

Title page

Transcatheter arterial embolization is an efficient and safe for paediatric blunt torso trauma: a case control study

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Abstract

Background: It remains unclear whether transcatheter arterial embolization (TAE) is as safe and effective for paediatric patients with blunt torso trauma as it is for adults in Japan, owing to few trauma cases and sporadic case reports. The study aimed to compare the efficacy and safety of TAE in paediatric patients (age ≤ 15 years) with blunt torso trauma to those of TAE in adult patients.

Methods: This was a single-centre, retrospective chart review study that included blunt torso trauma

patients who underwent TAE in the trauma centre from 2012 to 2017. The comparative study was carried out between a “paediatric patient group” and an “adult patient group”. The outcome measures for TAE were the success of haemorrhage control and complications and standardised mortality ratio (SMR).

Results: A total of 504 patients with blunt torso trauma were transported to the trauma centre. Among them, 23% (N=114) of patients with blunt torso trauma underwent TAE, including 15 paediatric and 99 adult patients. There was no significant difference between the use of TAE in paediatric and adult patients with blunt torso trauma (29% vs. 22%, $P=.221$). The median age was 11 (IQR 7–14) years for paediatric patients. The predicted mortality (PMR) rate and SMR for paediatric patients were lower than that for adult patients (18.3% vs. 25.9%, $P=.026$, and 0.37 vs. 0.54). The rate of effective haemorrhage control without repeated TAE or additional surgical intervention was 93% in paediatric patients, which was similar to that in adult patients (88%). There were no complications in the paediatric patients at our centre. There were no significant differences in the proportion of paediatric patients that underwent surgery before TAE or urgent blood transfusion (33% vs. 26%, $P=.566$, or 67% vs. 85%, $P=.084$).

Conclusions: It is possible to provide an equal level of care related to TAE for both paediatric and adult patients as it relates to TAE for blunt torso trauma with haemorrhage in the trauma centre. We should prepare alternative haemorrhage control procedures as soon as possible whenever the patients reach a hemodynamic unstable state.

Keywords:

Paediatric patients, trauma care, nonsurgical intervention, intervention radiology, transcatheter arterial embolization, complication, in-hospital mortality, standardized mortality ratio

Background

Although torso trauma with excessive bleeding has been associated with significant morbidity and mortality, the selection of the therapeutic strategy for patients who are haemodynamically unstable remains a challenge [1-3]. Due to advances in endovascular techniques for trauma patients, the therapeutic strategy in blunt torso trauma with haemorrhage changed from operative to non-operative management in the mid-1990s [4,5]. In adult patients, non-operative management has been established as a standard of care for trauma patients who are haemodynamically stable [3,4,6]. Previous studies reported transcatheter arterial embolization (TAE) as one of the non-operative management strategies to improve morbidity and mortality for blunt torso trauma patients with acute bleeding [3,5,6].

In contrast, children have age-dependent anatomical and physiological differences and a relatively low incidence of blunt torso trauma [7,8]. A previous study on children cohort reported that non-operative management for hemodynamically stable paediatric patients with blunt torso trauma was the gold standard of trauma care [7,9]. Most paediatric patients are now managed with observation. Paediatric patients who undergo additional therapeutic interventions, such as blood transfusion, TAE, or surgery are uncommon [7,9]. However, to the best of our knowledge, there is no research that evaluates the best management strategy, including non-operative and operative interventions, for hemodynamically unstable paediatric patients with torso blunt trauma. It remains unclear whether TAE for paediatric patients with blunt torso trauma is as effective and safe as that for adults, due to the relatively few trauma centres and sporadic case reports [10,11]. The aim of this study was to evaluate the efficacy and safety of TAE for paediatric patients with blunt torso trauma by comparing them with adult patients in Yokohama City University Medical Centre (Yokohama, Japan), which has adapted the same therapeutic algorithm in blunt torso patients with haemorrhage regardless of age.

Methods

Study Setting and Population

This was a single centre study, conducted retrospectively in Yokohama City University Medical Center (Yokohama, Japan). Our centre is one of the two Yokohama City Major Trauma Centres (YCMTCs), which were established to serve a population of 3.7 million, including 446,000 children, and to provide 24/7 trauma care by a specialized team including an interventional radiologist on call around the clock [12,13]. Before severe trauma patients arrive at our centre, an in-hospital trauma code is activated and preparations for blood transfusions, urgent surgery, and interventional radiology (IVR) are initiated. Whenever trauma patients are in an unstable condition, we can perform urgent surgical and/or radiological intervention within 30-60 minutes of arrival to hospital.

For this study, we used the dataset from our centre to include information from January 1, 2014 to December 31, 2017, which initially yielded the data for 19,207 patients. The inclusion criteria for this study were the following: blunt torso trauma and patients who underwent TAE. Patients who were dead on arrival were excluded from this study. Figure 1 presents a flow chart of the patient population in this study.

Emergency department algorithm in blunt torso patients with haemorrhage at YCMTC

All trauma patients underwent evaluation and trauma care in the acute care phase according to Japan trauma evaluation and care guidelines [14]. The general approach is based on the patients' hemodynamic stability and the patients' response to fluid resuscitation. If systolic blood pressure is less than 90 mmHg in an adult and less than the age-related baseline value in children [14], these patients are considered to be in hypovolemic shock.

As fluid resuscitation, 20 ml per body weight (kg) of crystalloid is administered rapidly, followed by whole blood transfusion. First, if the patients do not respond to fluid resuscitation and achieve hemodynamic stability, these patients are assessed to be “non-responders” and treated by surgical intervention with damage control techniques. In case of persistent hemodynamic instability with ongoing arterial bleeding, subsequent TAE is performed. Second, if the patient responds to fluid resuscitation and maintains hemodynamic stability, the patient is assessed to be a “responder” and will undergo contrast-enhanced computed tomography (CT) scan. In case of arterial extravasation, TAE is performed. Finally, if the patient responds to fluid resuscitation and achieves hemodynamic stability at least temporarily, they are assessed to be “transient-responder” and undergo contrast-enhanced CT scan. According to the patient’s condition and the results of the CT scan, the trauma team will perform TAE and/or surgical intervention for the transient-responders.

All blunt trauma patients with haemorrhage in this study underwent trauma care according to our institutional algorithm as mentioned above. Therefore, the trauma team performed operative and/or non-operative intervention in these patients using the same therapeutic strategy, regardless of age. However, in the case of paediatric patients, all interventions were performed under the management of general anaesthesia and mechanical ventilation. The technique for TAE started with percutaneous femoral artery vascular access with sheath placement. Arterial puncture in younger paediatric patients used an ultrasonically guided puncture needle to ensure safety and reliable manual operation. A 4-, 5-, or 6-Fr sheath was used to maintain arterial access throughout the procedure. Finally, all image diagnoses and IVR were performed by the interventional radiologist. Various materials are used for TAE, broadly categorized as permanent (coils or n-butyl-2-cyanoacrylate) or temporary (gelatine particles). The method of following up paediatric patients who underwent TAE is as follows: (1) an emergency physician confirmed that the

patients are in a hemodynamic stability state and removed the arterial sheath after 6 or 12 hours of TAE, (2) before and after TAE, the patients, with a pressure band, rested on the bed during 6 hours, (3) an emergency physician evaluated whether the patients have complications such as puncture site hematomas, arterial embolism, or pseudo-aneurysms.

Data collection and outcome measurements

We collected the following information: age (year), body weight, mechanism of injury, transportation method, vital signs and hemodynamic state on hospital arrival, Injury Severity Score (ISS) [16], Revised trauma score (RTS) [17], predicted survival rate (%) calculated by using the trauma and injury severity score (TRISS) [18], provision of an urgent examination and treatment during the acute care phase, duration of mechanical ventilation (days), intensive care unit (ICU) stay (days), and hospital stay (days), in-hospital mortality rate (%), Standardised mortality ratio (SMR), TAE data including treatment before IVR, time interval from arrival to the end of IVR, embolic agents, target region and artery of embolization, degree of haemorrhage control and complication rate. The SMR was calculated by dividing the in-hospital mortality rate by the mean predicted mortality rate.

The outcome measures for TAE were the success of haemorrhage control and complications following embolization, the need for surgical intervention or repeat embolization, and SMR. The degree of haemorrhage control was classified as follows: (1) effective haemorrhage control, (2) ongoing haemorrhage, and (3) exsanguination and death [8]. Complications were classified as major and minor using the Society of Interventional Radiology classification system [19].

Data analysis

The patients enrolled in this study were categorized into a “paediatric patient group” (younger than 15 years) and an “adult patient group” (older than 15 years). The age threshold of 15 years set by Basis Education Law, at which Japanese children must receive compulsory education was chosen to classify patients as either children or adult. The results of these comparisons are expressed as the medians and interquartile ranges (IQRs) [25th–75th percentile] for continuous variables and as the mean and percentages for the categorical variables. The Mann–Whitney *U* test and Kruskal–Wallis tests were used to analyse the continuous variables, whereas the Fisher’s exact test was used for the categorical variables. All statistical analyses were carried out by using STATA/SE software, version 16.0 (StataCorp; College Station, Texas, USA). A two-tailed *P*-value of <0.05 indicated statistical significance.

Results

During the 6-year study period, 19,207 patients were transported to our centre by the emergency medical service, including 504 patients with blunt torso trauma. Twenty-three percent (N=114) of all patients with blunt torso trauma underwent TAE. This study population included 15 paediatric and 99 adult patients.

There was not a significant difference between the incident rate of TAE for paediatric and adult patients with blunt torso trauma (29% vs. 22%, *P*=.221; Fig. 1). The median age was 43 (IQR 22–60). Fifty-two percent of all subjects were injured in traffic accidents.

Table 1 presents a comparison of the characteristics and outcome in paediatric and adult patients who underwent TAE for blunt torso trauma. The median age was 11 years old (IQR 7–14) for paediatric patients and 47 years old (IQR 34–64) for adults (*P*<.001). Compared with the adult patients, a higher proportion of paediatric patients were transported from other hospitals (67% vs. 12%, *P*<.001). The median RTS of paediatric patients was higher than adult patients [7.84 (IQR 5.82–24) vs. 6.61 (IQR 5.56–7.55),

$P=.031$]. The predicted mortality rate and SMR for paediatric patients was lower than that for adult patients (18.3% vs. 25.9, $P=.025$, and 0.37 vs. 0.54).

Table 2 presents a comparison of the vital signs and blood-examination upon arrival to the hospital between the paediatric and adult patients. With regard to the hemodynamic stability, there were no differences in the proportion of the patients classified as “non-responder”, “transient-responder”, and “responder”. When compared with adult patients, the median Glasgow Coma Scale was higher [15 (IQR 8–15) vs. 13 (IQR 7–14), $P=.046$], the median haemoglobin was higher [11.9 g/dL (IQR 9.4–11.9) vs. 12.2 (IQR 10.9–13.5), $P=.006$], the median base excess was higher [-0.9 mmol/L (IQR -2.9--0.9) vs. -4.0 (IQR -6.7--1.8), $P=.001$], and the median lactate was lower [2.3 mg/dL (IQR 1.3–3.2) vs. 3.7 (IQR 2.5–5.9), $P=.004$] in paediatric patients. There are no significant differences in the duration of mechanical ventilation/ICU stay/hospital stay (Table 1), the proportion of urgent blood transfusion, time interval from the arrival to blood transfusion, and dosage of blood transfusion (Table 3).

Table 4 presents a summary of 114 patients who underwent TAE. Despite the no differences in time interval from the arrival to IVR, the median time interval from the beginning to the end of IVR was significantly shorter [55 minutes (IQR 43–59) vs. 65 (IQR 51–76), $P=.007$]. With regard to the target region and artery embolized, the proportion of paediatric patients with pelvic region and intra-pelvic artery of embolization was lower (27% vs, 85%, $P<.001$, and 27% vs. 71%, $P=.001$). There were no significant differences in the embolic agents, degree of haemorrhage control, or the proportion of patients with repeated IVR and complication rate. Although no paediatric patient had repeated IVR and complications, two of adult patients underwent repeated IVR, and three patients experienced complications including two major complications (deviation of coil / necrosis of gluteus muscle), and one minor complication (self-limiting puncture site hematomas).

A detailed summary of the 15 paediatric patients who underwent TAE for blunt torso trauma is shown in Table 5. Two paediatric patients who were classified as “non-responder” underwent surgical intervention and/or resuscitative endovascular balloon occlusion before the IVR. Two of the six paediatric patients classified as “transient-responder” underwent surgical intervention before the IVR. One of the paediatric patients classified as “responder” underwent surgical intervention in a different target region of TAE. The proportion of paediatric patients classified as non-effective haemorrhage control (ongoing haemorrhage) after TAE and underwent additional surgical intervention was 7%.

Discussion

This study evaluated the efficacy and safety of TAE for blunt trauma patients at Yokohama City University Medical Centre. Applying the same diagnostic and therapeutic algorithm for blunt torso trauma patients with haemorrhage regardless of age, TAE might be equally effective and safe for paediatric blunt torso trauma in comparison to adult patients.

Since non-operative management has become the standard of care for blunt solid organ injury in children, the incidence of TAE for paediatric patients with blunt abdominal or pelvic trauma varies from 1.4 to 2.1% in previous study [7,8,20,21]. Moreover, there are very few studies on the incidence rate of TAE for blunt torso paediatric patients in comparison to adult patients. In patients with pelvic fracture, the incidence rate of IVR was not significantly different between paediatric and adult patients (2.1% vs. 4.8%) [20]. This study also showed the different results in that the incident rate of TAE for blunt torso trauma patients was higher than those of previous study and similar results in that the incident rate of TAE for blunt torso trauma patients was similar in paediatric and adult patients (29% vs. 22%, $P=0.221$; Fig. 1). The reason why there are big differences in the incident rate of TAE for paediatric patients with torso trauma between this study and

previous studies may be related to the association of the incident rate with varying severity and complexity of injuries in study cohort [7]. However, the number of paediatric patients who underwent TAE was extremely low compared to that of adults in both studies, as the incidence of severe trauma was limited. There were only 15 paediatric patients who underwent TAE during the 6-years study period of the current study. A previous study showed that hospitals with a high-volume of admitted patients and therapeutic experience can provide high-quality of care and lower the mortality rate for severe trauma patients [22]. To improve the outcome of TAE for torso trauma patients with haemorrhage, further centralization of trauma patients might be effective. In this study, the proportion of inter-hospital transportation was 67% of all the paediatric patients who underwent TAE; therefore, an appropriate transport protocol for long-distance or inter-hospital transportation especially for paediatric patients might be effective to centralize treatment for paediatric trauma patients and improve the outcome in a larger number of paediatric patients.

With regard to efficacy in this study, the rate of effective haemorrhage control without repeated TAE or additional surgical intervention was 93% for all paediatric patients, which was similar to that for adult patients (88%). The success rate of TAE was also similar to the results of previous studies that reported 75-100% as the success rate of TAE in paediatric cohorts [8,20,21] and 77-100% in cohorts with both paediatric and adult patients [5,6]. Although we cannot compare the mortality rate directly between the paediatric and adult patients because there are differences in the injury site and severity between two groups, we found that the SMR of paediatric patients was lower than that of adults in this study. These results suggest that trauma centres that do not specialize in paediatrics could provide TAE safely and effectively for both adult and paediatric patients.

There were no complications in paediatric patients, when we used the same diagnostic and therapeutic algorithm for blunt torso trauma patients with haemorrhage for all ages at our centre, which the

complication rate in this study is similar to that reported in previous studies as mentioned 0-7% [4-8]. With regard to additional urgent therapy before and after the TAE, there were no significant differences in the proportion of patients who underwent urgent blood transfusion, resuscitative endovascular balloon occlusion of the aorta (REBOA), or surgical intervention in this study between paediatric and adult patients. Although a previous study reported that few paediatric patients with blunt torso trauma who need the urgent intervention such as blood transfusion or surgical intervention [7,9], our results showed that there were not a few paediatric patients with blunt torso trauma who urgently need alternative haemorrhage control procedures before and after TAE. This result suggests that TAE is not only a tool which improves non-operative management success rates but also bridges the non-operative intervention and operative intervention. Therefore, we should aim to develop a therapeutic system that can provide the additional interventions such as fluid resuscitation by using blood transfusion, repeated TAE, and surgical intervention, for patients of any age any age who are haemodynamically unstable, whether before or after non-operative management.

Limitation

This study has several limitations. First, it is a retrospective analysis conducted at a single centre; thus, issues of a small sample size and selection bias could not be excluded from this study. In addition, we did not include pediatric patients younger than 4 years in this study. Second, we cannot consider the influence of the additional treatments such as blood infusion, REBOA, and surgical intervention, which the patients underwent before or after TAE. Finally, we cannot evaluate the long-term influence of TAE, including radiation-induced malignancies although it has been reported that paediatric patients have a higher risk of radiation-induced malignancies than adults [23]. Therefore, in the future, we intend to conduct additional and detailed studies and multivariate

analysis with a large cohort and longer follow-up duration to complement the limitations of this study.

Conclusions

It is possible to provide an equal level of care related to TAE for paediatric blunt torso trauma with haemorrhage similar to what we do for adults in the trauma centre. Although TAE is an efficient and safe tool for paediatric blunt torso trauma, we should prepare alternative haemorrhage control procedures such as blood transfusion, repeated TAE, and operative management as soon as possible to prepare for patients in hemodynamically unstable states.

List of abbreviations

TAE, transcatheter arterial embolization; YCMTC, Yokohama City Major Trauma Centre; IVR, interventional radiology; RBC, red cell concentrate; FFP, fresh frozen plasma; CT, Computed Tomography; ISS, Injury Severity Score; RTS, revised trauma score; TRISS, trauma and injury severity score; ICU, intensive care unit; SMR, standardised mortality ratio; IQR, interquartile; resuscitative endovascular balloon occlusion of the aorta, REBOA

Declarations

• Ethics approval and consent to participate:

This study was approved by the institutional ethics committees of Yokohama City University Medical Centre, Yokohama Municipal Citizen's Hospital, and National Hospital Organization Yokohama Medical Centre (approval no. B170400020). Requirement of informed consent from the patients was waived due to the observational nature of the study design.

• Consent for publication:

Not applicable.

- **Availability of data and materials:**

The datasets supporting the conclusions of this article are available from the corresponding author on reasonable request.

- **Competing interests:** The authors declare that they have no competing interests.

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- **Authors' contributions:**

C.T., M.G., and M.S. conceptualized and designed this study; M.G., C.T., T.M., N.Y., and M.S. analysed and interpreted the patient data; M.G. and C.T. wrote the manuscript; I.T. and T.M. gave technical support and conceptual advice. All authors read and approved the final manuscript.

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Figures, tables, and additional files

Figure 1. Flow diagram of the study population

Table 1. Characteristics and outcome compared between paediatric and adult trauma patients with transcatheter arterial embolization.

Table 2. Vital sign and blood examination at arrival to the hospital compared between paediatric and adult trauma patients with transcatheter arterial embolization.

Table 3. Blood transfusion during primary trauma care compared between paediatric and adult trauma patients with transcatheter arterial embolization.

Table 4. Summary of intervention radiology compared between paediatric and adult trauma patients with transcatheter arterial embolization.

Table 5. Detailed summary of paediatric patients with transcatheter arterial embolization.