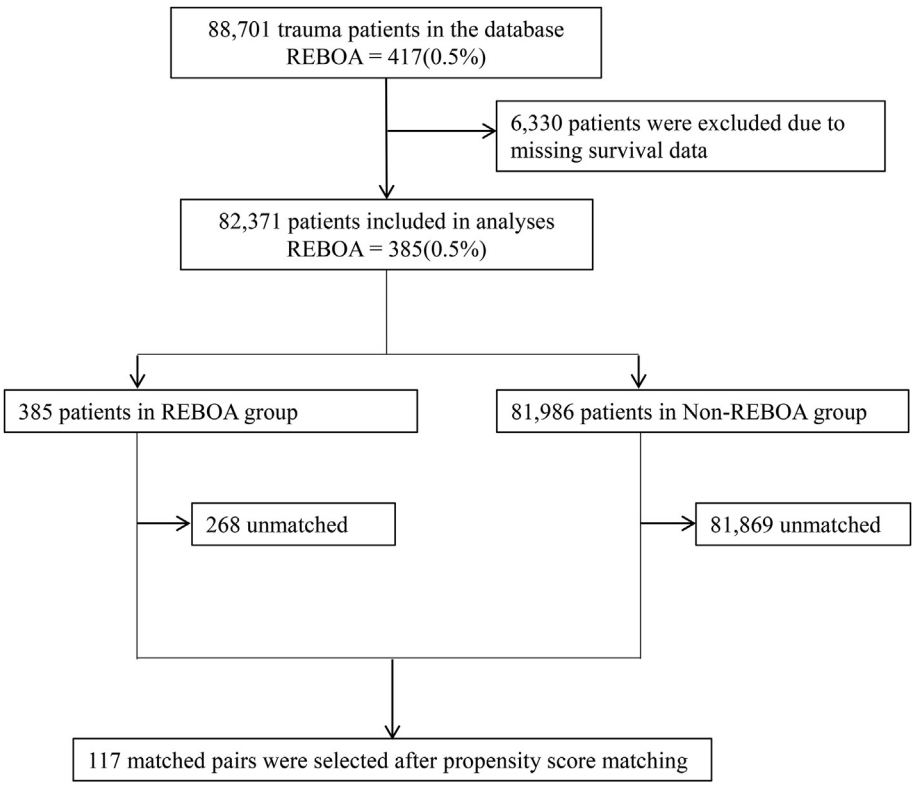

Fig. 1. Study Flow Diagram.
We identified 88,701 trauma patients who presented to collaborating centers during study period and excluded 6,330 patients due to missing survival data. A total of 82,371 patients were eligible for this study, among whom 385 (0.5%) were treated with REBOA. After propensity score matching, 117 pairs were selected. Abbreviations: REBOA = resuscitative endovascular balloon occlusion of the aorta.

Table 1
Characteristics of patients treated with or without REBOA.

	Before matching					After matching			
	REBOA		Non-REBOA		P value	REBOA		Non-REBOA	
Case	385		81986			117		117	
Age(y/o)	50 ± 21		57 ± 25		<0.001	52 ± 21		57 ± 23	
missing data	2	(1%)	88	(0%)					
Male sex	257	(67%)	51017	(62%)	0.86	82	(70%)	69	(59%)
missing data	0	(0%)	16	(0.02%)					
Vital Signs on Arrival									
GCS	8.0 ± 4.7		13.2 ± 3.4		<0.001	9.7 ± 4.8		8.9 ± 4.7	
missing data	10	(3%)	6902	(8%)					
Respiratory Rate (/min)	21 ± 13		20 ± 8		<0.001	23 ± 10		23 ± 12	
missing data	17	(4%)	11838	(14%)					
Heart Rate (/min)	92 ± 47		83 ± 25		<0.001	93 ± 35		96 ± 37	
missing data	5	(1%)	2379	(3%)					
BP systolic (mmHg)	71 ± 48		133 ± 40		<0.001	96 ± 45		91 ± 47	
missing data	4	(1%)	1559	(2%)					
BP diastolic (mmHg)	52 ± 33		77 ± 21		<0.001	65 ± 32		63 ± 30	
missing data	124	(32%)	5514	(7%)					
Mechanism of Injury									
Blunt	356	(92%)	76288	(93%)	0.009	112	(96%)	110	(94%)
Penetrate	21	(5%)	2524	(3%)		5	(4%)	7	(6%)
missing data	8	(2%)	3174	(4%)					
Self inflicted Injury	98	(25%)	4180	(5%)	<0.001	16	(14%)	23	(20%)
missing data	19	(5%)	3177	(4%)					
Alcohol related Injury	26	(7%)	8213	(10%)	0.09	9	(8%)	12	(10%)
missing data	144	(37%)	25944	(32%)					
FAST									
positive	182	(47%)	3916	(5%)	<0.001	54	(46%)	43	(37%)
negative	160	(42%)	41146	(50%)					
missing data	43	(11%)	36924	(45%)					
Transfusion within 24 h	364	(95%)	9198	(11%)	<0.001	111	(95%)	113	(97%)
missing data	0	(0%)	1643	(2%)					
Surgery	313	(81%)	37210	(45%)	<0.001	94	(80%)	85	(73%)
missing data	0	(0%)	0	(0%)					
Unplanned Surgery within 48 h	17	(4%)	77	(0%)	<0.001	1	(1%)	0	(0%)
missing data	0	(0%)	0	(0.1%)					
Angio	156	(41%)	4075	(5%)	<0.001	50	(43%)	36	(31%)
missing data	13	(3%)	3012	(4%)					
Unplanned Angio within 48 h	20	(5%)	129	(0.2%)	<0.001	3	(3%)	2	(2%)
missing data	0	(0%)	0	(0%)					
ISS	38 ± 15		15 ± 11		<0.001	35 ± 13		33 ± 11	
missing data	3	(1%)	1081	(1%)					
RTS	4.29 ± 2.61		7.16 ± 1.69		<0.001	5.55 ± 2.29		5.24 ± 2.23	
missing data	23	(6%)	16045	(20%)					
Ps	0.40 ± 0.35		0.88 ± 0.23		<0.001	0.56 ± 0.53		0.51 ± 0.31	
missing data	37	(10%)	19708	(24%)					

GCS = Glasgow Coma Scale, FAST = Focused Assessment with Sonography in Trauma, ISS = Injury Severity Score, RTS = Revised Trauma Score, Ps = Probability of Survival.

Table 2). Kaplan-Meier plots of survival curves for both of patients treated with REBOA and without REBOA were shown in Fig. 2. Although Hazard ratio (HR) was not significant until 2 days after injury (HR for day 1–2 = 1.04; 95% CI = 0.61–1.78; $p = 0.89$), REBOA was significantly associated with reduced mortality in patients who survived the first day of injury (HR after day 2 = 0.58; 95% CI = 0.34–0.98; $p = 0.04$). Hospital-free days to day 90 did not significantly differ between the REBOA and non-REBOA groups (15 ± 26 days vs. 11 ± 25 days; $p = 0.15$; Table 2).

Subgroup analyses performed to evaluate the heterogeneity of treatment effect of REBOA identified that REBOA was significantly associated with improved survival to discharge in patients with isolated abdominal injury or pelvis/lower extremity injury (14 [73.7%] in REBOA group vs. 3 [27.3%] in non-REBOA group; OR = 7.47; 95% CI = 1.40–39.84; $p = 0.02$; Table 3). Survival at 28 days and hospital-free days to day 90 in these patients are also shown in Table 3.

Missing data analyses on survival data revealed the no significant association between missing data on survival and REBOA use. Additional descriptive analyses on patients in the REBOA group identified that patients who were unmatched with any patients in non-REBOA group had higher ISS (39 ± 16 vs. 35 ± 13) and lower

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

	REBOA	Non-REBOA	P value	OR	95% CI
Survival to discharge	53(45.3%)	38(32.5%)	0.04	1.72	1.01–2.93
Discharged to home	22(41.5%)	14(38.9%)	0.81	1.12	0.47–2.65
Survival at 28 days	55(48.7%)	39(33.3%)	0.03	1.77	1.05–3.01
Hospital-free days to day 90 (days)	15 ± 26	11 ± 25	0.15		

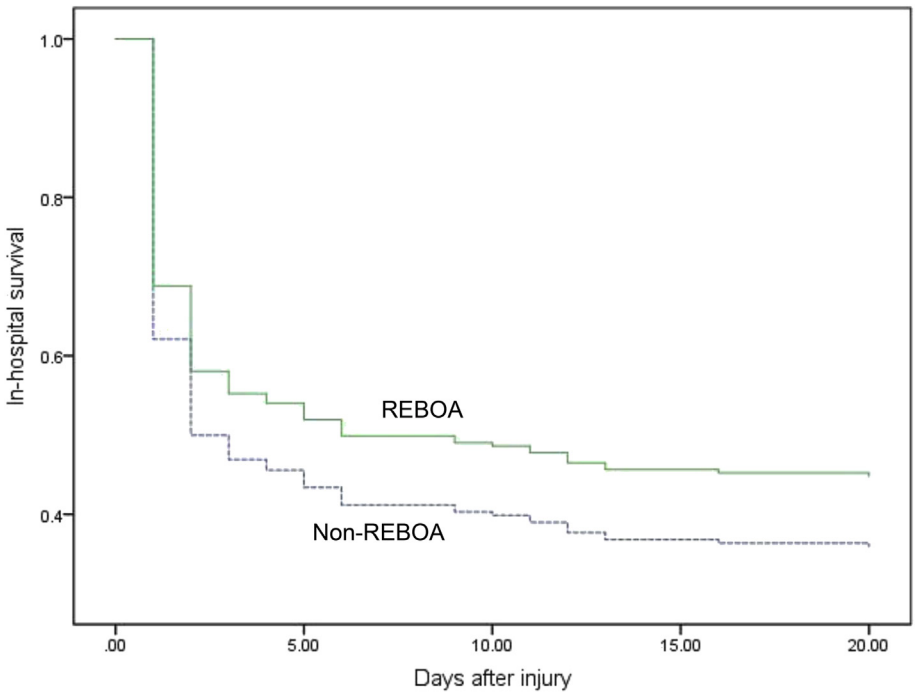

Fig. 2. Kaplan-Meier 28-day survival curves of patients treated with REBOA or without REBOA.
The significantly higher survival to discharge was identified in patients treated with REBOA compared with patients treated without REBOA. Survival at 28 days was also significantly higher in patients in the REBOA group than those in the non-REBOA group. Although the Hazard ratio (HR) was not significant until 2 days after injury (HR for day 1–2 = 1.04; 95% CI = 0.61–1.78; $p = 0.89$), REBOA was significantly associated with reduced mortality in patients who survived the first day of injury (HR after day 2 = 0.58; 95% CI = 0.34–0.98; $p = 0.04$).

RTS (3.69 ± 2.54 vs. 5.55 ± 2.29), compared those who were matched.

Discussion

In this study, we used propensity score matching to show that REBOA was independently associated with improved in-hospital survival in trauma patients. To the best of our knowledge, this is the first study to have reported this relationship using robust statistical methods on a large nationwide trauma database. Notably, the observed relationship was consistent in the survival at 28 days, and a significantly low hazard ratio of death from REBOA was detected among patients who survived the first day of injury.

While discussion has been ongoing regarding the overall effectiveness and optimal indications for REBOA,[1–6,11–15] some studies have suggested that patients who are severely injured would benefit most from REBOA.[1,2,4,15] A recent database study of AAST AORTA identified that REBOA was superior to RT for aortic occlusion when only hypotensive trauma patients not requiring CPR were included in analyses.[1] Another retrospective review of 16 patients treated with REBOA at an academic level 1 trauma center found that REBOA was placed in hemodynamically unstable patients with mean ISS of 39[3], indicating a very high degree of injury. Our study also revealed that patients who had REBOA placed were severely injured, having not only a mean ISS of 35, but additionally a low GCS and sBP on arrival, mean RTS of 5.55, and mean TRISS calculated Ps of 0.56 after propensity score matching.

Although various animal studies and retrospective or prospective observational studies have shown a promising effect of REBOA,[1–6,11–16,27,28] unfavorable clinical outcomes were reported in two studies comparing in-hospital survival between patients treated with REBOA and not treated with REBOA, using propensity score matching with the JTDB.[17,18] The first one included adult patients suffering blunt trauma and the second one analyzed adult patients who arrived with a pulse and underwent surgery or interventional radiology. Both found that REBOA was associated with increased in-hospital mortality, although we revealed the opposite results.

There are two main differences between our study and the other mentioned studies which suggested REBOA might be harmful. First, in the previous two studies, the number of covariates included in propensity score calculation was fewer than in our study. We considered that outcome predictors, such as the result of a FAST exam, the performance of a hemostatic procedure (surgery and angiography), an unplanned second surgical procedure or interventional angiography, or the transfusion of blood products should be entered into the propensity model regardless of their relevance to REBOA placement, since biased distribution of these factors

Table 3
Effectiveness of REBOA in patients with isolated abdominal or pelvis/lower extremity injury.

	REBOA	Non-REBOA	P value	OR	95% CI
Survival to discharge	14(73.7%)	3(27.3%)	0.02	7.47	1.40–39.84
Survival at 28 days	14(73.7%)	4(36.4%)	0.04	4.90	2.30–10.46
Hospital-free days to day 90 (days)	33 ± 36	21 ± 36	0.40		

would significantly affect survival to discharge.[26] Second, we performed matching through a greedy matching algorithm with a caliper width of less than 0.03 in the logit-transformed propensity score, which is stricter than the other two studies. Accordingly, only 117 (30.4%) patients in the REBOA group were matched with those in the non-REBOA group in our study, while other studies produced pairs with 77.7–98.6% of patients treated with REBOA.[17,18] Since the deliberate selection of covariates and the strict matching algorithm could make patient characteristics of the REBOA and non-REBOA groups more similar, including TRISS calculated Ps (0.56 in the REBOA group vs. 0.51 in the non-REBOA group; Table 1), the significant association found between REBOA and improved survival in our study suggests that REBOA use could be beneficial in severely injured patients.

The results of this study must be interpreted in the context of the study design. We analyzed data of the JTDB, in which indication for REBOA was not recorded. The result might have been modified if the reason that some patients had REBOA placed was an unmeasured strong outcome predictor, such as insufficient blood product storage, unavailability of interventional radiologists, or necessity of transfer of the patients. However, given that we included all measured outcome predictors to the propensity model and probabilities of survival were statistically comparable between the REBOA and non-REBOA groups after matching, our result would still show the effectiveness of REBOA. It should also be noted that subgroup analyses of patients with isolated abdominal injury or pelvis/lower extremity injury identified similar results, where REBOA was indicated as an adjunct for life-threatening hemorrhage below the diaphragm based on recent literatures.

Another limitation of our study concerns the fact that 268 (69.6%) of patient in the REBOA group were excluded from propensity score calculation or matching process, which may limit the generalizability of our findings. The association between REBOA and improved survival might not be applicable in patients who were excluded during propensity model development nor in patients outside the database. Although limited in scope, considering that the patient characteristics of the REBOA group after matching in this study (in-hospital mortality was 54.7%, mean ISS was 35, and mean RTS was 5.55) were similar to the population reported in other studies,[1,2,12] we believe our results might be adopted in severely injured trauma victims across the world.

Furthermore, because neither the timings of REBOA placement nor the postprocedural response such as GCS and BP were recorded in the JTDB, the physiological effects of REBOA to improve survival was not elucidated in this study. Since REBOA is a technique for temporary control of hemorrhage and a significantly low HR with REBOA (HR after day 2 = 0.58) was identified in patients who survived the first day of injury, REBOA might contribute to fewer complications in trauma patients as an adjunct treatment.

Finally, because this is a retrospective study, results are not conclusive. Although we revealed higher survival to discharge in patients treated with REBOA than in those treated without REBOA, indicating that we might need to consider placing the REBOA catheter in such severely injured patients, residual cofounding and unmeasured survival predictors would exist as impediments to confirm the efficacy of REBOA. Additional clinical investigations, including a randomized control trial, are needed to validate our results.

Conclusions

In severely injured trauma patients, REBOA use was associated with improved survival to discharge as well as at 28 days after injury. The use of REBOA should therefore be considered in conjunction with trauma resuscitation during the management of severely injured trauma patients.

Funding

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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, which were used under license for the current study, and so are not publicly available. 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.

Conflicts of 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.2019.09.007.

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