Comparison between External Fixation and Pelvic Binder in Patients with Pelvic Fracture and Haemodynamic Instability who Underwent Various Haemostatic Procedures

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Abstract

Haemostatic procedures such as preperitoneal pelvic packing (PPP), pelvic angiography (PA), and internal iliac artery ligation are used for haemorrhage control in pelvic fracture patients with haemodynamic instability. Pelvic external fixation (PEF) and pelvic binder (PB) are usually applied with haemostatic procedures to reduce the pelvic volume. This study aimed to compare the clinical outcomes between patients who underwent PEF and PB. Among 173 patients with pelvic fracture admitted to the emergency room of three regional trauma centres between January 2015 and December 2018, the electronic charts of haemodynamically unstable patients were retrospectively analysed. Among 92 patients included in the analysis, 21 patients underwent PEF and 71 patients underwent PB. There were significant differences in tile classification and laparotomy between the PEF and PB groups ($p = 0.018$ and $p = 0.046$). PPP tended to be more frequently preformed in the PEF group ($p = 0.074$), whereas PA tended to be more commonly performed in the PB group than in the PEF group ($p = 0.058$). After propensity score matching to adjust for differences in patient characteristics and adjunct haemostatic procedure, there was a significant difference in haemorrhage-induced mortality between the PEF and PB groups (0% vs 25%, $p = 0.047$). Kaplan–Meier curve analysis also showed a significant difference in haemorrhage-induced mortality between the two groups (log-rank test, $p = 0.020$). Among the volume reduction procedures performed with other haemostatic procedures in patients with pelvic fracture and haemodynamic instability, PEF significantly reduced haemorrhage-induced mortality compared to PB.

Introduction

Despite advances in haemostatic procedures for patients with haemodynamic instability and pelvic fractures, the mortality rate among them is high (1–4). Haemorrhage is the most common cause of death in such patients, and internal iliac artery ligation, pelvic angiography (PA), preperitoneal pelvic packing (PPP), and resuscitative endovascular balloon occlusion of the aorta (REBOA) are used in various combinations for achieving haemostasis (3, 5–9). Early pelvic stabilisation reduces the pelvic cavity due to fracture and induces retroperitoneal tamponade to reduce bleeding and prevent further pelvic damage. Recently, pelvic external fixation (PEF) and pelvic binder (PB) have been mainly used as damage control orthopaedic techniques in patients with pelvic fracture and haemodynamic instability in the acute phase (2, 10, 11). In addition, a pelvic orthotic device has been developed and marketed that can be conveniently used in various emergency centres for patients with unstable pelvic fractures (T-POD, Morrisville, NC, US) (11). Although various studies on the application of PPP and PA in such patients have been published recently, limited studies have compared PEF and PB (8, 12–14). Therefore, this study aimed to compare clinical outcomes between patients who underwent PEF and PB for pelvic volume reduction.

Results

Patient characteristics

The average patient age was 55.0 ± 16.7 years, and the proportion of males was 69.9%. The most common injury mechanism was fall from a height (33.7%), followed by pedestrian traffic accidents (32.6%) and crushes (10.9%). In total, 54.3% and 44.6% patients were classified into types B and type C according to tiles classification. The average systolic blood pressure was 96.0 ± 29.1 mmHg, and the average initial lactate level was 5.49 ± 3.23 mmol/L. REBOA and PPP were performed in 12 (13%) and 50 (53.4%) patients, respectively. Laparotomy was performed in 17 patients (18.5%), and arterial embolization was performed in 30 (69.8%) of 43 patients who underwent PA. Further, 21 (22.8%) patients underwent PEF and 71 (77.2%) patients underwent PB. Among the associated injuries (AIS > 3), chest injury was the most common, followed by head and neck and abdominal injuries. The mean injury severity score (ISS) was 39.0 ± 11.9. The mortality rate and haemorrhage-induced mortality rate were 29.3% and 12.0%, respectively (Table 1).

Table 1
Patient characteristics

Variables	N = 92
Age	55.0 ± 16.7
Sex (male)	64 (69.6)
Injury mechanism	
Fall	31 (33.7)
Motor vehicle crash	7 (7.6)
Motorcycle	8 (8.7)
Pedestrian traffic accident	30 (32.6)
Crushing	10 (10.9)
Other	6 (6.5)
Title classification	
A	1 (1.1)
B	50 (54.3)
C	41 (44.6)
Open fracture	4 (4.3)
Initial systolic blood pressure	96.0 ± 29.1
Initial haemoglobin	10.9 ± 2.6
Initial lactate	5.49 ± 3.23
Initial lactate > 4 mmol/L	52 (56.5)
REBOA	12 (13.0)
PPP	50 (54.3)
Laparotomy	17 (18.5)
Pelvic angiography/embolization	43 (46.7) / 30 (69.8)
Pelvic external fixation	21 (22.8)
Pelvic binder	71 (77.2)
OR and IF	55 (59.8)

REBOA, resuscitative endovascular balloon occlusion of the aorta; PPP, preperitoneal pelvic packing; OR and IF, open reduction and internal fixation; AIS, Abbreviated Injury Scale; ISS, Injury severity score; RBC, red blood cell; ICU, intensive care unit

Variables	N = 92
Combined injury	
Head or neck injury (AIS > 3)	14 (15.2)
Chest injury (AIS > 3)	16 (17.4)
Abdomen injury (AIS > 3)	9 (9.8)
ISS	39.0 ± 11.9
Requirement of RBC for 4 h	8 (0–88)
Requirement of RBC for additional 24 h	7 (0–107)
ICU stay	10.0 (0–256)
Hospital stay	41 (1–315)
Mortality	27 (29.3)
Haemorrhage-induced mortality	11 (12.0)
REBOA, resuscitative endovascular balloon occlusion of the aorta; PPP, preperitoneal pelvic packing; OR and IF, open reduction and internal fixation; AIS, Abbreviated Injury Scale; ISS, Injury severity score; RBC, red blood cell; ICU, intensive care unit	

PEF group vs PB group before PSM

There were significant differences in the injury mechanism, tile classification, and laparotomy between the PEF and PB groups (p = 0.039, p = 0.018, and p = 0.046, respectively). PPP tended to be more frequently performed in the PEF group than in the PB group (p = 0.074), whereas PA tended to be more commonly performed in the PB group than in the PEF group (p = 0.058; Table 2).

Table 2
Comparison between the pelvic external fixation group and the pelvic binder group

Variables	**PEF group** **N = 21**	**Pelvic binder group** **N = 71**	**p value**
Age	53.3 ± 18.5	55.5 ± 16.8	0.594
Sex (male)	19 (82.6)	56 (63.6)	0.084
Injury mechanism			0.039*
Fall	2 (9.5)	29 (40.8)	
Driver	3 (14.3)	4 (5.6)	
Motorcycle	4 (19.0)	4 (5.6)	
Pedestrian	7 (33.3)	23 (32.4)	
Crushing	4 (19.0)	6 (8.5)	
Other	1 (7.0)	5 (7.0)	
Tile classification			0.018*
A	0	1 (1.4)	
B	6 (28.6)	44 (62.0)	
C	15 (71.4)	26 (36.6)	
Initial systolic blood pressure	97.8 ± 31.0	95.5 ± 28.8	0.754
Initial haemoglobin	10.9 ± 2.9	10.9 ± 2.5	0.991
Initial lactate	5.26 ± 3.19	5.56 ± 3.26	0.712
Initial lactate > 4 mmol/L	11 (52.4)	41 (57.7)	0.663
Combined Injury			
Head or neck Injury (AIS > 3)	2 (9.5)	12 (16.9)	0.510*
Chest injury (AIS > 3)	1 (4.8)	15 (21.1)	0.107*
Abdomen injury (AIS > 3)	2 (9.5)	7 (9.9)	0.695*
ISS	37.3 ± 9.6	39.5 ± 12.5	0.473
REBOA	3 (14.3)	9 (12.7)	1.000*
PPP	15 (71.4)	35 (49.3)	0.074

AIS, Abbreviated Injury Scale; ISS, injury severity score; REBOA, resuscitative endovascular balloon occlusion of the aorta; PPP, preperitoneal pelvic packing; OR and IF, open reduction and internal fixation; RBC, red blood cell; ICU, intensive care unit; PEF, pelvic external fixation

Variables	PEF group N = 21	Pelvic binder group N = 71	p value
Pelvic angiography	6 (28.6)	37 (52.1)	0.058
Laparotomy	7 (33.3)	10 (14.1)	0.046
OR and IF	13 (61.9)	42 (59.2)	0.821
Requirement of RBC for 4 h	7 (0–32)	8 (0–88)	0.881
Requirement of RBC for additional 24 h	10 (0-102)	6 (0-107)	0.269
ICU stay	14 (0–160)	8 (0–256)	0.448
Hospital stay	65 (1–315)	32 (1–260)	0.097
Haemorrhage-induced mortality	0	11 (15.5)	0.063*
Mortality	6 (28.6)	21 (29.6)	0.929

AIS, Abbreviated Injury Scale; ISS, injury severity score; REBOA, resuscitative endovascular balloon occlusion of the aorta; PPP, preperitoneal pelvic packing; OR and IF, open reduction and internal fixation; RBC, red blood cell; ICU, intensive care unit; PEF, pelvic external fixation

PEF group vs PB group after PSM

One-to-one PSM was performed for four variables—tile classification, PPP, PA, and laparotomy. After PSM, these variables were similar between the PEF and PB groups. The haemorrhage-induced mortality rate in the PEF group was significantly lower than that in the PB group (0% vs 25%, p = 0.047). However, there was no difference in the mortality rate between the two groups (30% vs 35%, p = 0.736). There were no significant differences in RBC requirement between the PEF and PB groups at 4 h and 24 h (p = 0.430 and p = 0.282, respectively; Table 3).

Table 3
Comparison between the pelvic external fixation group and pelvic binder group after propensity score matching

Variables	PEF group N = 20	Pelvic binder group N = 20	p value
Age	54.4 ± 18.3	56.8 ± 15.2	0.655**
Sex (male)	16 (80.0)	11 (55.0)	0.091
Injury mechanism			0.016*
Fall	2 (10.0)	9 (45.0)	
Driver	3 (15.0)	1 (5.0)	
Motorcycle	4 (20.0)	1 (5.0)	
Pedestrian	7 (35.0)	8 (40.0)	
Crushing	4 (20.0)	0	
Other	0	1 (5.0)	
Tile classification			0.723
B	6 (30.0)	5 (25.0)	
C	14 (70.0)	15 (75.0)	
Burges and Young classification			0.088*
APC type II	4 (20.0)	0	
APC type III	4 (20.0)	2 (10.0)	
LC type II	2 (10.0)	5 (25.0)	
LC type III	2 (10.0)	0	
VS type	7 (35.0)	12 (60.0)	
Initial systolic blood pressure	97.2 ± 31.6	96.3 ± 33.4	0.850**
Initial haemoglobin	10.8 ± 2.9	10.8 ± 2.8	0.892**
Initial lactate	5.16 ± 3.24	6.64 ± 3.30	0.185**

APC, anterior-posterior compression; LC, lateral compression; VS, vertical shear; AIS, Abbreviated Injury Scale; ISS, injury severity score; REBOA, resuscitative endovascular balloon occlusion of the aorta; PPP, preperitoneal pelvic packing; OR and IF, open reduction and internal fixation; RBC, red blood cell; ICU, intensive care unit; PEF, pelvic external fixation

*Result of Fisher’s exact test

**Result of the Mann–Whitney U test

Variables	PEF group N = 20	Pelvic binder group N = 20	p value
Initial lactate > 4 mmol/L	10 (50.0)	15 (75.0)	0.102
Combined Injury			
Head or neck Injury (AIS > 3)	2 (10.0)	4 (20.0)	0.661*
Chest injury (AIS > 3)	1 (5.0)	7 (35.0)	0.044*
Abdomen injury (AIS > 3)	2 (10.0)	0	0.487*
ISS	37.5 ± 9.8	43.9 ± 12.6	0.194**
REBOA	2 (10.0)	2 (10.0)	1.000*
PPP	14 (70.0)	15 (75.0)	0.723
Pelvic angiography	5 (25.0)	5 (25.0)	1.000
Laparotomy	6 (30.0)	6 (30.0)	1.000
OR and IF	12 (60.0)	12 (60.0)	1.000
Requirement of RBC for 4 h	8.5 (0–32)	14.0 (0–88)	0.303**
Requirement of RBC for additional 24 h	8.5 (0–102)	8 (0–107)	0.914**
ICU stay	12.5 (0–160)	7 (0–256)	0.524**
Hospital stay	64 (1–315)	34.5 (1–260)	0.194**
Haemorrhage-induced mortality	0	5 (25.0)	0.047*
Mortality	6 (30.0)	7 (35.0)	0.736
APC, anterior-posterior compression; LC, lateral compression; VS, vertical shear; AIS, Abbreviated Injury Scale; ISS, injury severity score; REBOA, resuscitative endovascular balloon occlusion of the aorta; PPP, preperitoneal pelvic packing; OR and IF, open reduction and internal fixation; RBC, red blood cell; ICU, intensive care unit; PEF, pelvic external fixation			
*Result of Fisher's exact test			
**Result of the Mann–Whitney U test			

Further, Kaplan–Meier survival analysis of haemorrhage-induced mortality rate according to time reveal significant difference between the two groups (log-rank test, p = 0.020; Fig. 1).

In Cox proportional hazard regression analysis, multivariate analysis for correction of covariates (age and abdominal injury) showed that the 7-day mortality rate in the PEF group tended to be lower than that in the PB group, but the difference was not statistically significant (adjusted hazard ratio, 0.120; 95% confidence interval, 0.014–1.048; p = 0.055; Table 4; Fig. 2).

Table 4
Cox proportional hazard ratio analysis for the 7-day mortality rate

Variable	Crude hazard ratio	P value	Adjusted hazard ratio	p value
Age	1.035 (0.990–1.083)	0.131	1.060 (0.999–1.124)	0.054
Lactate > 4 mmol/L	6.381 (0.796–51.132)	0.081		
Head and neck Injury (AIS > 3)	1.812 (0.376–8.733)	0.459		
Chest injury (AIS > 3)	2.207 (0.551–8.836)	0.263		
Abdomen injury (AIS > 3)	10.524 (2.011–55.088)	0.005	70.326 (5.180–954.803)	0.001
PEF	0.449 (0.112–1.799)	0.258	0.120 (0.014–1.048)	0.055
AIS, Abbreviated Injury Scale; PEF, pelvic external fixation				

The adjusted covariates were age and abdominal injury (Abbreviated Injury Scale > 3).

Cox proportional hazard regression analysis showed that the 7-day mortality rate in the pelvic external fixation (PEF) group tended to be lower than that in the pelvic binder (PB) group, but the difference was not statistically significant.

Discussion

Recent studies have reported that PEF plays an important role in haemostasis through stabilisation of the pelvic ring in pelvic fracture with shock to reduce additional damage and the reduction effect of the pelvic cavity (11-13). However, a recent study that analysed 10-year data on external emergent stabilisation using the German pelvic trauma registry showed a decreasing trend in the use of PEF in patients with pelvic ring fracture. In contrast, the use of PB has increased rapidly, and it was used in almost 40% patients (10). Moreover, in a recent multi-centre study conducted in a level I trauma centre in the United States, PB was performed in 50% patients with pelvic fracture and shock, and PEF was performed in only 4% patients (12). These results show that PB has been increasingly used instead of PEF, and its use has been continuously increasing due to its simplicity and speed in application (11, 15). It is difficult to compare the effects of PEF and PB in the treatment of patients with haemorrhage due to pelvic fracture compared to haemorrhage due to other injuries because a combination of various modalities is possible. In 2007, in a comparative study between the PEF and PB groups, Croce et al. showed that the mortality rates were similar, but the requirement for packed RBC transfusion at 24 and 48 h was significantly lower in the PB group than in the PEF group. However, there was a difference in characteristics between the two groups. Since the recently used procedures such as PPP or REBOA were not analysed together, it is difficult to accept the results in the current scenario (11). In our study, to minimise the effect of other haemostatic procedures and compare the differences between the effects of PB and PEF, the proportions of patients who had undergone PPP, PA, and laparotomy were corrected using PSM. The results showed that PEF was superior to PB in terms of haemorrhage-induced mortality and 7-day mortality rates. There are several reasons for this difference. First, if PB is not removed quickly or over-tighten, complications such as skin necrosis and pressure ulceration may occur; therefore, it is recommended that PB be maintained for >24–48 h (2, 16). In the trauma centres included in this study, PB was removed within 48 hours when the patient was haemodynamically stabilised, but the definitive fixation of the pelvis was determined considering the patient's condition and was performed after an average of 6 days after injury. Therefore, it is thought that the effect of pelvic stabilisation in PEF, but not in PB, lasted sufficiently until definitive fixation. Second, PEF maintains constant pelvic stabilisation during additional procedures such as PA, REBOA, and femoral vessel access after application, whereas PB may increase the risk of bleed because of the possibility of additional damage when reapplied after removal for additional procedures. Although not statistically significant in this study, the amount of packed RBCs transfused after 4 h in the PEF group tended to be lower than that in the PB group. This result seems to be consistent with that reported by the Denver group, showing that patients with pelvic fracture and haemodynamic instability undergoing PEF with PPP had a very good overall mortality rate (5, 13). Third, the tile classification of the PEF and PB groups was equally corrected by PSM, but there was a difference in the pattern of the type of pelvic ring fracture according to the Burges and Young classification between the two groups. In other words, the PB group tended to have more vertical shear-type pelvic fractures than the PEF group (60% vs 35%, $p = 0.205$). Unlike APC-and LC-type pelvic fractures, vertical shear-type injuries are best stabilised by posterior C-clamp (17, 18), and C-clamp is not commonly used in trauma centres in Korea due to the lack of orthopaedic trauma specialists (19).

Therefore, it appears that in patients with vertical shear-type pelvic fracture, PB was first applied rather than PEF, and then definitive fixation was performed when their condition was haemodynamically stabilised. The difference in the mortality rate might be due to the difference in the incidence of acute haemorrhage between the two groups. The pelvic trauma management algorithm of the World Society of Emergency Surgery was used to defined severe lesions (WSES grade IV) regardless of mechanical instability in cases of haemodynamic instability. After application, haemostatic procedures such as PPP, mechanical fixation, REBOA, and PA should be performed complementarily (2). In our study, before PSM, PPP with PEF was the most commonly performed in the PEF group (71.4%), whereas PA was most commonly performed in the PB group (52.1%). This result shows that PEF was mainly applied in the operating room while performing surgery such as PPP or laparotomy. When moving to the angiography suite for PA, it is thought that PB that can be easily and quickly removed and reapplied is combined.

REBOA has recently been increasingly used in patients with haemodynamic instability instead of emergent resuscitative thoracotomy (20-23). In Korea, REBOA was first used in regional trauma centres in 2016. It is being used as a bridge procedure before other haemostasis in patients with pelvic fracture accompanied by severe shock (23). In our study, 12 patients were treated with REBOA, of which 11 (91.7%) patients underwent PPP and nine (75%) patients underwent PA. The haemorrhage-induced mortality and total mortality rates in these patients were 33.3% and 66.7%, respectively, and PEF was performed in only three (25%) patients. These results are thought to be because REBOA was used in patients with a clinically critical condition, and PB, which can be easily applied, was preferred over PEF when it was necessary to move to the operating room. Although patients were not matched according to REBOA application by PSM, the application rate between the two groups was the same after PSM; therefore, it is judged that the effect of REBOA application did not affect the clinical outcome.

Since this was a retrospective study, this study has limitations, such as a selection bias between the two groups. Further, the statistical power was low because the number of patients who underwent PEF was very small. Nevertheless, this study is a rare study on the effectiveness of pelvic stabilisation procedures performed with various haemostatic procedures in patients with haemodynamic instability and pelvic fractures. The advantages of this study are that PSM was performed to correct various confounding factors and that patients from three institutions were included in the study. However, a larger prospective study is needed to confirm the results of our study.

Methods

Study setting

Wonju Severance Christian Hospital, Ajou University Hospital, and Gachon University Gil Medical Center participated in this study. All three hospitals are regional trauma centres designated and supported by the Ministry of Health and Welfare of Korea. These hospitals operate in accordance with the American Association for the Surgery of Trauma level 1 trauma centre standards in terms of facilities, equipment, personnel, and operations.

This study was conducted according to the guidelines of the Declaration of Helsinki, and the study protocol was approved by the institutional review board of Gachon University Gil Medical Center (IRB No. GCIRB2021-111). The committee waived the requirement of informed consent due to the retrospective nature of the study. Patients with haemodynamic instability underwent pelvic AP radiography and extended focused assessment with sonography for trauma as soon as they arrived at the trauma resuscitation room, and if pelvic fracture was found to be the main cause of bleeding with instability of the pelvic ring, a trauma pelvic orthotic device (T-POD) was applied. Depending on the patient's condition, the trauma surgeon decided to apply haemostatic procedures such as REBOA, PPP, and PA. Moreover, the application of PEF was decided after consultation with trauma and orthopaedic surgeons in charge of the trauma department.

Study population

Among the patients with pelvic fracture who visited the trauma resuscitation room from January 2015 to December 2018, patients with an Abbreviated Injury Scale (AIS) score of ≥4 points and a blood pressure of <90 mmHg or blood lactate level of ≥2 mmol/L in the emergency room (ER) were included in the study. Patients who had more haemorrhages due to other causes than due to pelvic fractures and those without haemorrhagic shock were excluded. After screening, 173 patients were included in this study. Among them, 66 patients who did not undergo PEF or PB for pelvic cavity reduction and 15 patients who developed cardiac arrest in the ER were excluded. Consequently, 92 patients were included in this study. Twenty-one patients who underwent PEF (PEF group) were compared with 71 patients who underwent PB (PB group) (Figure 3).

Outcome measures

The primary outcome was the haemorrhage-induced mortality rate. Hospital mortality rate, 7-day mortality rate, requirements of packed red blood cells (RBCs) for 4 and 24 hours, length of intensive care unit (ICU) stay, and duration of hospitalisation were evaluated as the secondary outcomes.

Statistical analysis

Continuous variables, expressed as mean ± standard deviation or median (minimum – maximum), were analysed using Student's t-test or the Mann–Whitney U test. Categorical variables were analysed using the chi-square test or Fisher's exact test. Logistic regression analysis estimated the propensity score model, and the probability that each subject will be included in the control group by the given covariance corresponds to the propensity score. We performed nearest-neighbour matching. This method matches the absolute differences of the estimated propensity score differences of all subjects in both groups, starting with the smallest difference. The C-statistic of the logistic regression model for propensity score matching (PSM) was 0.790. The covariates included in the calculation were tile classification, PPP, laparotomy, and PA ($p < 0.1$). Survival curves were constructed using the Kaplan–Meier method and compared. Cox proportional hazard regression analysis was performed as multivariate analysis to compare the 7-day mortality rate corrected for covariates between the two groups. Statistical significance was set at $p < 0.05$. Statistical analyses were performed using IBM SPSS ver. 23.0 (IBM Inc., Armonk, NY, USA) and SAS 9.4 software (SAS Inc., Cary, NC, USA).

Declarations

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Author contributions:

J.Y.J.: Data curation; Formal analysis; Investigation; Methodology; Writing-original draft

K.S.B.: Methodology, Writing-review and editing

B.H.K.: Data curation, Formal analysis, Investigation; Methodology; Writing-original draft; Writing-review and editing

G.J.L.: Data curation, Formal analysis, Methodology; Writing-orginal draft; Writing-review and editing.

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Competing interests:

The authors declare no competing interests.

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Figures

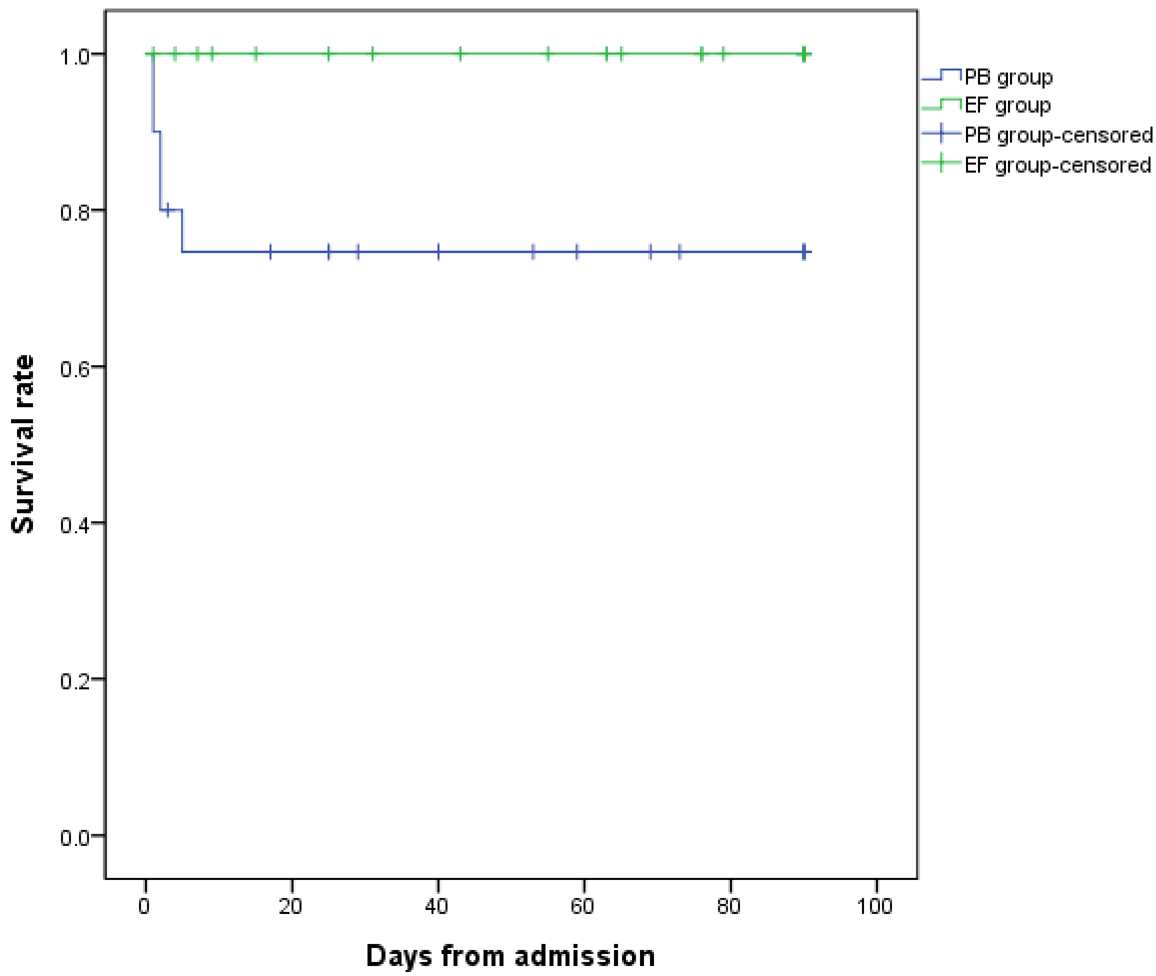

Figure 1

Kaplan−Meier survival analysis of haemorrhage-induced mortality rate according to time between the two groups

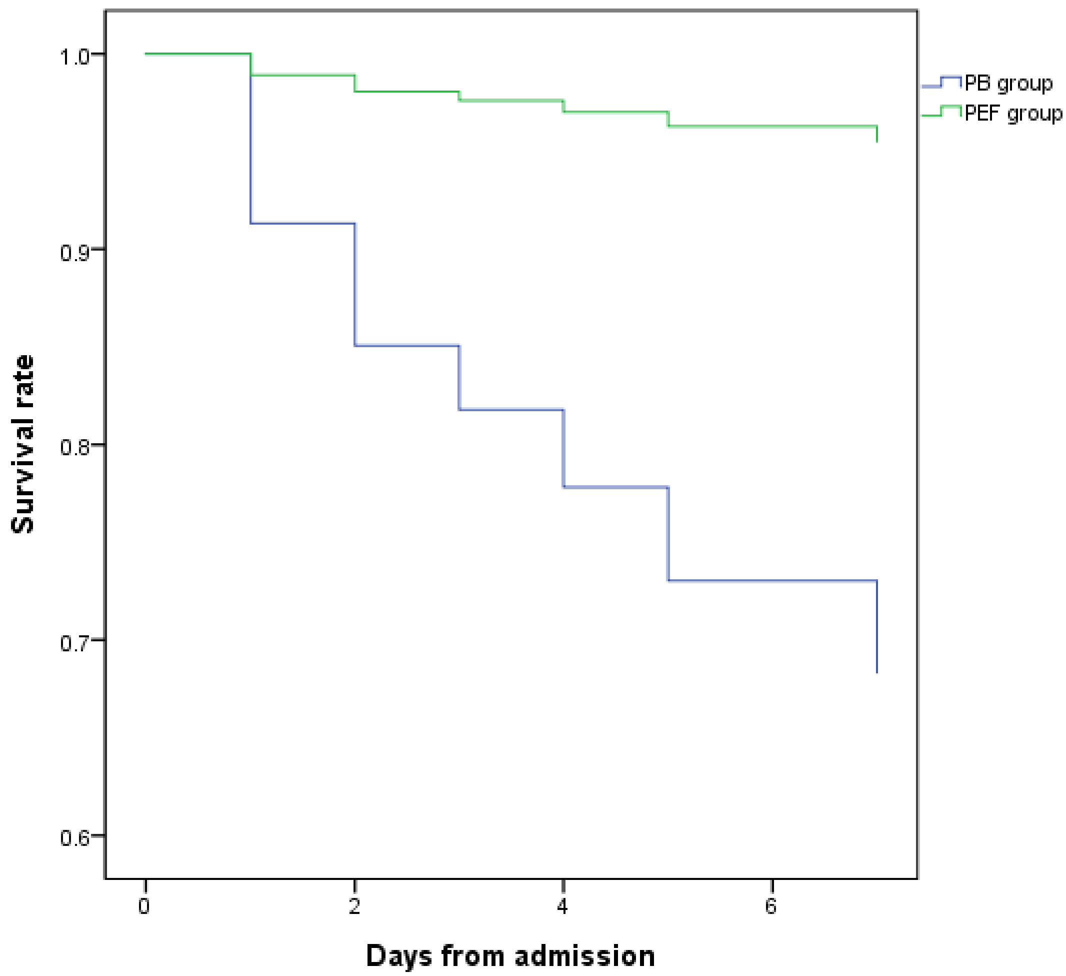

Figure 2

Association between pelvic external fixation and the 7-day mortality rate according to Cox proportional hazard ratio analysis

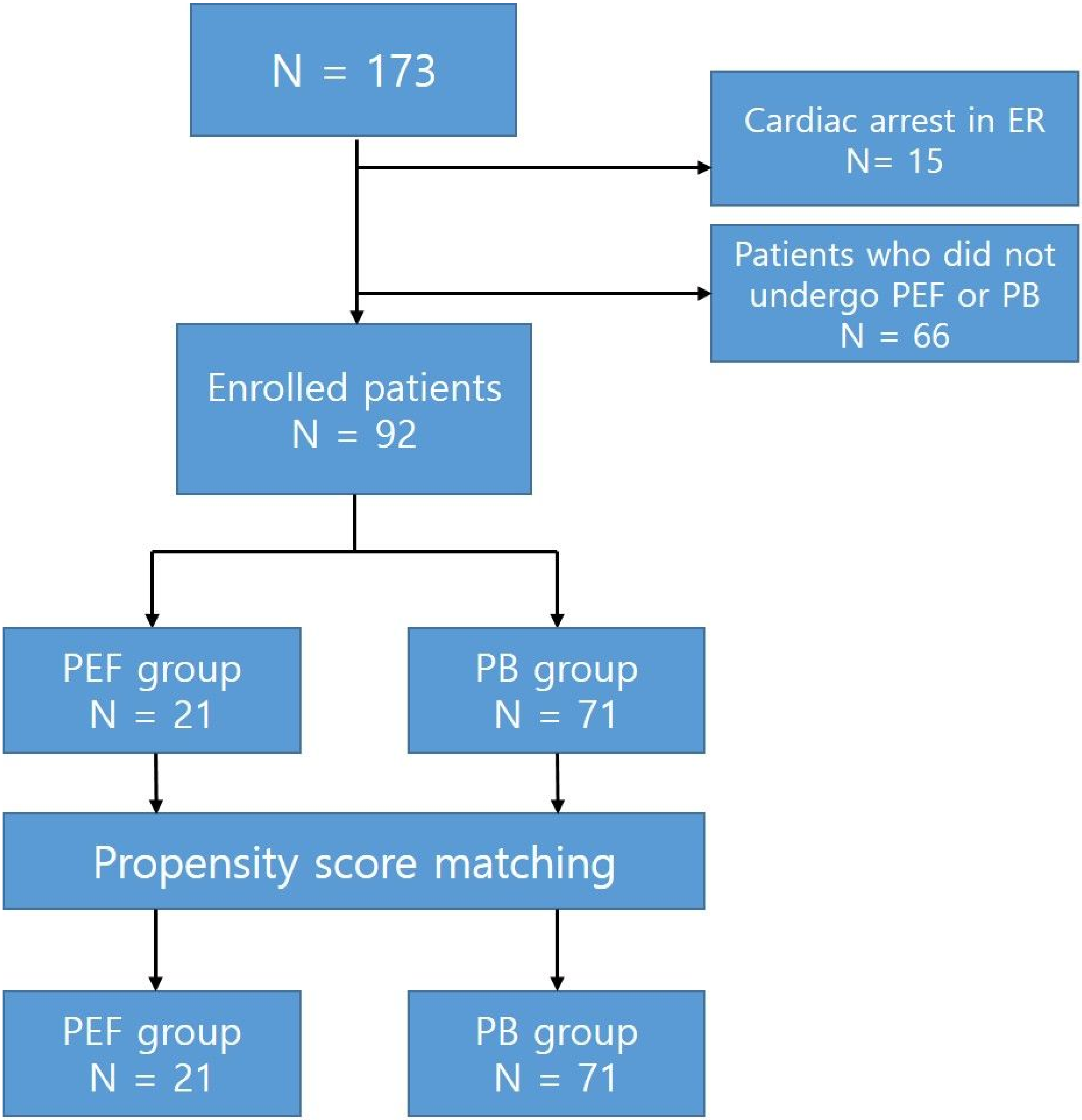

Figure 3

Patient flowchart