

BMJ Open Minimising the biases in the observational study of resuscitative endovascular balloon occlusion of the aorta: a research protocol for a prospective study analysed with propensity score matching with time-varying covariates

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ABSTRACT

Introduction Resuscitative endovascular balloon occlusion of the aorta (REBOA) has been used as a bridge to definitive bleeding control of subdiaphragmatic injury. Since previous observational studies have poorly adjusted for confounding factors, it is necessary to incorporate REBOA-specific and time-varying covariates in the model. We hypothesised that REBOA improves the survival of haemodynamically unstable torso trauma patients after comparing the REBOA group with a matched control group (non-REBOA group).

Methods and analysis The Japanese Association for the Surgery of Trauma-REBOA Study is a prospective, multicentre, matched cohort study organised by the Clinical Trial Committee of the Japanese Association for the Surgery of Trauma. To minimise observational study biases, this study will prospectively register traumatic shock patients who require bleeding control within 60 min upon arrival at the emergency department, with in-hospital mortality as the primary outcome. After the data set is fixed, the missing values for all variables will be imputed using the multiple imputation technique. In the primary analysis, propensity scores for the probability of REBOA decision (regardless of the actual REBOA deployment) will be calculated from the baseline information using a logistic regression generalised linear mixed-effects model, which will be performed for both the REBOA use and non-REBOA use groups.

Ethics and dissemination This study was approved by the ethics committee of each participating hospital. The results will be disseminated to the participating hospitals, submitted to peer-reviewed journals for publication and presented at congresses.

Trial registration number UMIN Clinical Trials Registry (UMIN000035458).

INTRODUCTION

Haemorrhagic shock is the leading cause of preventable trauma-related death.¹ Hence,

Strengths and limitations of this study

- Propensity score matching substitutes the randomised controlled trials conducted in critically ill patients who have undergone resuscitative endovascular balloon occlusion of the aorta by equalising the patients similar to that performed in an observational trial.
- Adjusting with time-varying covariates can minimise the survivorship biases (resuscitation time bias) and physiological changes in the patients.
- The multiple imputation method can substitute missing or unmeasured values and minimise selection biases.
- Within-cluster matching may allow the adjustment of unobserved cluster-level variables to minimise the institutional biases.
- The significant heterogeneity of the trauma patients might not be able to equalise the groups.
- This prospective, multicentre, matched cohort study compares the resuscitative endovascular balloon occlusion of the aorta (REBOA) and non-REBOA groups using a research protocol, thus, minimising biases.

immediate surgical and/or endovascular intervention is required for definitive control of non-compressible torso haemorrhages involving the thorax, abdomen or pelvis. Recently, resuscitative endovascular balloon occlusion of the aorta (REBOA),² which temporarily regulates the aortic flow via balloon occlusion, has been used as a bridge to definitive bleeding control of subdiaphragmatic injury. The proximal aortic pressure from this injury can be elevated by augmenting the afterload, thus increasing

the risk of ischaemic complications in the distal organ or lower extremities.

Observational studies using a multicentre database from Japan (Japan Trauma Data Bank, JTDB)^{3 4} and the USA (Trauma Quality Improvement Program, TQIP)⁵ suggested a possible negative effect of REBOA on the survival outcome. By contrast, another study using the JTDB recently reported better survival in patients undergoing REBOA,⁶ which is contradictory to the results of previous studies using the same Japanese database. Although these studies analysed a considerable number of patients from multiple centres, the results might be biased due to the lack of REBOA-specific information in the data set.

The American Association for the Surgery of Trauma (AAST) prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry demonstrated a possible survival benefit of REBOA compared with resuscitative thoracotomy (RT) in patients with hypotension who did not experience cardiac arrest.⁷ Additionally, the ABOTrauma registry, a Swedish-based international registry, presented the potential benefits of partial or intermittent REBOA compared with those of complete REBOA.⁸ The Diagnostic and Interventional Radiology in Emergency, Critical Care and Trauma (DIRECT)-Intraaortic Balloon Occlusion (IABO) registry, a Japanese multicentre, retrospective, observational database, has also shown fewer access-related complications associated with the use of a smaller profile REBOA device.⁹ These registries included detailed REBOA-related information but did not have an appropriate control group (non-REBOA group). Thus, clinical questions comparing 'REBOA and RT', 'partial/intermittent REBOA and complete REBOA', and 'small and large profile' do not need to be clarified.

Notably, these previous studies have also poorly adjusted their confounding factors. Although the JTDB and TQIP analyses compared the REBOA group with a matched cohort (non-REBOA group), the database did not include REBOA-specific variables or time-varying covariates. By contrast, the AAST-AORTA Study compared the REBOA group with the RT group, which is not the proper control group for comparison. Even the DIRECT-IABO and ABOTrauma registry only included REBOA cases and did not make any comparison between the REBOA and non-REBOA groups. Moreover, the results of these previous studies suggested high heterogeneity among the enrolled patients.

Therefore, REBOA-specific and time-varying covariates must be incorporated in the model. To overcome the limitations of previous studies, a feasible prospective observational study should be conducted to evaluate the risks and benefits of REBOA in traumatic haemorrhagic shock patients. Our clinical question aims to investigate whether REBOA has survival benefits in trauma patients with haemorrhagic shock. We then hypothesised that REBOA would improve the survival of trauma patients with haemorrhagic shock compared with that of a matched control group.

This study aims to compare the standard trauma care alone (non-REBOA group) with standard trauma care plus REBOA (REBOA group) for haemodynamically unstable torso trauma patients who require haemostatic surgical or endovascular bleeding control based on the evaluation of the emergency physicians and surgeons.

METHODS AND ANALYSIS

Study setting of the Japanese Association for the Surgery of Trauma-REBOA Study

The Japanese Association for the Surgery of Trauma-REBOA (JAST-REBOA) Study is a prospective, observational, multi-institutional, matched cohort study organised by the Clinical Trial Committee of the JAST.

Patient enrolment and eligibility criteria

To minimise the biases inherent in observational studies and to substitute a randomised controlled trial, the JAST-REBOA Study prospectively registered traumatic shock patients; their data will be collected from trauma or tertiary care centres. This study will then enrol patients with truncal haemorrhage requiring surgical or endovascular bleeding control within 60 min upon arrival at the centre. The establishment of a prospective registration system will allow the smooth enrolment of study patients, and approximately 100 patients who underwent REBOA are likely to be registered every year, which was estimated from the registered cases of JTDB.

Although head injury and multiple injuries are fatal exacerbation factors, these injuries are often accompanied by subdiaphragmatic injury. Thus, we will include patients with multiple injuries, regardless of the presence or absence of head injury. We will enrol patients aged 16 years and older based on the previous studies that included children.^{10 11} By contrast, we will exclude patients who presented with cardiac arrest before the initial presentation, regardless of return of spontaneous circulation, and apparent contraindication to REBOA such as exsanguinating thoracic injuries.

The methodology of the study

All data collected in each facility will be anonymised; the data will be collected and managed using the Research Electronic Data Capture (REDCap) electronic data capture tools hosted at the Kameda Medical Center.^{12 13} REDCap is a secure web-based software platform designed to collect data for studies. It (1) provides an intuitive interface for validated data capture, (2) has audit trails for tracking data manipulation and export procedures, (3) has automated export procedures for seamless data downloads of common statistical packages, and (4) has procedures for data integration and interoperability using external sources. One or two persons (a physician, a research nurse or a medical clerk) in charge of inputting information at each facility will register the patient information in the database.

Outcome measurements

The following patient data will be collected: demographics, mechanism of injury, vital signs on arrival, bleeding control decision, medical history, trauma severity, blood examination results, diagnostic imaging results, trauma care time course, site of bleeding control, bleeding control method, blood transfusion requirement, information of arterial access for REBOA placement, initial aortic occlusion method, hospital course and complications (table 1). The access-related complications will also include dissection, pseudoaneurysm (requiring surgical repair or endovascular therapy), puncture haematoma, retroperitoneal haematoma (requiring bleeding control procedure rather than compression), distal embolism, arteriovenous fistula, arterial stenosis (requiring thrombectomy, angioplasty or surgical operation), arterial rupture and leg ischaemia (requiring fasciotomy or lower limb amputation). The device-related complications will include catheter malposition (catheter indwelling in an unintended vessel), balloon migration (downstream movement of the balloon) and balloon rupture. The primary outcome of this study will be in-hospital mortality.

Statistical analyses

The data analysis will involve propensity score matching with time-varying covariates, where the baseline time point is defined as the moment of bleeding control decision. The baseline time point can be the patients' arrival (determined based on the prehospital information or physiological instability), the moment of imaging diagnosis (X-ray, focused assessment with sonography for trauma or CT scan) or recognition of the physiological deterioration. In patients who are expected to require bleeding control in the prehospital setting, the arrival time was used as the baseline time point as the prehospital diagnosis is not definite. To minimise survivorship biases, the patients in whom the treating physician has decided to attempt bleeding control will be enrolled, regardless of whether bleeding control will actually occur or not. In fact, older patients or those taking anti-thrombotic drugs may present with delayed shock and can even be enrolled. Thus, patients judged by a physician to require bleeding control within 60 min upon arrival at the emergency room will be enrolled, which may decrease apparent mortality in the REBOA group due to survivorship biases (immortal time bias or resuscitation time bias).¹⁴ In certain cases, the physiological derangement in REBOA cases might even increase the apparent mortality rate.

Data of several variables that will be used in this study will be collected in the resuscitation room during the initial trauma assessment. Therefore, many variables might have missing or incorrect data, especially in patients with severe cases, since excluding those with missing data induces selection bias. Moreover, this study will query each facility about missing and erroneously entered values following the completion of registration. This data cleaning process involves treatment of the missing values and outliers. Missing values

Table 1 Patients' data collected in this study

Demographics	Age
	Sex
Mechanism of injury	Driver of motor vehicle
	Motorcycle
	Bicycle
	Pedestrian
	Fall
Vital signs on arrival and at the decision of bleeding control	Tumble (fall on the ground)
	Others
	Respiratory rate
	SpO ₂
	Systolic blood pressure
Medical history	Heart rate
	Glasgow Coma Scale
	Body temperature
	Charlson Comorbidity Index ¹⁷
	Abbreviated Injury Scale
Trauma severity	Injury Severity Score
	Haemoglobin (g/dL)
	Haematocrit (%)
	Platelet (10 ⁹ /L)
	PT-INR
Blood examination	APTT (s)
	Fibrinogen (mg/dL)
	FDP (µg/mL)
	D-dimer (µg/mL)
	pH
Diagnostic imaging	PaO ₂
	PaCO ₂
	BE (mEq/L)
	Lactate (mmol/L)
	FAST (positive or negative)
The time course of trauma care	Chest X-ray (chest injury requiring bleeding control)
	Pelvis X-ray (pelvic fracture requiring bleeding control)
	Injury
	Arrival
	Thoracoabdominal CT
	Decision of haemostasis (baseline)
	Arterial access placed
	Decision of REBOA
	Inflation of REBOA
	Deflation of REBOA

Continued

Table 1 Continued

	Decision of transfusion
	Start of definitive haemostasis
	ICU admission
The site of haemostasis	Chest, abdomen, pelvis, retroperitoneum
Haemostasis method	Surgery or interventional radiology
Blood transfusion requirement within the first 24 hours	Packed red blood cell
	Fresh frozen plasma
	Platelet
	Other blood products
Arterial access information	Location
	Anatomical site (R/L, femoral/brachial)
	Puncture method (blind, US guided, cut-down)
	Sheath size
Initial aortic occlusion method	Resuscitative thoracotomy, REBOA, none
Hospital course	Days on mechanical ventilation
	ICU discharge
	In-hospital mortality
	Cause of death
Complications	Device-related complications
	Access-related complications
	Systemic complications

APTT, activated partial thromboplastin time; BE, base excess; FAST, focused assessment with sonography for trauma; FDP, Fibrin and fibrinogen degradation product; ICU, intensive care unit; PaCO₂, partial pressure of carbon dioxide; PaO₂, arterial oxygen pressure; PT-INR, prothrombin time-international normalized ratio; REBOA, resuscitative endovascular balloon occlusion of the aorta; SpO₂, Saturation of Peripheral Oxygen; US, ultrasound.

include all missing values for all study variables within the observation period. The outliers of a nominal variable are any contradiction between two or more nominal variables (eg, treatment performed after death). The outliers of numerical variables are statistically detected using robust regression analysis. A datasheet containing the detected missing values and outliers is returned to the participating sites for reinput. This process will be repeated twice. After the data set in the analysis is fixed, the missing values will be substituted for all variables using the multiple imputation method (multiple imputations by the chained equation, number of iterations: 20, number of data sets: 25).

Primary analysis

In the primary analysis of this study, propensity scores for the probability of REBOA decision (regardless of the actual REBOA deployment) will be calculated using baseline information at the time that bleeding control was decided, not the time of arrival at the emergency room. The baseline information would include demographics, medical history, mechanism of injury, prehospital treatment intervention, physiological parameters after hospital arrival, trauma severity score (Revised Trauma Score, Abbreviated Injury Scale (AIS) and Injury Severity Score), blood test findings, diagnostic imaging findings and clusters from each facility using a logistic regression generalised linear mixed-effects model. After obtaining the baseline information, propensity score matching for the REBOA use and non-REBOA use groups will be performed.¹⁵

Furthermore, the absolute standardised difference in variables for propensity score estimation will be used to assess the match balance between the two groups; an absolute standardised mean difference of <0.1 is generally considered an acceptable match balance. Intergroup comparisons will involve assessment of the risk differences (primary outcome), in-hospital mortality risk ratio and survival time.

Moreover, the primary outcome will be analysed using linear regression. Sensitivity analysis of three models will be performed in propensity score-matched participants using propensity score matching on rolling entry interventions, inverse probability of treatment weighting, within-cluster matching and a generalised estimating equation (GEE). Specifically, propensity score matching on rolling entry interventions using minutes from the decision to perform REBOA can further eliminate immortal time bias.¹⁶ Immortal time is the period of follow-up during which, by design, death or the study outcome cannot occur. In this study, the patients who 'underwent' bleeding control surgery should not die prior to surgery. Thus, we chose the timing of decision as the baseline time point. Meanwhile, the inverse probability of treatment weighting will be used to compensate for the selection bias in cases where the propensity scores are overlapping between the treatment and control groups, while within-cluster matching and GEE will be used to determine the facility differences in terms of use tendency, skill level and outcome of REBOA cases. The significance level was set to $p < 0.05$ in the two-tailed test, and correction using multiple comparisons was not performed.

Assuming a 50% mortality rate in the control group and a 35% mortality rate in the REBOA group, a total of 140 patients are required per group, as the required sample size has increased 1.5 times compared with that calculated in the matching. A more specific number of cases will be presented using an adaptive design with interim analyses. When the REBOA group registration reaches 100 and 200 cases, the study sample size will be recalculated using absolute differences in the primary outcome incidence, with a significance level of 0.05 and a power of 0.8. The

assumed increase in the required sample number due to missing data and propensity score matching was 1.5, with the maximum registered number capped at 500.

Secondary analysis

Secondary endpoints will include haemorrhagic death, blood transfusion requirement within the first 24 hours, complications (systemic complications, device-related complications and vascular access-related complications), intensive care unit-free days, and ventilator-free days within 28 days after hospitalisation.

Subgroup analysis

Based on the subgroup analysis in a previous study,⁴ the analysis of interaction for REBOA use and primary outcome were predefined.

- ▶ Sex (male vs female).
- ▶ Age (<60 vs ≥60).
- ▶ Type of trauma (blunt vs penetrating).
- ▶ Systolic blood pressure on arrival (<80 mm Hg vs ≥80 mm Hg).
- ▶ AIS chest (0–3 vs 4–5).
- ▶ AIS abdomen (0–3 vs 4–5).
- ▶ AIS pelvis and lower extremities (0–3 vs 4–5).
- ▶ REBOA use per institute per year (≥2 vs <2).
- ▶ Angioembolisation (no vs yes).

Other analyses

Analysis comparing REBOA and non-aortic occlusion will be performed for the subgroup that did not experience cardiac arrest upon arrival at the emergency room using an analysis method similar to that of primary analysis. In contrast, analysis comparing REBOA and RT will be performed in the subgroup of patients who experienced cardiac arrest within 60 min after arrival at the emergency room using the same aforementioned analysis method.

ETHICS AND DISSEMINATION

Ethical approval and consent to participate

This clinical trial will be conducted according to the principles of the Declaration of Helsinki and Ethical Guidelines for Medical and Health Research Involving Human Subjects published by the Ministry of Health, Labour and Welfare of Japan and Japanese Ministry of Education, Culture, Sports, Science and Technology. This observational study was approved by the ethics committee of each participating hospital and ethics committee of the JAST (2018-1).

Since this observational study will only record and collect clinical data during routine trauma care, patients' privacy invasion will not be breached during their participation in the study, and individual consent will not be required. The patients' data will be anonymised and registered in the electronic data capture system, and the data obtained during the investigation will not be used for purposes other than research. After withdrawal

of consent, relevant data will be deleted, unless already published.

Dissemination

The results of this study will be submitted to peer-reviewed journals for publication and presented at congresses. The data set of this study will be disseminated to the participating hospitals and board-certified educational institutions of the JAST. Technical appendix, statistical code and data set will be available from the participating researchers after the publication of the main results.

Patient and public involvement

The study patients and the public were not involved in the study design, conduct, reporting or dissemination plans of this study.

Limitations

There are some potential limitations of this study. The REBOA use group was defined as the cases that were required to undergo REBOA. The exact number of cases that underwent REBOA and whose outcome will likely change will remain unclear. In addition, significant heterogeneity was observed in the study population, which may have an effect on the matching process.

Trial status

The first edition of the trial protocol was approved on 31 May 2018, and the latest protocol was approved on 9 July 2020, at the Chiba University Graduate School of Medicine. The ethical committee of the JAST has approved this latest protocol. Exactly 19 hospitals participated in this study and were approved by the Institutional Ethical Committee. Patient enrolment was initiated on 1 October 2019. This study was initiated on 31 May 2018 (approved at the primary institute) and was planned to end on 31 March 2024.

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Contributors YM, the principal investigator of the Japanese Association for the Surgery of Trauma (JAST)-REBOA Study, conceived the research proposal. YM and AS designed the protocol and drafted the manuscript. AS drafted the statistical plan. SK supervised the planning of the JAST-REBOA in the multi-institutional research committee of the JAST. All authors read and approved the final manuscript.

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