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Effectiveness of pelvic circumferential compression device for lower body trauma: Insights from a Japan Trauma Data Bank retrospective study

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Abstract

Aim: Pelvic ring fractures (PRFs) due to high-energy trauma often result in severe bleeding and high mortality. Pelvic circumferential compression devices (PCCD) are widely used to stabilize PRF and decrease bleeding. However, evidence supporting their effectiveness is still inconclusive.

Methods: We conducted an observational study using the Japan Trauma Data Bank (JTDB) from 2019 to 2021. Patients with blunt lower body trauma aged 15 years or older were included. We used propensity score matching (PSM) and inverse probability of treatment weighting (IPTW) to evaluate the association of PCCD and mortality.

Results: Of the 74,393 patients in the database, 235 PCCD group and 23,429 control group were analyzed. After PSM, 231 patients in both groups were enrolled. Crude analysis indicated significantly higher in-hospital mortality in the PCCD group (odds ratio (OR) = 3.8 [95% CI = 2.51–5.75]). However, PSM and IPTW analysis indicated that PCCD was associated with decreased in-hospital mortality (PSM: OR = 0.79 [0.43–1.42]; IPTW: OR = 0.73 [0.62–0.86]). In a subgroup analysis of the IPTW analysis, PCCD fitting resulted in increased in-hospital mortality in the group without PRF (OR = 2.08 [1.91–2.27]), a decrease in stable PRF (OR = 0.74 [0.6–0.91]), and a further decrease in unstable PRF (OR = 0.18 [0.12–0.27]). Additional factors, such as a fall from a height, a fall downstairs, and pre-hospital PCCD placement also influenced the treatment effect.

Conclusion: The present, large, registry-based study found that PCCD reduced mortality in patients with a lower body injury, especially those with an unstable PRF.

KEYWORDS
high-energy trauma, pelvic circumferential compression devices, pelvic ring fracture

INTRODUCTION

Pelvic ring fractures (PRF), caused by high-energy trauma, such as a fall from a height or a motor vehicle accident, often involve hemodynamic instability due to pelvic artery bleeding and are associated with a high mortality.[1–6] In recent years, the mortality among patients with PRF has decreased partly due to the increased use of pelvic circumferential compression devices (PCCD).[7] The PCCD are easier, faster, and noninvasive devices compared to the conventional pelvic clamp.[8–10] PCCD were found to be effective in stabilizing the pelvic ring and reducing the pelvic volume in experimental studies using cadavers.[11–13]

A large, observational study demonstrated clinical evidence of a reduction in transfusion volume and length of hospital stay.[14] Similarly, several, observational studies

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have demonstrated a reduction in the transfusion requirement,[15–17] pelvic volume,[16] and length of hospital stay[14–16] while other observational studies found no improvement in these endpoints.[18,19] Nonetheless, because the PCCD are able to control bleeding effectively, many guidelines recommend its early placement despite the low quality of supporting evidence.[20–23]

However, there are serious problems with these studies. First, many of the studies either did not assess or improve the mortality.[14,18,19,24] Thus, the EAST guideline[21] stated that PCCD would limit pelvic bleeding but could not reduce the mortality (level III recommendation). Second, the population of previous studies were often with an unstable PRF, which could not be diagnosed often in the prehospital setting.[25] We therefore evaluated whether PCCD placement improved mortality in a demographically more diverse patient population with PRF registered in a large database.

METHODS

Design and setting

The present, retrospective, observational study was conducted using the Japan Trauma Data Bank (JTDB), a large registry established in 2003 by the Japanese Association for The Surgery of Trauma (JAST) and the Japanese Association for Acute Medicine (JAAM) to improve and ensure the quality of trauma care in Japan. In 2023, 303 hospitals in Japan submitted data on 74,393 patients to the JTDB. The present study used patient data from January 2019 to December 2021 shortly after the launch of the JTDB. The study protocol was approved by the ethics committee of Tokyo Metropolitan Tama General Medical Center. The study's findings have been reported in accordance with the STROBE.

Patients

Patients in the JTDB who were aged 15 years or older were included. The exclusion criteria were burns, sharp trauma, pre-hospital transfer to another hospital, and incomplete data. Lower body injuries were also excluded because the JTDB includes minor, isolated, upper extremity injuries which do not necessarily require PCCD placement. The intervention group were defined as patients with PCCD placement in an ambulance or after arrival at the hospital. The control group consisted of all the other patients.

Data collection

The following patient information was collected: age, sex, injury mechanism, emergency medical service vehicle ("doctor car") use, treatment in an ambulance (infusion, cardiopulmonary resuscitation, PCCD), treatment after hospital arrival (PCCD, internal or external fixation, transcatheter arterial embolization, surgery for a condition other than PRF), Glasgow coma scale (GCS), systolic blood pressure (sBP), heart rate (HR), respiratory rate (HR), respiratory rate (RR), Abbreviated Injury Scale (AIS) score, Injury Severity Score (ISS), Revised Trauma Score (RTS), Trauma and Injury Severity Score (TRISS), PRF classification according to JAST, survival time in days, blood transfusion volume, ICU stay, hospital stay, and duration of ventilator use in days. ER mortality, 7-day mortality, and 28-day mortality were calculated based on the length of survival in days, and ICU-free days (ICU-FD), hospital-free days (HFD), and ventilator-free days (VFD) were calculated by subtracting 28 from the number of days for ICU stay, hospital stay, and ventilator use. These numbers were set to 0 days if the patient died during hospitalization. The variables were categorized as follows: median age, TRISS 0.5, RR 30, and sBP 90, ISS 3–14, 15–24, 25–34, and 35 or higher; and GCS 3–7, 8–12, and 13–15. PRF were classified as stable (JTA Class 1) or rotationally or vertically unstable (JTA Class 2 and 3).

Statistical analysis

Continuous variables were expressed as the mean ± standard deviation (SD) or the median with the interquartile range (IQR). Continuous variables were compared using Welch's *t*-test, and categorical variables were expressed as a number and a percentage and were compared using the Chi-squared test with Yates's continuity correction. The extent to which PCCD placement improved the patient outcomes was assessed; ER mortality, 7-day mortality, 28-day mortality, and in-hospital mortality were chosen as the primary endpoints, and red cell concentrate transfusion, VFD, ICU-FD, and HFD were chosen as the secondary endpoints. To reduce bias and make fair comparisons between patients who received PCCD and those who did not, we used propensity scoring. This statistical technique estimates the probability of receiving PCCD based on various patient characteristics (age, sex, injury mechanism, infusion, CPR in the ambulance, contact with a physician in a doctor car, GCS, RR, and sBP) using a logistic regression model. This helps to create a balanced comparison between the two groups. A crude analysis and propensity score matching (PSM) analysis were first conducted using a caliper width equal to 0.2 of the standard deviation of the logit propensity score. After matching, we used inverse probability of treatment weighting (IPTW) to further adjust for differences between the groups. This method weights patients based on their propensity scores to create a synthetic sample in which the distribution of measured baseline covariates is independent of treatment assignment. This helps to mimic a randomized controlled trial. We also adjusted for severity scores that were available only after hospital arrival to account for patient severity. The effect of the intervention on IPTW analysis was evaluated using coefficients of regression analysis. These analyses were stratified by the class of PRF and other patient characteristics to identify any effect

modifiers. A Kaplan–Meier (KM) curve was drawn for each analysis and the mortality trend was evaluated. The KM curves were stratified by PRF severity. A complete case analysis was performed utilizing only the cases without incomplete data. Multiple imputation utilizing the predictive mean matching (PMM) method was used to address missing values for sensitivity analysis. Twenty datasets were generated, and 50 iterations of the imputation process were conducted. Two-sided $p < 0.05$ was considered to indicate statistical significance. R4.3.1 was used for the analyses.

RESULTS

In total, 74,393 patient records from 2018 to 2021 were available; of these, records of 235 patients with PCCD and 23,429 control subjects were included for analysis (Figure 1). Propensity scores were then calculated and matched to caliper 0.2. After PSM, 234 eligible patients in each group were analyzed. Figures S1 and S2 show the receiver operating characteristics (ROC) curves of the propensity scores and the histograms before and after matching. The IPTW analysis increased the number of patients to 17,691 in the treatment group and 23,667 in the control group. Table 1 shows the patient background of each group. The standard mean difference of the variables used for the propensity scores except injury mechanism and HR were equal to or <0.2.

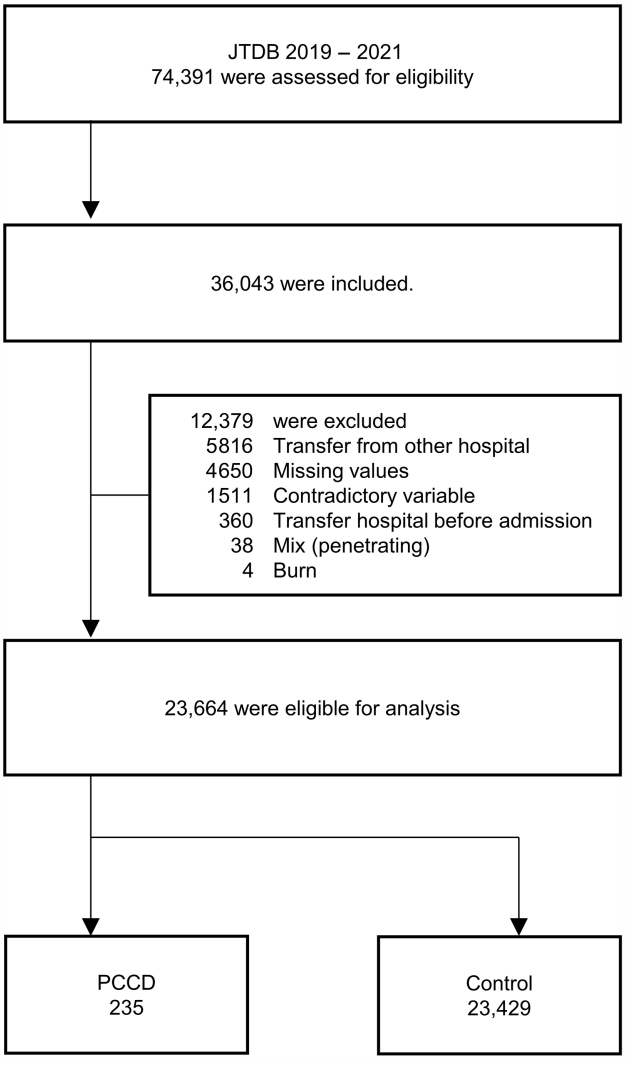

FIGURE 1 Flowchart of patient eligibility. JTDB, Japan Trauma Data Bank; PCCD, Pelvic circumferential compression device.

Table 2 showed the primary outcomes. The odds ratio of in-hospital mortality with PCCD placement was significantly higher on crude analysis (OR = 3.8 [95% confidence interval (CI): 2.51–5.75], $p < 0.001$), non-significant on PSM analysis (OR = 0.79 [0.43–1.42], $p = 0.4$), and significantly lower on IPTW analysis (OR = 0.73 [0.62–0.86], $p < 0.001$). Also, a similar trend was observed for ER mortality (crude analysis: OR = 3.8 [2.51–5.75], $p < 0.001$; PSM analysis, OR = 0.79 [0.43–1.42], $p = 0.4$; IPTW analysis, OR = 0.73 [0.62–0.86], $p < 0.001$), 7-day mortality (crude analysis: OR = 4.14 [2.87–5.96], $p < 0.001$; PSM analysis: OR = 0.94 [0.55–1.6], $p = 0.8$; IPTW analysis: OR = 0.81 [0.7–0.93], $p = 0.004$) and 28-day mortality (crude analysis: OR = 3.86 [2.71–5.49], $p < 0.001$; PSM analysis: OR = 0.91 [0.54–1.53], $p = 0.71$; IPTW analysis: OR = 0.82 [0.71–0.94], $p = 0.004$).

Table 3 showed the secondary outcomes. PSM analysis showed few complications such as pelvic organ damage, PTSD, and pressure ulcer damage in both groups, while the IPTW analysis showed a fewer trend of these complications in the PCCD group. More red cell concentrate transfusions and fewer, ICU-free days were observed in the PCCD group, but these differences were reduced on PSM and IPTW analysis. Crude analysis demonstrated more invasive mechanical ventilator use and fewer, ventilator-free days in the PCCD group, but these results were the opposite of those observed on PSM and IPTW analysis.

We conducted several subgroup analyses (Figure 2). Crude analysis demonstrated a higher probability of survival in the PCCD group than in the control group, but this was the opposite of the result obtained with PSM analysis. On the stratified IPTW analysis, PCCD increased the probability of survival to a greater degree in patients with a PRF than in those with no PRF as well as in those with an unstable PRF than in those with a stable PRF. Figure 3 showed the primary outcomes of IPTW stratified by pelvic fracture severity. The odds ratios increased in patients without a PRF but significantly improved in those with a stable pelvic fracture and those with an unstable pelvic fracture in increasing order. Stratification was also performed using other patient characteristics to explore effect modifiers (Figures S3–S6). A fall from a height or downstairs and pre-hospital PCCD placement had a lower odds ratio. There was no consistent trend in the patient baseline, such as in sex, age, severity as assessed with TRISS, RTS or ISS, vital signs, impaired consciousness or treatment after arrival to the hospital, including TAE and pelvic fixation. The multiple imputation performed as a sensitivity analysis showed similar results to the main analysis (Table S1, Figures S7 and S8).

TABLE 1 Patient characteristics.

	Crude analysis			PSM analysis			IPTW analysis		
	Control	PCCD		Control	PCCD		Control	PCCD	
	N = 23,429	*N* = 235	SMD	*N* = 231	*N* = 231	SMD	*N* = 23,667	*N* = 17,691	SMD
Patient characteristics									
Age, years	67 (22.4)	54 (23.1)	0.601	52 (21.5)	54 (23.2)	0.061	67 (22.5)	58 (24.5)	0.39
Female sex, (%)	12,088 (51.6)	87 (37.0)	0.297	81 (35.1)	86 (37.2)	0.045	12,180 (51.5)	5399 (30.5)	0.436
Length of hospital stay, days	21 [12, 33]	27 [11, 50]	0.246	27 [7, 46.5]	27 [11, 50]	0.066	21 [12, 33]	23 [11.6, 37]	0.053
RCC transfusion, units	0.00 [0.00, 0.00]	0.69 [0, 2.30]	0.978	0 [0, 1.39]	0.69 [0, 2.3]	0.471	0.00 [0.00, 0.00]	0 [0, 0.7]	0.369
Vital signs									
Systolic blood pressure, mmHg	138 (38.7)	109 (50)	0.652	111 (50.8)	110 (49.9)	0.023	137 (38.9)	131 (44.4)	0.155
Heart rate/min	83 (23.0)	88 (34)	0.175	83 (37.4)	87 (34.2)	0.133	83 (23.2)	79 (25.2)	0.152
Respiratory rate/min	20 (7.3)	22 (11.9)	0.226	21 (11.2)	22 (11.9)	0.111	20 (7.3)	21 (9.0)	0.042
Glasgow coma scale	15 [14, 15]	14 [9.50, 15]	0.556	14 [8.5, 15]	14 [10, 15]	0.044	15 [14, 15]	15 [14, 15]	0.162
Score									
Revised trauma score	7.84 [7.84, 7.84]	7.55 [5.81, 7.84]	0.557	7.84 [5.97, 7.84]	7.55 [5.97, 7.84]	0.019	7.84 [7.84, 7.84]	7.84 [7.55, 7.84]	0.182
Injury severity score	9 [9, 14]	24 [16, 37]	1.06	22 [10, 33]	24 [16, 35.50]	0.143	9 [9, 16]	16 [9, 24]	0.443
Trauma and injury severity score	0.97 [0.96, 0.98]	0.92 [0.58, 0.98]	0.671	0.95 [0.56, 0.98]	0.92 [0.59, 0.98]	0.013	0.97 [0.96, 0.98]	0.97 [0.91, 0.98]	0.232
Mechanism, *n* (%)									
Motor vehicle accident	7562 (32.3)	138 (58.7)	0.968	147 (63.6)	135 (58.4)	0.137	7707 (32.6)	7482 (42.3)	0.575
Fall downstairs	2242 (9.6)	22 (9.4)		22 (9.5)	22 (9.5)		2261 (9.6)	1845 (10.4)	
Fall from height	2177 (9.3)	51 (21.7)		38 (16.5)	50 (21.6)		2220 (9.4)	4092 (23.1)	
Others	11,448 (48.9)	24 (10.2)		24 (10.4)	24 (10.4)		11,479 (48.5)	4273 (24.2)	
Class of pelvic ring fracture, *n* (%)									
Non-fracture	20,657 (88.2)	107 (45.5)	1.033	103 (44.6)	107 (46.3)	0.079	20,764 (87.7)	14,464 (81.8)	0.167
Stable fracture	2052 (8.8)	67 (28.5)		66 (26.8)	66 (28.6)		2120 (9)	2318 (13.1)	
Unstable fracture	720 (3.1)	61 (26.0)		66 (28.6)	58 (25.1)		784 (3.3)	910 (5.1)	
Treatment, *n* (%)									
Infusion in ambulance	1437 (6.1)	68 (28.9)	0.629	59 (25.5)	64 (27.7)	0.049	1508 (6.4)	2330 (13.2)	0.23
Cardiopulmonary resuscitation in ambulance	407 (1.7)	11 (4.7)	0.168	15 (6.5)	11 (4.8)	0.075	421 (1.8)	510 (2.9)	0.073
Doctor car	6674 (28.5)	106 (45.1)	0.35	109 (47.2)	105 (45.5)	0.035	6785 (28.7)	7199 (40.7)	0.255
Surgery other than pelvic surgery	3419 (14.6)	77 (32.8)	0.438	65 (28.1)	75 (32.5)	0.094	3491 (14.8)	2596 (14.7)	0.002
Pelvic fixation	993 (4.2)	60 (25.5)	0.627	37 (16)	59 (25.5)	0.236	1037 (4.4)	1546 (8.7)	0.177
Transcatheter arterial embolization	205 (0.9)	33 (14.0)	0.518	12 (5.2)	32 (13.9)	0.298	218 (0.9)	775 (4.4)	0.217
PCCD placement in ambulance	0 (0.0)	134 (57.0)	1.629	0 (0.0)	133 (57.6)	1.648	0.0 (0.0)	13,775 (77.9)	2.652

Abbreviations: IPTW, Inverse probability of treatment weighting; PCCD, Pelvic circumferential compression devices; PSM, Propensity score matching; SMD, Standardized mean difference.

TABLE 2 Primary outcomes.

	Crude analysis		PSM analysis		IPTW analysis*	
Outcome	**Odds ratio [95% CI]**	***p* Value**	**Odds ratio [95% CI]**	***p* Value**	**Odds ratio [95% CI]**	***p* Value**
ER mortality	3.8 [2.51–5.75]	<0.001	0.79 [0.43–1.42]	0.4	0.73 [0.62–0.86]	<0.001
7-day mortality	4.14 [2.87–5.96]	<0.001	0.94 [0.55–1.6]	0.8	0.81 [0.7–0.93]	0.004
28-day mortality	3.86 [2.71–5.49]	<0.001	0.91 [0.54–1.53]	0.71	0.82 [0.71–0.94]	0.004
In-hospital mortality	3.5 [2.46–4.97]	<0.001	0.89 [0.53–1.48]	0.62	0.66 [0.58–0.75]	<0.001

Abbreviations: IPTW, Inverse probability of treatment weighting adjusted by Trauma and Injury Severity Score; PSM, Propensity score matching.

TABLE 3 Secondary outcomes.

	Crude analysis		PSM analysis		IPTW analysis	
Outcome	**Estimate [95% CI]**	***p* Value**	**Estimate [95% CI]**	***p* Value**	**Estimate [95% CI]**	***p* Value**
Categorical variables, odds ratio						
Invasive mechanical ventilation	5.22 [4 to 6.81]	<0.001	0.98 [0.66 to 1.46]	0.92	0.97 [0.9 to 1.05]	0.47
Organ injury	3.45 [0.47 to 25.42]	0.22	∞ [0.03 to ∞]	1.0	0.12 [0.04 to 0.37]	<0.001
PTSD	2.27 [0.31 to 16.55]	0.42	0 [0 to 0]	0	0.09 [0.03 to 0.27]	<0.001
Pressure sore injury	0 [0 to ∞]	N/A	0 [0 to 5.32]	0.5	0 [0 to ∞]	N/A
Continuous variables, absolute differences						
Red cell concentrate transfusion, units	6.27 [4.78 to 7.75]	<0.001	3.77 [2.06 to 5.49]	<0.001	1.2 [1.04 to 1.36]	<0.001
ICU-free days, days	−5.88 [−7.19 to −4.58]	<0.001	−0.02 [−1.98 to 1.93]	0.98	−0.73 [−0.85 to −0.61]	<0.001
Ventilator-free days, days	−4.16 [−5.51 to −2.81]	<0.001	0.86 [−1.13 to 2.85]	0.39	0.4 [0.29 to 0.51]	<0.001
Hospital-free days, days	−3.79 [−4.76 to −2.82]	<0.001	−0.38 [−1.81 to 1.05]	0.61	−1.13 [−1.35 to −0.92]	<0.001

Abbreviations: PSM, Propensity score matching; IPTW, Inverse probability of treatment weighting adjusted by Trauma and Injury Severity Score; N/A, not available.

DISCUSSION

The present study was the first to utilize a large registry to examine the efficacy of PCCD. Mortality in the PCCD group demonstrated a lower trend on propensity score matching analysis and a significantly lower trend on IPTW analysis than in the control group (Table 2). Sensitivity analysis by multiple imputation for missing data demonstrated a similar trend although fewer outcomes were found to be statistically significant (Table S1), indicating a high level of robustness of this study. Propensity scores are generally created using only information available before the intervention is implemented. Therefore, we did not use RTS, ISS, and TRISS for the propensity score, but these SMDs were unbalanced in both groups (Table 1). This means that the propensity score could not adjust for patient severity. Given these results and the patient backgrounds shown in Table 1, it can be seen that the propensity score failed to adjust adequately for patient severity, and that adjusting for confounders was needed in IPTW analysis.

All the guidelines[20–23] were based on the results of these observational studies of small sample sizes. Although many previous studies[8–17] concluded that PCCD was effective, no studies found any improvement in hard outcomes, such as mortality, possibly due to the small sample sizes and correspondingly lower power of detection. Therefore, the EAST guidelines[21] noted that "PCCD reduces blood transfusion but may not affect mortality." On the other hand, the present study had the largest sample size to date and produced two, novel findings. First, PCCD decreased the mortality on IPTW analysis, which was a more appropriate method of evaluating causal inferences.[26,27] Although the ROC for the propensity score were high, they were insufficient to adjust for severity, and the standardized mean differences for TRISS and PRF severity between the two groups was greater than 0.2. IPTW analysis demonstrated decreased mortality for the PCCD group, including the results of sensitivity analysis, keeping the large sample size. Previous studies[8–17] recommended PCCD based on improvements in surrogate markers of mortality. The results of the present study were in line with these findings and strengthened the scientific evidence for recommending PCCD. Second, this study identified effect modifiers. Previous studies had differing eligibility criteria, and these discrepancies made it difficult to identify the patient population for whom PCCD was effective. None of the guidelines describe patient findings or the timing of PCCD placement. The lack of clarity in the recommendations might confuse clinicians and lead to inappropriate PCCD use. As well, there were concerns that PCCD placement might cause pressure sores or excessive bleeding in PRF.

The present study included patients with some lower body trauma, including PRF; the population was more diverse in this sense than those of previous studies. However, PCCD were also used in patients without PRF. Subgroup analysis demonstrated that the treatment efficacy increased with increasing PRF severity (Figure 3). On the other hand, the mortality among patients with no PRF was higher in the PCCD group possibly due to insufficient adjustment

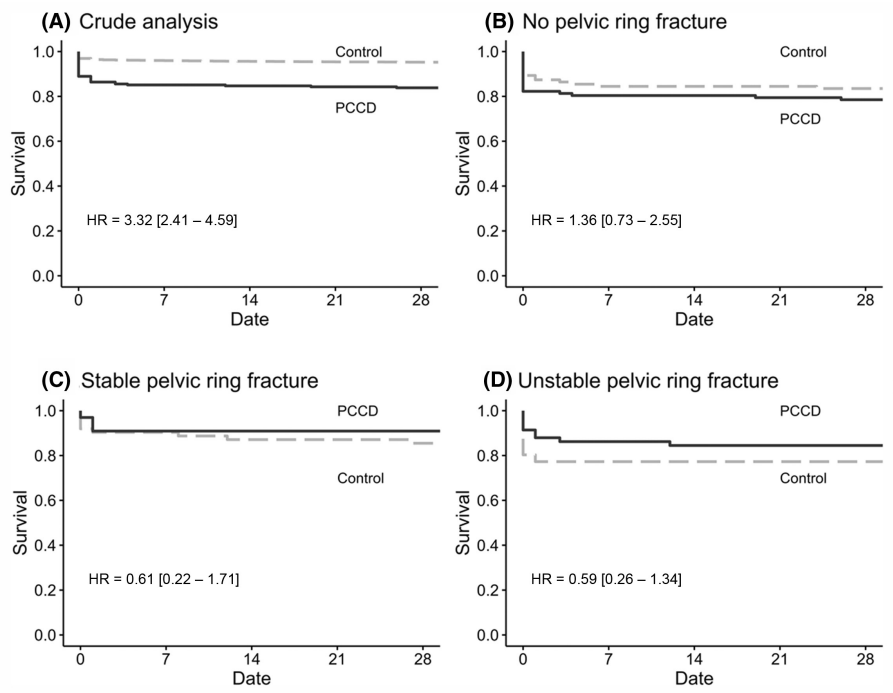

FIGURE 2 Kaplan–Meier curve of crude analysis (A), propensity score matching analysis of no pelvic ring fracture (B), propensity score matching analysis of stable pelvic ring fracture (C) and propensity score matching analysis of unstable pelvic ring fracture (D). PCCD, Pelvic circumferential compression device.

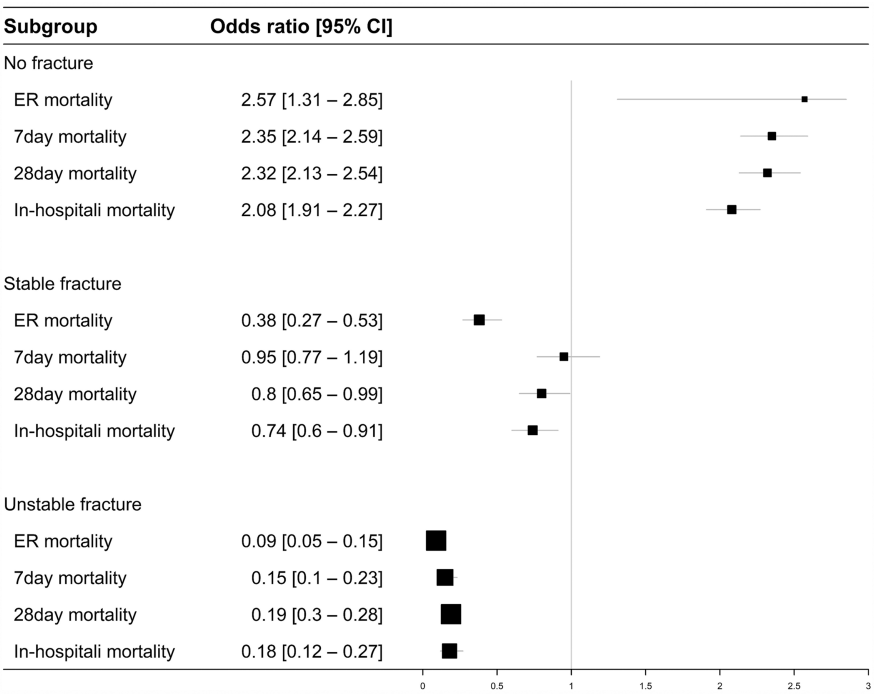

FIGURE 3 Forest plot of subgroup analysis of inverse probability of treatment weighting analysis. HR, Hazard ratio on COX hazard model; PCCD, Pelvic circumferential compression device.

for trauma severity. Other effect modifiers, including the mechanism of fall injuries, injury severity in terms of vital signs, consciousness status, and pre-hospital PCCD placement, were also identified (Figures S3–S6). According to these results, the greatest benefit may be achieved by placing PCCD as early as possible (Table S2) in patients with unstable pelvic fractures, shock vitals (RR > 30/min, sBP < 90 mmHg), and falls (from stairs or height). These results were logically reasonable for the patient population for whom PCCD is effective. In addition, PCCD was less effective in patients with impaired consciousness. In the presence of impaired consciousness, the diagnosis of PRF may be more difficult, and furthermore, the primary factor of prognosis may not necessarily be PRF. Based on our findings, prospective studies should be conducted to confirm the effectiveness of PCCD in these target populations.

In addition to the biases due to observational studies, the present study had two limitations. First, PCCD placement did not demonstrate a reduction in transfusion volume, which can be considered a surrogate marker of mortality. The quality of the other treatment might have been better in the PCCD group than in the control group. Second, there was no information on the types of PCCD or the method of their placement. PCCD would be used inappropriately to be ineffective.

CONCLUSION

The present study used a large database to evaluate the effectiveness of PCCD placement in treating lower body trauma. Adjusted IPTW analysis demonstrated decreased mortality in the PCCD group, while subgroup analysis demonstrated a greater treatment effect on the vital signs, injury origin, and pre-hospital PCCD use. Randomized controlled trials are needed to standardize treatment strategies.

ACKNOWLEDGEMENTS

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The datasets generated and/or analyzed during the current study are not available since the dataset was obtained from the Japan Trauma Data Bank through a formal request/approval process as above but is available from the corresponding author on reasonable request.

ETHICS STATEMENT

Approval of the research protocol: The study protocol was approved by the ethics committee of Tokyo Metropolitan Tama General Medical Center.

Informed consent: We applied the opt-out method on an institutional website to obtain patient consent.

Registry and the registration no. of the study/trial: N/A.

Animal studies: N/A.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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