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Combined computed tomography and C-arm resuscitation room system (CTCARM) is associated with decreased time to definitive hemostasis and reduces preperitoneal pelvic packing maneuvers in severe pelvic trauma

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ABSTRACT

Objectives Severe pelvic fracture concomitant with massive bleeding is potentially lethal, and intervention for hemorrhage control still depends on institutional supplies. With the recent installation of a CT and C-arm combined resuscitation room system (CTCARM) for treatment of trauma patients in our institution, the strategic process and options for hemorrhage control after pelvic fracture have changed. We retrospectively reviewed the procedures we performed and their outcomes.

Methods The CTCARM was installed in our trauma resuscitation room in April 2020. Patients who were diagnosed as having pelvic fracture and underwent interventional radiology for hemorrhage control within 2.5 hours after arrival were compared before and after CTCARM installation. We reviewed the time process for hemorrhage control, treatment options performed, blood products used and their outcomes.

Results Included in this study were 56 patients treated between 2016 and 2022, of whom 36 patients were treated before (original group) and 20 patients after CTCARM installation (CTCARM group). Patient characteristics and vital signs at admission were not statistically different. Preperitoneal pelvic packing was performed significantly more frequently in the original group (p<0.01), whereas resuscitative endovascular balloon occlusion of the aorta use was much more frequent in the CTCARM group (p=0.02). Although the times from admission to first angiography (p=0.014) and to complete hemostasis (p=0.02) were significantly shorter in the CTCARM group, mortality was not statistically different. Four preventable trauma deaths occurred in the original group, but there were none in the CTCARM group. Six unexpected survivors were observed in the original group and four in the CTCARM group.

Conclusions Although the CTCARM had no direct effects on patient mortality for now, it has allowed us to accelerate the treatment time process, shorten preperitoneal pelvic packing procedural time, and potentially avoid subsequent preventable trauma deaths.

Level of evidence Level IV.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The resuscitative strategy for severe pelvic fracture concomitant with hemorrhagic shock is still difficult and underdeveloped in each country and institution.

WHAT THIS STUDY ADDS

⇒ Recently, the CT and C-arm combined resuscitation room system (CTCARM), which allows us to perform immediate CT scanning, immediate operation including thoracotomy or laparotomy, was installed in our institution.

⇒ We retrospectively reviewed our time processes for bleeding control, concomitantly performed procedures such as insertion of resuscitative endovascular balloon occlusion of the aorta, the rate of performed preperitoneal pelvic packing, and their outcomes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The CTCARM allowed us to accelerate the treatment time process, shorten preperitoneal pelvic packing procedural time, and potentially avoid subsequent preventable trauma deaths.

BACKGROUND

Massive bleeding associated with severe pelvic fracture is still one of the critical main causes of death, and the strategy for bleeding control is lifesaving.[1–4] One of the recent multi-institutional observational studies organized by the American Association for the Surgery of Trauma reported that the mortality rate of patients with hemorrhagic shock concomitant with severe pelvic fracture reached 32%.[4] Traditionally, the diagnosis of severe pelvic trauma is made during the primary survey of the patient with plain X-ray film,[5–7] but recently, new modalities such as the hybrid emergency room system (HERS) and the CT and C-arm combined resuscitation room system (CTCARM), which allows us to perform immediate CT scanning, immediate operation including thoracotomy or laparotomy, and insertion of resuscitative endovascular balloon occlusion of the aorta (REBOA) under fluoroscopy

Figure 1 Overall view of the CTCARM. The patient resuscitation table is combined with a 64-helical CT scanner and C-arm fluoroscopy (red arrow). This system allows us not only to perform CT scanning but also emergency surgery, including thoracotomy and laparotomy, without transferring the patient. Although C-arm fluoroscopy is not the resolution required for interventional radiology procedures, we can perform essential cannulation of arteries or veins with the guidance of this fluoroscopy system. CTCARM, CT and C-arm combined resuscitation room system.

without patient transfer, offer the potential for innovation of bleeding control strategies, algorithms, and time processes for managing pelvic trauma.[8 9]

Figure 2 (A,B) The pictures of actual REBOA insertion scenes for pelvic trauma patient. And after the placement of REBOA, we rapidly implemented laparotomy on this bed for the concomitant intra-abdominal bleeding without patient transfer. REBOA, resuscitative endovascular balloon occlusion of the aorta.

Furthermore, in this innovative environment, the role and risk–benefit profile of REBOA and preperitoneal pelvic packing (PPP) undergone prior to radical hemorrhage control by interventional radiology (IVR) have also sparked great controversy.[10–12] Currently, the rate that these concomitantly performed procedures are administered mostly depends on institutional resources.[13 14]

As the CTCARM for trauma patients had been in use in our institution for 2 years, we retrospectively reviewed our time processes for bleeding control, concomitantly performed procedures such as insertion of REBOA, the rate of performed PPP, and their outcomes.

MATERIALS AND METHODS

This was a single-center retrospective review of patients admitted to the Trauma and Critical Care Center of Osaka Metropolitan University Hospital, a level 1 urban area trauma center in the third largest city by population in Japan. We reviewed all patients admitted with pelvic trauma during April 2016 through October 2022 who were over 16 years old and included the patients who had blunt pelvic trauma and required IVR procedures within 2.5 hours after arrival for control of bleeding. Pelvic trauma was defined as having any pelvic bone fracture detected by CT scan and coded with the rule of Abbreviated Injury Scale 2005 updated 2018 version as 856100.2 to 856272.3.[15]

We excluded patients whose systolic blood pressure on arrival was <40 mm Hg and also those patients who required immediate thoracotomy and/or laparotomy and/or IVR without CT scanning.

The preventable trauma deaths (PTDs) were defined as the non-survived patients with a probability of survival (Ps) score calculated by the Trauma and Injury Severity Score (TRISS)[16 17] of >0.5. Moreover, the survived patients with a calculated Ps of less than 0.5 are considered as unexpected survivors.

Resuscitation strategy for pelvic trauma

Our resuscitation strategy for pelvic trauma patients is based on the Advanced Trauma Life Support guidelines and basically emphasizes the importance of early administration of blood transfusion. Traditionally, when a trauma patient arrived at the hospital, we evaluated the severe pelvic fracture in the primary survey during the patient's clinical examination mainly by plain X-ray films. If a severe pelvic fracture was suspected on X-ray and the patient was hemodynamically stable, we usually transferred the patient for contrast-enhanced CT scanning, which was located approximately 80 m away from the resuscitation room. If a patient is hemodynamically unstable, a massive transfusion protocol (MTP) including cryoprecipitate can be activated immediately 24 hours/day 365 days/year. Our MTP is based on the current 1:1:1 ratio theory of usage of platelets:fresh frozen plasma (FFP):red blood cells, and packs are constantly brought to the resuscitation room in that ratio of composition. Cryoprecipitate is always prepared in three bottles (FFP 4 units=20 mL/bottle) and if we activate MTP, cryoprecipitate is administered prior to FFP, as it is faster to be thawed. Tranexamic acid was used as defined in CRASH-2 trial for those patients who had detected torso bleeding.[18] We routinely administrate pelvic binders for pelvic ring fracture such as open-book-type pelvic fracture. But as globally noted, we carefully use or hardly use it for lateral compression-type fractures. We also used REBOA, which is also always available and inserted blindly via a common femoral artery. PPP was mostly performed during the waiting time for IVR. In the past, especially before the implementation

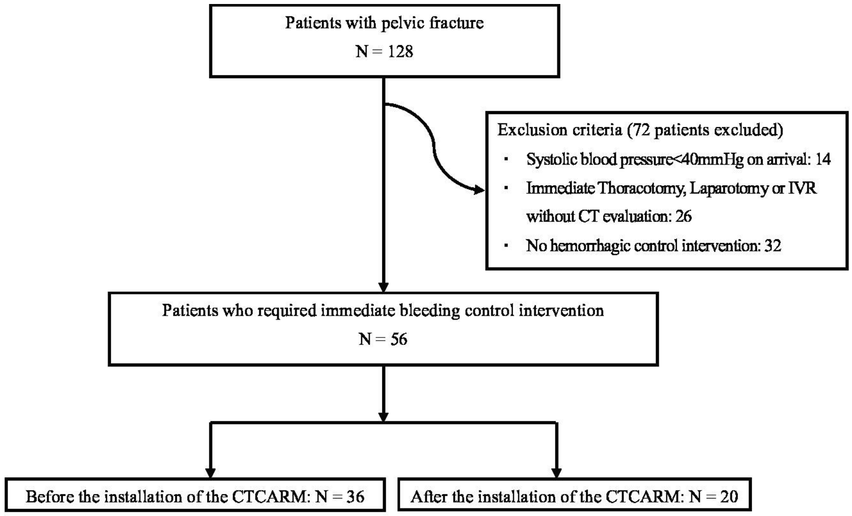

Figure 3 Patient selection. CTCARM, CT and C-arm combined resuscitation room system; IVR, interventional radiology.

of the CTCARM, we preferred to perform PPP as there was available evidence and suggestions that REBOA was potentially associated with increased complications such as acute kidney injury, limb ischemia, and mortality at that time.

After the CTCARM was installed in April 2020 in our trauma resuscitation room (figures 1 and 2), we now seldom use plain X-ray film to screen for pelvic trauma even in the primary survey because an immediate trauma pan-scan CT can be performed without requiring patient transfer. If the patient was hemodynamically unstable, we tended to use REBOA primarily instead of PPP as we could initiate REBOA safely in a short time and place the balloon in the appropriate zone by using C-arm fluoroscopy. For control of radical retroperitoneal bleeding after severe pelvic fracture, IVR is available around the clock in our institution by on-call interventional radiologists. Technically, we could handle guidewire to insert internal iliac artery under fluoroscopy; however, the current C-arm fluoroscopy could not allow us to capture whole high-quality image of terminal aorta to internal iliac artery bifurcation because of the radiation permeability of resuscitation bed combined with CT scan. Hence, we currently do not permit to perform any kind of radical bleeding control under the guide of fluoroscopy because of safety issues.

Furthermore, if the hemodynamics of the patients were not stable enough for performing CT scan, we just took only a scout view which was usually used for locating the CT scan area. The scout view takes approximately less than 1 min and we could get the information whether the patients have unstable pelvic fracture or not. But in this present study, we had excluded these patients as the patients who required immediate thoracotomy and/or laparotomy and/or IVR without CT evaluation.

Table 1 Demographic data of the patients

	Original N=36	CTCARM N=20	P value
Sex, male/female	16/20	9/11	1
Age, years	55 (40–71)	48 (21–65)	0.17
ISS	34 (22–49)	33 (21–38)	0.73
Mechanism of injury			0.57
Motor vehicle accident	12	9	
Fall from height	24	11	
Physiological data on arrival			
GCS	14 (10–15)	12 (10–15)	0.34
RR (breaths per min)	28 (24–30)	30 (20–33)	0.88
HR (beats per min)	120 (112–124)	112 (98–120)	0.07
Systolic blood pressure (mm Hg)	90 (64–104)	76 (40–95)	0.25
Body temperature (°C)	36.1 (35.7–36.5)	35.8 (34.9–36.2)	0.44
Concomitant injury			
Brain injury	8	4	1
Thoracic injury	21	9	0.41
Abdominal injury	7	5	0.74
Bony spinal injury	12	7	1
Extremity fracture	27	11	0.15
Probability of survival	0.83 (0.53–0.97)	0.81 (0.23–0.97)	0.71

Statistical data are presented as median (25–75% IQR) or number.
CTCARM, CT and C-arm combined resuscitation room system; GCS, Glasgow Coma Scale; HR, heart rate; ISS, Injury Severity Score; RR, respiratory rate.

Outcomes evaluation

We reviewed the clinical time process for radical hemorrhage control, compared the performed treatment procedures including PPP and REBOA insertion and blood products used, and evaluated the in-hospital outcomes of the patients with severe pelvic trauma both before and after the installation of the CTCARM. The hemostasis completed time was defined as just the time IVR team confirmed finishing the hemostasis procedure by performing final angiography.

Table 2 Examination results

	Original N=36	CTCARMN=20	P value
Positive extended FAST	8	4	1.00
Base excess	−3.8 (−8.3 to −2.1)	−4.8 (−8.5 to −2.3)	0.81
pH	7.36 (7.26–7.39)	7.35 (7.30–7.38)	0.76
Lactate level (mmol/L)	4.3 (2.7–7.2)	5.3 (2.2–7.5)	0.33
Fibrinogen level (mg/dL)	201 (158–258)	215 (170–269)	0.57
PT-INR	1.09 (1.02–1.16)	1.12 (1.02–1.42)	0.33

Statistical data are presented as median (25–75% IQR).
CTCARM, CT and C-arm combined resuscitation room system; FAST, focused assessment with sonography for trauma; PT-INR, prothrombin time-international normalized ratio.

Table 3 Clinical courses

	Original N=36	CTCARMN=20	P value
Activation of MTP	21	13	0.78
Pelvic binder used	24	16	0.36
Tranexamic acid used	36	20	1.0
Administration of REBOA	9	12	0.02
PPP	16	0	<0.01
Time to start BT (min)	24 (18–44)	22 (16–35)	0.74
Time to initial CT (min)	42 (34–56)	28.5 (18–47)	0.01
Time to first angiography (min)	96 (78.5–153)	72 (57–113)	0.014
Time to complete hemostasis (min)	177 (146–238)	153 (135–177)	0.02
Infused volume of ECF (mL)	5630 (3480–7560)	4780 (2960–8350)	0.74
Total amount of blood transfusion (unit)	32 (6–56)	30 (6–54)	0.49
Cryoprecipitate (FFP 4 units=20 mL/bottle)*	12 (0–12)	12 (0–12)	0.63
RBC (2 units=280 mL)	6 (4–14)	4 (4–12)	0.52
FFP (2 units=240 mL)	4 (2–10)	4 (2–8)	0.85
PC (10 units=200 mL)	10 (0–20)	10 (0–20)	0.79

Statistical data are presented as median (25–75% IQR) or number.
*Cryoprecipitate was administered to only MTP-activated patients.
BT, blood transfusion; CTCARM, CT and C-arm combined resuscitation room system; ECF, external cellular fluid; FFP, fresh frozen plasma; MTP, massive transfusion protocol; PC, platelet concentrate; PPP, preperitoneal pelvic packing; RBC, red blood cell; REBOA, resuscitative endovascular balloon occlusion of the aorta.

Statistical analysis

All statistical data are presented as the median (25% to 75% IQR) or number. Categorical variables were analyzed with Fisher's exact test. Non-parametric numerical data (presented as median with IQR) were compared using the Mann-Whitney U test. A value of $p<0.05$ was considered statistically significant. Data were analyzed using IBM SPSS Statistics, V.22. Moreover, the power analysis for evaluating appropriate sample size for this study was performed with G*power software V.3.1.9.6 (http://www.gpower.hhu.de/).[19]

RESULTS

During the study period, 128 patients were admitted with pelvic fracture after blunt traumatic injury. We excluded 14 patients because their systolic blood pressure was <40 mm Hg, 26 patients who required immediate thoracotomy and/or laparotomy and/or IVR without CT scanning, and 32 patients who did not need IVR for retroperitoneal bleeding. Finally, 56 patients with pelvic ring fracture and who required immediate bleeding control were included, and their clinical results were compared in this study. Thirty-six patients were diagnosed and treated before the installation of the CTCARM (original group), and the remaining 20 patients underwent treatment in the CTCARM (CTCARM group) (figure 3).

The epidemiologic characteristics and initial clinical presentation of the patients before and after installation of the CTCARM are shown in table 1. The median age of the original group versus CTCARM group was 55 (40–71) versus 48 (21–65) years old (p=0.17), and almost 40% of the patients were males in both groups. There were no significant differences between the two groups in terms of the mechanism of injury. The Injury Severity Score was 34 (22–49) versus 33 (21–38) (p=0.73). There were no significant differences in physiological signs such as Glasgow Coma Scale, heart rate, respiratory rate, body temperature, and systolic blood pressure between the two groups. The Ps score calculated with the TRISS between the two groups was also not significantly different (0.83 (0.53–0.97) vs. 0.81 (0.23–0.97); p=0.71).

Table 2 shows the results of the examinations performed at admission. There were no significant differences between the two groups with regard to the results of the extended focused assessment with sonography for trauma, base excess, pH, and lactate level. None of the coagulation-related factors showed a significant difference between the original group and the CTCARM group.

The clinical courses of and the resuscitative procedures performed on the patients prior to IVR are shown in table 3. MTP was activated in 21 (58.3%) versus 13 (65.0%) patients (p=0.78). The number of patients undergoing REBOA and PPP in each group is also shown in table 3. PPP was performed at a significantly higher rate in the original group, but the rate of REBOA administration was significantly higher in the CTCARM group. The time for initial administration of blood products from the patient arrival was not significantly different between the two groups (24 (18–44) vs. 22 (16–35) min; p=0.74).

The approximate time required to initial CT scan after admission was 42 (34–56) min in the original group and 28.5 (18–47) min in the CTCARM group (p=0.01). Time from admission to first angiography was 96 (78.5–153) versus 72 (57–113) min for the two groups (p=0.014) and also time from admission to complete hemostasis time was also significantly shortened (177 (146–238) vs. 153 (135–177) min; p=0.02). There were also no significant differences in the volume of external cellular fluid infused in the initial 24 hours after admission (5630 (3480–7560) vs. 4780 (2960–8350) mL; p=0.74). The total amount of blood transfused within 24 hours after admission was also not significantly different between the two groups (32 (6–56) vs. 30 (6–54) units; p=0.49).

Four PTDs occurred in the original group (table 4), but none occurred in the CTCARM group. Six unexpected survivors were observed in the original group, whereas there were four in the CTCARM group. In-hospital mortality was not statistically different between the two groups (19.4% vs. 10.0%; p=0.47) (table 5).

DISCUSSION

Pelvic ring fracture with severe hemorrhagic shock remains a lethal condition, and its mortality is still reported to be up to 30% to 40%,[1–4] even in the analysis of a databank in a developed country (USA).[20] Although several globally known practice guidelines and several studies have described the best practice management for bleeding control of retroperitoneal bleeding secondary to severe pelvic fracture as a combination using PPP, REBOA, and IVR,[21–23] there are currently no strong guidelines or recommendations with regard to bleeding control strategies for pelvic trauma

Table 4 Description of the patients who had scored as potentially preventable trauma deaths

Patients	Age (years)/ sex	Accident type	Status during transport	Accident to physician contact time (min)	Status on arrival	FAST	ISS	Ps on arrival	Time to BT if performed (min)	Time to CT if performed (min)	Time to IVR if performed (min)	Diagnosis	Course after physician contact (hours later after arrival)	Considerable problems	Cause of death
1	44/F	Fall	Airway open RR 20 bpm HR 100 bpm Radial Pulseless GCS 10	29	Airway open RR 36 bpm HR 110 bpm BP 110/77 GCS 10	Negative	48	70.9	12	30	56	Blunt thoracic aortic injury (grade III), lung contusion, multiple rib fractures, renal injury, pelvic ring fracture, femoral fracture	0:17 intubation 0:30 cardiac arrest during transfer to CT 0:40 ERT/PPP 06:00 dead	Transfer for diagnosis	Bleeding
2	79/F	TA	Airway open RR 20 bpm HR 100 bpm BP 134/90 GCS 10	21	Airway open RR 30 bpm HR 122 bpm BP 96/67 GCS 13	Negative	29	81.6	23	40	116	Traumatic SAH, pelvic ring fracture, humerus fracture	0:15 intubation 0:40 BP fell <50 mm Hg during transferring from CT 0:60 ERT/ PPP 14:00 dead	Transfer for diagnosis	Bleeding, brain edema
3	42/F	TA	Airway open RR 40 bpm HR 117 bpm BP 112/70 GCS 8	30	Airway open RR 30 bpm HR 124 bpm BP 119/84 GCS 9	Negative	57	66.5	18	25	70	Traumatic SAH, acute epidural hemorrhage, brain contusion, multiple rib fractures, lung contusion, hemothorax, pelvic ring fracture	0:16 intubation 0:16 tube thoracostomy 0:30 BP fell <70 mm Hg during CT scan 0:40 PPP 08:00 craniotomy 22:00 dead	Delay in recognizing hemodynamics during CT scan	Bleeding, brain edema
4	86/F	TA	Airway open RR 40 bpm HR 90 bpm BP 143/81 GCS 8 Anisocoria+	24	Airway open RR 27 bpm HR 71 bpm BP 91/58 GCS 13	Negative	57	70.1	12	25	76	Traumatic SAH, brain contusion, hemopneumothorax, multiple rib fractures, lung contusion, pelvic ring fracture, humerus fracture, femoral fracture	0:10 intubation 0:11 tube thoracostomy 0:40 BP fell <70 mm Hg during CT scan 0:45 PPP 42:00 dead	Delay in recognizing hemodynamics during CT scan	Bleeding, brain edema

BP, blood pressure; bpm, breaths per minute; bpm, beats per minute; BT, blood transfusion; ERT, emergency resuscitative thoracotomy; F, female; FAST, focused assessment with sonography for trauma; GCS, Glasgow Coma Scale; HR, heart rate; ISS, Injury Severity Score; IVR, interventional radiology; PPP, preperitoneal pelvic packing; Ps, probability of survival; RR, respiratory rate; SAH, subarachnoid hemorrhage; TA, traffic accident.

Table 5 In-hospital outcomes

	Original N=36	CTCARMN=20	P value
Survival	29 (19.4%)	18 (10.0%)	0.47
Unexpected survivor (Ps <0.5)	6	4	0.73
Preventable trauma death (Ps >0.5)	4	0	0.28

Statistical data are presented as median (25–75% IQR) or number.
CTCARM, CT and C-arm combined resuscitation room system; Ps, probability of survival.

especially from the viewpoints of the superiority of using REBOA or performing PPP. In the real world, the retroperitoneal hemorrhage control strategies practiced after pelvic fracture and temporary bleeding control prior to IVR mostly depend on institutional resources and the availability of supplies and human personnel.[13 14 24]

For the past decades, the trauma pan-scan CT for hemodynamically unstable patients were warned because of the risk of transfer for the patient, delaying the resuscitation,[5] and plain X-ray film acquired during the primary survey of the patient was the first-priority recommendation when screening for pelvic fracture.[6 7] Recently, however, as brand-new concepts such as HERS and the CTCARM were developed, the utility and potential of these systems to decrease the mortality of severe trauma patients, and especially those in a hemodynamically unstable condition, have been reported,[8 9 13 25 26] primarily because these systems allow immediate CT diagnosis and rapid bleeding control without patient transfer.[8] Although there has been only one study that described about the quality-adjusted life years-analyzed outcomes of HERS,[27] the cost for initial installation of HERS is extortionate amount of money. On the other hand, the CTCARM costs almost one-tenth lower than HERS. It costed us approximately $315 500 ($1=135 Japanese yen) for installing in our institution.

In the present study, the CTCARM contributed not only to decreasing the time from admission to CT scan and time to IVR but also potentially reduced the number of PTDs. Likely, this was due to PTD observed in the original group being mostly related to the patient transfer process or misreading of the radiological findings in the primary survey. Therefore, we assume that CTCARM has worked well as it has minimized the risk of patient transfer and permitted us to diagnose with greater accuracy and much more confidence.

We had also considered that the results were potentially affected by some other factors. However, the other considerable factors such as the time for administration of MTP from the patient arrival and the used units of total blood products, usage proportion of fast flow fluid warmer and so on were not different between the two periods. Furthermore, the faculty members of trauma unit were not changed between the two periods. The only considerable change was that we tend to use REBOA instead of PPP after the installation of the CTCARM. But even this change was also the impact secondary to the installation of CTCARM because we could insert REBOA under the guide of fluoroscopy. Fluoroscopy also helped us to make sure placing REBOA at zone 3. Although we sometimes had to place the REBOA at zone 1 especially in hemodynamically unstable patients, but for those patients, we could adjust the zone as soon as possible under the fluoroscopy. Furthermore, we also recognized the use of partial inflation REBOA to minimize the risk of distal organ or limb ischemia with careful hemodynamics monitoring of the patients. As is well-known, every minute in the delay of definitive bleeding control increases the mortality of patients with severe pelvic fracture,[28 29] and thus, prompt management and omission of unnecessary procedures are mandatory to save these patients. Although IVR team is available 24/7, the required time of angiographer's arrival to the hospital could not be shorten dramatically especially in the midnight or weekend. Hence, in this current study, the time from admission to first angiography had been shortened only about 20 min, but still it had significant difference. Furthermore, as we can now safely and rapidly place REBOA under the guidance of C-arm fluoroscopy after the installation of the CTCARM with minimal wasting of time, we tend to perform PPP less and less prior to radical hemorrhage control by IVR. We consider this to be one of the factors related to the statistically shorter process time from patient admission to IVR in the CTCARM group compared with the original group.

Lastly, the sample size power calculation with two-tailed t-test suggested that a sample of at least 110 participants in each group had 95% power to detect a 20% effect with a significance level of 5% (α). However, as this size was not able to be obtained in a single-center study, we performed post hoc power analysis which showed the power of our study using the existing number of patients assessed at 0.40.

Limitations

As this is a single-center retrospective study, there is no institutional bias or differences in the data caused by human biases. To provide stronger evidence of the benefits of a CTCARM, prospective randomized surveys with larger numbers of patients are needed to evaluate the impact of CTCARM or concomitant procedures for hemorrhage control and assess outcomes of the patients with severe pelvic trauma on the basis of this study.

CONCLUSIONS

Although the CTCARM had no direct effects on mortality or decreasing the volume of blood products used for managing patients with severe pelvic fracture, it has allowed us to accelerate the treatment time process, shorten PPP procedural time, and potentially avoid subsequent PTD.

Contributors KU organized and coordinated the study design and wrote the initial draft of this article. And KU is responsible for the overall content as guarantor. KU, RD, HH, HYo, YS and TN contributed to data cleaning and interpretation of the data. HYa and YM reviewed and revised the article. All authors read and approved the final article.

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Competing interests None declared.

Patient consent for publication Obtained.

Ethics approval This study involves human participants and the institutional review board of Osaka Metropolitan University approved this study (approval number 2022-183). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Due to the nature of this study and to protect the identity of each patient, our institutional review board agree for the data to be shared. Hence, the data and materials with

regard to this study are available upon reasonable request. The materials and methods used are described in the manuscript.

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