World J Surg (2019) 43:1700–1707
https://doi.org/10.1007/s00268-019-04968-2

ORIGINAL SCIENTIFIC REPORT

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Severe Torso Trauma in Japan: A Descriptive Study

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Published online: 1 March 2019

Abstract

Background Resuscitative endovascular balloon occlusion of the aorta (REBOA) has the potential to be an alternative to open aortic cross-clamping (ACC). However, its practical indication remains unknown. We examined the usage trend of REBOA and ACC in Japan for severe torso trauma and investigated whether these procedures were associated with the time of death distribution based on a large database from the Japan Trauma Data Bank (JTDB).

Methods The JTDB from 2004 to 2014 was reviewed. Eligible patients were restricted to those with severe torso trauma, which was defined as an abbreviated injury scale score of ≥4. Patients were classified into groups according to the aortic occlusion procedures. The primary outcomes were the rates of REBOA and ACC use according to the clinical situation. We also evaluated whether the time of death distribution for the first 8 h differed based on these procedures.

Results During the study period, a total of 21,533 patients met our inclusion criteria. Overall, REBOA was more commonly used than ACC for patients with severe torso trauma (2.8% vs 1.5%). However, ACC was more frequently used in cases of thoracic injury and cardiac arrest. Regarding the time of death distribution, the cumulative curve for death in REBOA cases was elevated much more slowly and mostly flat for the first 100 min.

Conclusions REBOA is more commonly used compared to ACC for patients with severe torso trauma in Japan. Moreover, it appears that REBOA influences the time of death distribution in the hyperacute phase.

Introduction

Resuscitative endovascular balloon occlusion of the aorta (REBOA) has recently become an important topic in trauma and emergency medicine. Traditionally, open aortic cross-clamping (ACC) has been performed for aortic occlusion for

This paper was presented at the 77th Annual Meeting of the AAST in San Diego, California, on September 26, 2018.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00268-019-04968-2) contains supplementary material, which is available to authorized users.

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trauma patients with life-threatening hemorrhage. However, REBOA shows promise as a less invasive substitute for ACC, and the use of REBOA is spreading worldwide. Japan is one of the countries in which the use of REBOA in the clinical setting spread early, as the catheter used specifically for REBOA was developed as a commercial product and approved by the Japanese Ministry of Health in 2000.

The optimal timing and indications for REBOA and ACC remain unclear. A few management algorithms for REBOA and ACC were recently proposed based on sparse evidence and expert opinions in the USA [1, 2]. The algorithm was theoretically created with consideration of anatomical injury and physiological status. However, REBOA has been used without evidence-based or expert-based guidelines in Japan. Although some large cohort studies on REBOA have been reported from Japan, none considered the indications for the procedure [3–6]. The effectiveness of REBOA is likely to be affected by the patient's physiological status and the target injured sites. Moreover, an improvement in survival outcome with REBOA in hemorrhage control has not been demonstrated. However, REBOA may provide life-extending effectiveness in the acute phase for patients with severe torso trauma.

In this study, we examined 1) the usage trend of procedures of aortic occlusion for resuscitation (REBOA and ACC) in Japan for severe torso trauma and 2) whether these procedures were associated with the time of death distribution based on a large database from the Japan Trauma Data Bank (JTDB). The descriptive statistics from this study can be used to determine whether Japanese physicians properly utilize REBOA.

Materials and methods

Data source and patient selection

The JTDB was established in 2003 as a Japanese nationwide trauma registry. Currently, more than 200 major hospitals in Japan participate in the registry. The JTDB from 2004 to 2014 was retrospectively reviewed to select data for this study. This retrospective study was approved by our institutional review board (Project #151611X).

Eligible patients were restricted to those with severe torso trauma. Severe torso trauma was defined as an abbreviated injury scale (AIS) score of $\geq$4 for chest, abdomen and pelvic fracture. Patients with severe pelvic fracture were selected with AIS codes (852606.4, 852606.4 and 852610.5).

Outcome and data collection

Patients were classified into three groups according to resuscitative procedures for aortic occlusion: non-aortic procedure, REBOA and ACC. Demographics and injury-specific factors were compared among the three groups. The following data were collected for this study: age, sex, mechanism of injury, systolic blood pressure (SBP), Glasgow Coma Scale (GCS), injury severity score (ISS) and AIS. Based on a proposed REBOA management algorithm for the control of torso hemorrhage by Biffl et al. [1] (Figure, Online Appendix 1), we classified the clinical situation for the resuscitative procedures according to the patient's SBP and injured torso part (Fig. 2). SBP was categorized into the following groups: 0, 1–59, 60–80 and >80 mmHg. Although the proposed algorithm uses the primary source of hemorrhage, the JTDB dataset does not include data on the primary source of hemorrhage. Therefore, we regarded the severe torso trauma area as the source of hemorrhage. The severe trauma area was categorized into chest, abdomen and pelvic fractures. Multiple torso trauma was defined as two or more of each torso injury. The primary outcomes were the rates of REBOA and ACC use according to the clinical situation.

We also evaluated whether the time of death distributions differed according to the resuscitative procedures. The time of death distribution was examined for the first 28 days and for hyperacute phase death (within 8 h). The database does not include prehospital deaths. Time of death was obtained and calculated from the JTDB based on the time of admission and death.

Statistical analysis

Descriptive statistics were used, with median and interquartile range (IQR) for continuous variables, and frequencies and percentages for categorical variables. Univariate analyses were performed with the Kruskal–Wallis test because the data were not normally distributed. Univariate analyses of categorical variables were performed using Pearson's chi-squared test.

To identify factors independently associated with REBOA and ACC use by Japanese physicians, two multinomial regression models with potential characteristics that were clinically important were used. The non-aortic procedure was defined as the reference category. Data are presented as odds ratios (ORs) and 95% confidence intervals (CIs).

To analyze the time of death distribution, the cumulative incidence of in-hospital death was calculated according to the time or days from admission for each resuscitative procedure. A time-to-event multivariate Cox proportional-hazards model was used to adjust for sex, age, injury type, SBP, cardiac arrest, AIS and ISS. Data are presented as hazard ratios (HR) with 95% CIs. A value of $p < 0.05$ was considered statistically significant. All statistical analyses

were performed using IBM SPSS for Windows version 24.0 (SPSS Inc., Chicago, IL, USA).

Results

Patient selection and characteristics

Figure 1 shows the patient selection flowchart. During the 11-year study period, a total of 21,533 patients met the inclusion criteria. Of these, 611 patients (2.8%) underwent REBOA and 322 patients (1.5%) underwent ACC. The rates of REBOA and ACC use did not remarkable vary during the study period (Figure, Online Appendix 2).

The clinical characteristics of the patients according to the procedures are summarized in Table 1. Patients in the REBOA group and in the ACC group, in particular, had significantly more severe injuries, more abnormal vital signs and higher in-hospital mortality than those in the non-aortic procedure group. Regarding the proportion of procedures according to SBP, the REBOA group had a lower proportion of patients with severe hypotension (0–59 mmHg) than did the ACC group (28.8% [172/597] vs 46.7% [134/287]). Notably, the REBOA group had only a few patients with cardiac arrest, compared to a much greater number in the ACC group (1.8% [11/597] vs 15.3% [44/287]). In contrast, the REBOA group had the higher proportion of patients with more than 59 mmHg SBP compared with the ACC group (71.2% [425/597] vs 53.3% [153/287]). At each blood pressure cohort, the more severe was the hypotension, the worse was the outcome in all groups. The difference was particularly evident in non-aortic procedure group (Online Appendix 3). In the REBOA group, 35 patients (5.7%) had cardiac or aortic injury, which was a contraindication for REBOA; of these, 27 (77.1%) patients died. Further details of the clinical characteristics in patients with cardiac or aortic injury are presented in Online Appendix 4.

Use of REBOA and ACC

Figure 2 shows the use of REBOA and ACC according to the site of injury and blood pressure. With respect to the site of injury, REBOA was more frequently used in abdominal, pelvic and multiple injuries than was ACC. However, ACC was more frequently used in thoracic injury. The REBOA usage rate was 0.8% for thoracic, 6.2% for abdominal, 4.1% for pelvic and 10.6% for multiple torso injuries (Fig. 2a). Patients with severe hypotension (1–59 mmHg) were more likely to receive REBOA. The ACC usage rate was 0.9% for thoracic, 2.4% for abdominal, 1.0% for pelvic and 4.0% for multiple torso injuries (Fig. 2b). Unlike for REBOA, patients with cardiac arrest were more likely to receive ACC (2.4% [11/449] vs 9.8% [44/449]).

Table 2 outlines the results of the multinomial regression for the procedures. Patients with hypotension, a lower GCS score, severe abdominal injury and pelvic fracture were more likely to receive REBOA, and patients with severe head injury were less likely to receive REBOA and ACC. Of note, patients in the oldest age category and those with cardiac arrest were more likely to receive ACC, but not REBOA.

Time of death analysis

Figure 3 shows the adjusted incidence proportion of death within the first 28 days and the first 8 h. In the entire cohort, REBOA and ACC had significant differences in time to death (vs REBOA: adjusted HR [aHR]: 1.23, 95%

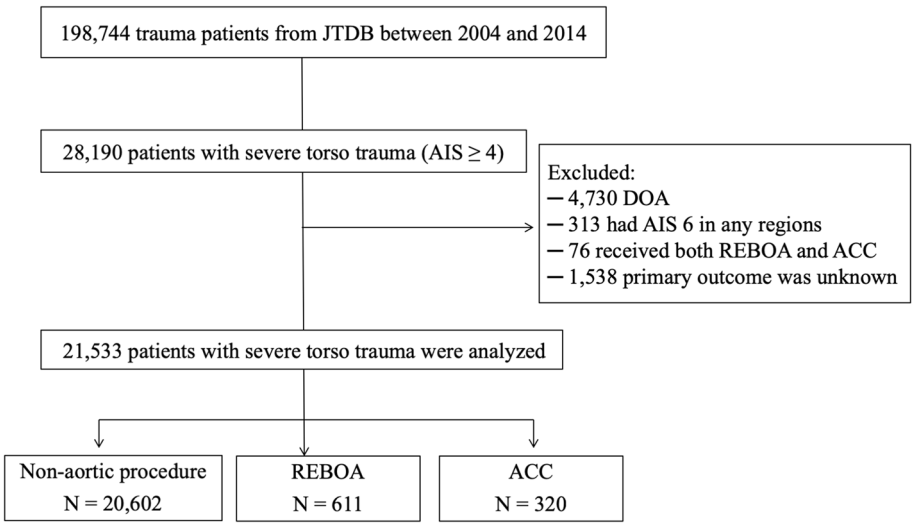


Fig. 1 Flowchart of patients with severe torso trauma who underwent resuscitative aortic procedures. *ACC* open aortic cross-clamping, *AIS* abbreviated injury scale, *DOA* dead on arrival, *JTDB* Japanese Trauma Data Bank, *REBOA* resuscitative endovascular balloon occlusion of the aorta

Table 1 Characteristics of patients with severe torso trauma according to REBOA and ACC use using data from the Japanese Trauma Data Bank (2004–2014)

	Non-aortic procedure (n = 20,602)	REBOA (n = 611)	ACC (n = 320)	p
Sex (male)*	14,566 (70.7)	400 (65.5)	232 (72.5)	0.015
Age group, y*				
<20	1573 (7.6)	39 (6.4)	14 (4.4)	0.023
20–39	4613 (22.4)	159 (26.0)	66 (20.8)	
40–59	5533 (26.9)	155 (25.4)	84 (26.4)	
60–79	6731 (32.7)	185 (30.2)	108 (34.0)	
≥80	2121 (10.3)	73 (11.9)	46 (14.5)	
Mechanism of injury*				
Blunt	19761 (97.0)	580 (95.6)	299 (93.7)	0.001
Penetrating	614 (3.0)	27 (4.4)	20 (6.3)	
SBP, mmHg*				
0	394 (2.0)	11 (1.8)	44 (15.3)	<0.001
1–59	944 (4.7)	161 (27.0)	90 (31.4)	
60–79	1584 (7.9)	141 (23.6)	53 (18.5)	
≥80	17,084 (85.4)	284 (47.6)	100 (34.8)	
Heart rate, bpm*	90.0 (76.0–109.0)	107.0 (85.0–129.0)	100.5 (70.0–127.0)	<0.001
GCS score*	14.0 (11.0–15.0)	10.0 (4.0–14.0)	3.0 (3.0–9.5)	<0.001
ISS*	29.0 (20.0–36.0)	38.0 (29.0–50.0)	35.0 (26.0–45.0)	<0.001
Injured region, AIS score				
Head AIS ≥4	3745 (18.2)	121 (19.8)	52 (16.3)	0.391
Chest AIS ≥4	15,633 (75.9)	320 (52.4)	221 (69.1)	<0.001
Abdomen AIS ≥4	2921 (14.2)	276 (45.2)	107 (33.4)	<0.001
Pelvic fracture AIS ≥4	4194 (20.4)	283 (46.3)	100 (31.3)	<0.001
Cardiac or aortic injury	1335 (6.5)	35 (5.7)	68 (21.3)	<0.001
In-hospital mortality	3831 (18.6)	417 (68.2)	297 (92.8)	<0.001

Continuous variables are presented as median (IQR). Categorical variables are presented as number (%)

*Proportion of participants with missing values of covariates: Sex 0.0% (6), Age 0.2% (33), Mechanism of injury 1.1% (232), SBP 3.0% (643), Heart rate 4.4% (947), GCS 5.3% (1150), and ISS 1.2% (253)

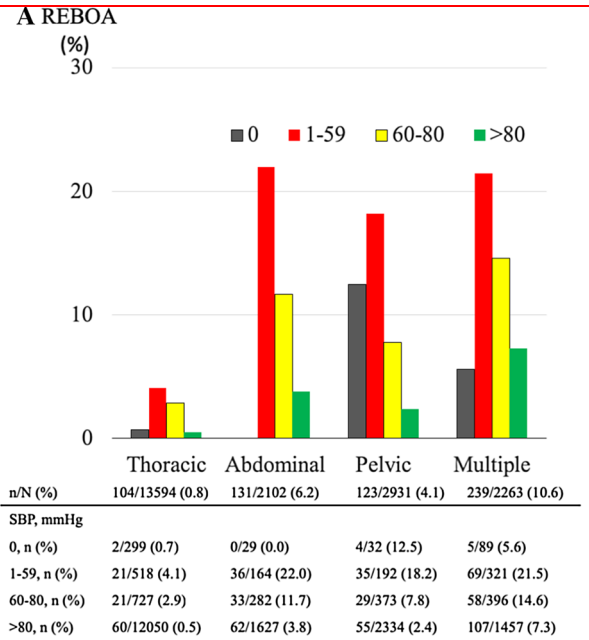
REBOA resuscitative endovascular balloon occlusion of the aorta, *ACC* open aortic cross-clamping, *SBP* systolic blood pressure, *GCS* Glasgow coma scale, *ISS* injury severity score, *AIS* abbreviated injury scale

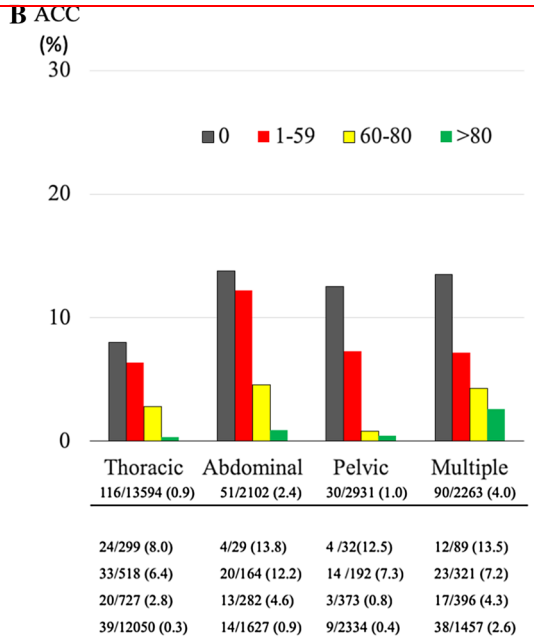
CI, 1.09–1.39; vs ACC: aHR: 2.37, 95% CI, 2.04–2.75; Online Appendix 5). The majority of deaths occurred within the first day in all groups, especially in the REBOA and ACC groups (non-aortic procedure [1663/2475, 67.2%], REBOA [280/333, 84.1%] and ACC [198/204, 97.1%] as the second peak described in the classic trimodal pattern of mortality). These cumulative curves for death were similar forms but did not have the discernible third peak of the classic trimodal pattern. However, regarding the first 8 h, the cumulative curve for death differed according to the procedure (Fig. 3b). The cumulative curve for death for REBOA was much more slowly elevated like a "sigmoid curve" and surpassed that of the non-aortic procedure at around 5 h. Of note, the cumulative curve for death for REBOA was mostly flat for the first 100 min. However, the cumulative curve for ACC was the most markedly elevated from the onset.

The rate of cardiac arrest was significantly higher for patients who underwent ACC (1.8% [11/287] vs 15.3% [44/597], $p < 0.001$). As hypotension and cardiac arrest should have been strong confounding factors, the cumulative curve for death within the first 8 h was stratified by the SBP (Fig. 3c–f). The more severe the hypotension was, the more sharply the curve was elevated. In all circulation status, the cumulative curve for death for REBOA was much more slowly elevated within the first 2 h.

Discussion

This study evaluated REBOA and ACC use in Japan and the difference in the proportion of death according to these procedures for aortic occlusion. REBOA is currently one of the most popular resuscitative modalities and has been





	A REBOA			
n/N (%)	104/13594 (0.8)	131/2102 (6.2)	123/2931 (4.1)	239/2263 (10.6)
SBP, mmHg				
0, n (%)	2/299 (0.7)	0/29 (0.0)	4/32 (12.5)	5/89 (5.6)
1-59, n (%)	21/518 (4.1)	36/164 (22.0)	35/192 (18.2)	69/321 (21.5)
60-80, n (%)	21/727 (2.9)	33/282 (11.7)	29/373 (7.8)	58/396 (14.6)
>80, n (%)	60/12050 (0.5)	62/1627 (3.8)	55/2334 (2.4)	107/1457 (7.3)

	B ACC			
n/N (%)	116/13594 (0.9)	51/2102 (2.4)	30/2931 (1.0)	90/2263 (4.0)
SBP, mmHg				
0, n (%)	24/299 (8.0)	4/29 (13.8)	4 /32(12.5)	12/89 (13.5)
1-59, n (%)	33/518 (6.4)	20/164 (12.2)	14 /192 (7.3)	23/321 (7.2)
60-80, n (%)	20/727 (2.8)	13/282 (4.6)	3/373 (0.8)	17/396 (4.3)
>80, n (%)	39/12050 (0.3)	14/1627 (0.9)	9/2334 (0.4)	38/1457 (2.6)

Fig. 2 The use of REBOA and ACC according to the site of injury and blood pressure in patients with severe torso injuries (AIS score ≥4). Multiple torso trauma was defined as two or more occurrences of each torso injury. *ACC* open aortic cross-clamping, *AIS* abbreviated injury scale, *REBOA* resuscitative endovascular balloon occlusion of the aorta, *SBP* systolic blood pressure

more commonly used than ACC in Japan. We observed no notable change in the use of REBOA and ACC between 2004 and 2014. The results of this study showed that 9.1% of patients with severe torso injuries with hypotension (SBP < 80 mmHg) underwent REBOA. Furthermore, it appears that the indications differ between REBOA and ACC and that the cumulative curve for death differed according to each procedure.

Japan was the first country to develop a commercial device for REBOA. The first device (intra-aortic occlusion balloon [IABO], MERA Tokyo, Japan) was sold as a kit that included the balloon catheter, a 10-Fr sheath and vascular puncture set in 2000 (Online Appendix 6A). Given the demand for the catheter kit, a competing product (Rescue Balloon, Tokai Medical Products, Aichi, Japan) was developed in 2013, which has a 7-Fr sheath (Online Appendix 6B). Several case reports and series about IABO have been published in a domestic medical journal; however, few clinical trials for REBOA have been conducted in Japan.

REBOA can potentially improve severe trauma outcomes. REBOA has been shown to improve survival outcome in many animal studies, but clinical data are equivocal [7–11]. Two large retrospective Japanese studies from the JTDB suggest that REBOA may be dangerous [3, 4]. However, one large study from the JTDB reported that REBOA was associated with lower mortality compared to ACC [5]. One of the most important limitations acknowledged by the authors of the previous studies was the absence of an indication for REBOA use. The present study demonstrated a selection bias regarding the different aortic procedures. Therefore, survival comparisons using the JTDB data in these previous studies are questionable despite the sophisticated analysis.

In one proposed algorithm for the management of patients with torso hemorrhage, Biffl et al. [1] considered hemodynamic conditions and the site of primary hemorrhage. Their algorithm suggested that patients in extremis or who have more proximal torso injury should receive ACC rather than REBOA. Interestingly, the REBOA strategy used in Japan is relatively similar to their proposed algorithm. According to another proposed algorithm from the University of Maryland, REBOA may be applied in traumatic cardiac arrest, but a major intrathoracic injury is a contraindication for REBOA [12, 13]. However, the present study showed that among patients who received REBOA, 52.4% had severe thoracic injuries. Of note, 5.7% of patients had cardiac or aortic injuries, which are absolute contraindications of REBOA, and these patients had high mortality. In Japan, REBOA seems to have been applied incorrectly in some cases.

In the present study, patients with severe hypotension (1–59 mmHg) were more likely to receive REBOA than ACC. This may be because in-house attending trauma surgeons are still uncommon in Japan, and emergency physicians usually manage severe trauma. ACC had a

Table 2 Multivariate multinomial logistic regression analysis for REBOA and ACC

	REBOA vs non-aortic procedure			ACC vs non-aortic procedure		
	OR	95% CI	*p*	OR	95% CI	*p*
Gender						
Male (reference)	1			1		
Female	0.97	0.81–1.18	0.778	0.74	0.55–0.99	0.739
Age group, y*						
<20 (reference)	1			1		
20–39	1.21	0.82–1.78	0.341	1.23	0.68–2.48	0.432
40–59	1.40	0.95–2.06	0.089	1.69	0.89–3.20	0.110
60–79	1.30	0.89–1.90	0.178	2.03	1.09–3.78	0.026
≥80	1.39	0.90–2.14	0.138	2.72	1.39–5.31	0.004
Mechanism of injury*						
Blunt (reference)	1			1		
Penetrating	1.41	0.92–2.18	0.117	1.72	0.98–3.03	0.061
SBP, mmHg*						
≥80 (reference)	1			1		
60–79	2.89	2.31–3.62	<0.001	2.72	1.89–3.92	<0.001
1–59	4.93	3.91–6.22	<0.001	5.65	4.07–7.86	<0.001
0	1.00	0.48–2.11	0.994	5.11	3.14–8.31	<0.001
GCS						
9–15 (reference)	1			1		
3–8	2.01	1.63–2.47	<0.001	6.06	4.42–8.30	<0.001
ISS						
<25 (reference)	1			1		
25–39	1.96	1.48–2.60	<0.001	3.40	2.07–5.60	<0.001
40–75	3.18	2.22–4.55	<0.001	4.00	2.17–7.30	<0.001
Injured region, AIS score						
Head AIS <4 (reference)	1			1		
Head AIS ≥4	0.66	0.50–0.87	0.003	0.37	0.25–0.56	<0.001
Chest AIS <4 (reference)	1			1		
Chest AIS ≥4	0.87	0.68–1.10	0.234	1.06	0.71–1.57	0.783
Abdomen AIS <4 (reference)	1			1		
Abdomen AIS ≥4	5.00	3.94–6.31	<0.001	2.95	2.03–4.29	<0.001
Pelvic fracture AIS <4 (reference)	1			1		
Pelvic fracture AIS ≥4	2.70	2.09–3.47	<0.001	1.50	1.01–2.22	0.043

REBOA resuscitative endovascular balloon occlusion of the aorta, *ACC* open aortic cross-clamping, *OR* odds ratio, *CI* confidence interval, *SBP* systolic blood pressure, *GCS* Glasgow coma scale, *ISS* injury severity score, *AIS* abbreviated injury scale

significantly higher use in patients who were ≥80 years old and who had cardiac arrest. However, REBOA was not significantly used and may be difficult to apply in these patient groups. This is because older age is one of the major risk factors for atherosclerosis and REBOA in Japan is usually used with the Seldinger technique through a needle puncture [14].

Regarding the time to death distribution, the cumulative curve for death differed according to the procedure in the hyperacute phase. The cumulative curve for death for REBOA was much more slowly elevated than that for the other groups. One possible reason for this is that REBOA could be effective for prolonging the life of a patient in the hyperacute phase. In contrast, more patients who underwent ACC tended to die from the onset. Apart from the high trauma severity of patients who underwent ACC, the high invasiveness of the procedure may result in early death for patients in extremis. Further investigation is needed.

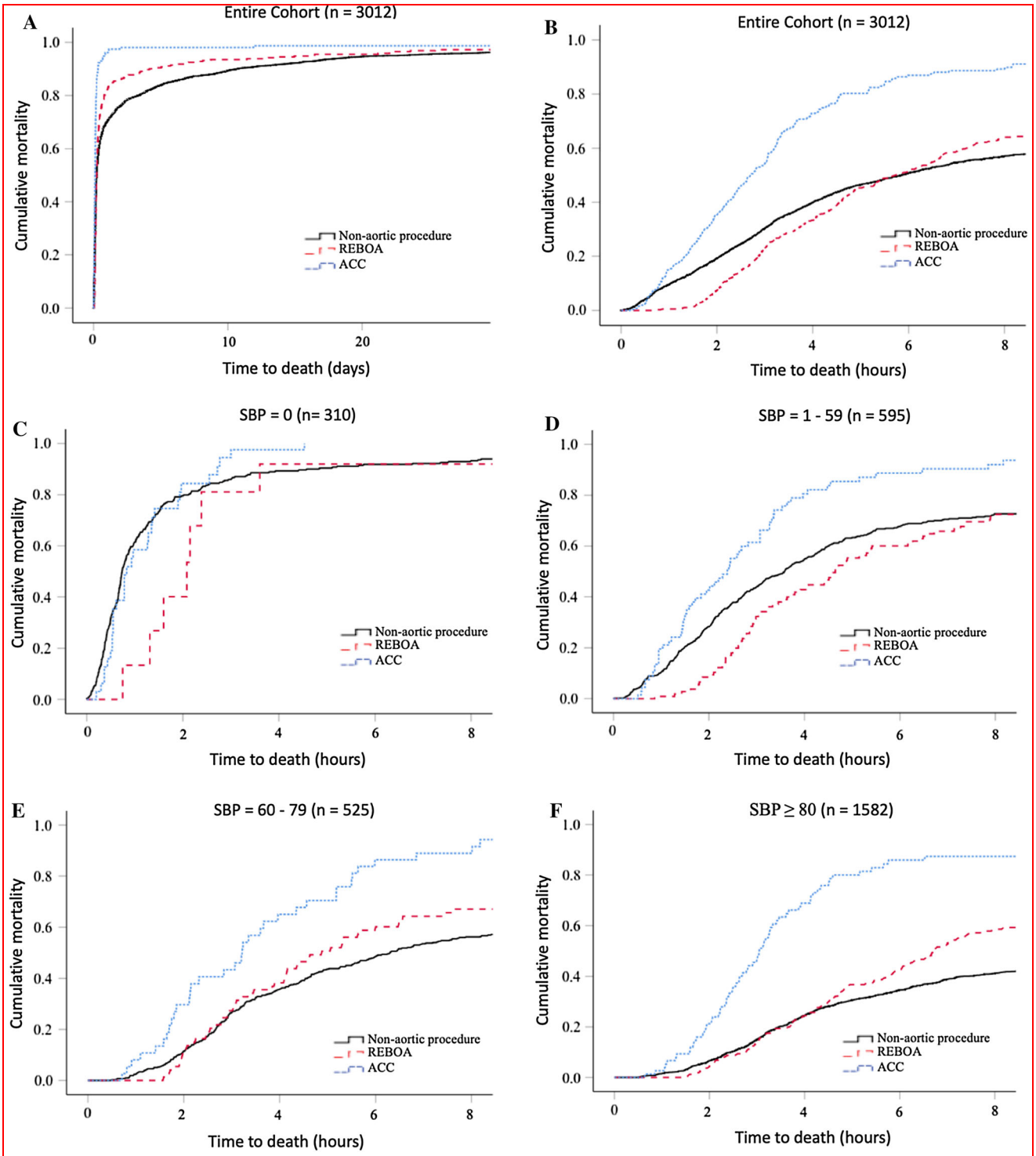


Fig. 3 Time distribution of cumulative mortality in trauma deaths according to aortic clamping over 28 days (**a**), and the first 8 h, stratified by SBP (**b**, **c**, **d**, **e**, **f**). *Regarding the time from admission to death, 24.5% (1114) of the data were missing. **a**, **b** Non-aortic procedure (n = 2475), REBOA (n = 333), ACC (n = 204). **c** Non-aortic procedure (n = 271), REBOA (n = 8), ACC (n = 31). **d** Non-aortic procedure (n = 425), REBOA (n = 106), ACC (n = 64). **e** Non-aortic procedure (n = 415), REBOA (n = 73), ACC (n = 37). **f** Non-aortic procedure (n = 1364), REBOA (n = 146), ACC (n = 72). *ACC* open aortic cross-clamping, *REBOA* resuscitative endovascular balloon occlusion of the aorta, *SBP* systolic blood pressure

There are several limitations to this study. First, the study was limited by several factors inherent to the retrospective analysis of large databases. The study involved "convenience samples" submitted voluntarily from hospitals that are actively involved in trauma care. Second, patients' background differed according to the aortic procedures because the non-aortic procedure group also contained many patients without hypotension. Our analysis for time to death is also limited by the existence of unmeasured confounders. Third, this study considered an AIS score of $\geq$4 in evaluating the relationship between severe torso trauma and REBOA use; however, these patients may not necessarily have hemorrhage and the AIS score is unknown at the initial management. Finally, the technique and anatomical deployment of REBOA are crucial. However, this study did not include this information. REBOA should be deployed at zones 1 and 3 depending on the location of the hemorrhage [1]. Nevertheless, it is quite doubtful that Japanese physicians take the zone concept into consideration. Despite these limitations, we believe that this study provides valuable data regarding REBOA use in Japan during the last decade.

In conclusion, in Japan, REBOA is more commonly used than ACC for patients with severe torso trauma. However, in some cases, it appears that REBOA is used inappropriately for thoracic injury, including cardiac and aortic injury; thus, thorough preventive measures against inappropriate use are required. In addition, REBOA influences the time of death distribution in the hyperacute phase. Future studies of REBOA should consider both its indications and proper use.

Author's contribution SM, TA, TF, and KJ participated in the study design. SM and KH participated in the analysis and interpretation of data. SM and KS participated in drafting the article. TM critically revised the manuscript.

Compliance with ethical standards

Conflicts of interest The authors declare that there is no conflict of interest.

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