Improvement of Outcomes in Hemodynamically Unstable Patients With Pelvic Fracture Following The Establishment of a Trauma Center: A Single Center Observational Study in Korea

Mina Lee

Gachon University

Byungchul Yu (✉ kane2123@gilhospital.com)

Gachon University <https://orcid.org/0000-0002-2444-2343>

Giljae Lee

Gachon University

Junnam Lee

Gachon University

Kangkook Choi

Gachon University

Youngeun Park

Gachon University

Jihun Gwak

Gachon University

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Abstract

Background: The trauma center and multidisciplinary management protocols have been proved to improve the outcomes of severely injured patients. Hemorrhage from pelvic injury is associated with high mortality and is a common cause of preventable trauma death. This study aims to evaluate the effects of the establishment of a trauma center and management protocols on the outcomes of hemodynamically unstable patients with pelvic fractures.

Methods: Hemodynamically unstable patients with pelvic fractures were reviewed retrospectively over a 10-year period. They were grouped into periods 1 and 2, which were defined as before and after the establishment of a trauma center and protocols, respectively. Basic characteristics and outcomes were compared between periods.

Results: This study enrolled a total of 106 patients. Basic and physiological characteristics were not significantly different in both periods. Pre-peritoneal packing (PPP) and resuscitative endovascular balloon occlusion of aorta (REBOA) were only performed in period 2 (PPP, N = 27; REBOA, N = 10). In period 2, the time from emergency room arrival to hemostatic intervention was significantly shorter (269 ± 132.4 min. vs. 147.2 ± 95.5 min., $p < 0.0001$), and mortality due to acute hemorrhage was significantly decreased (33.3% vs. 8.6%, $p = 0.018$). The multivariate logistic regression analysis identified age, ISS, and period 1 as independent risk factors for mortality.

Conclusion: The establishment of a trauma center and multidisciplinary management protocols, such as PPP and REBOA, improved the outcomes of hemodynamically unstable patients with pelvic fractures.

Introduction

Trauma is a leading cause of death for young people in Korea. The rate of preventable deaths is reportedly decreasing but still higher compared to those in developed countries.(1, 2) Therefore, the Ministry of Health and Welfare and medical professionals decided to establish regional trauma centers in 2012. The first regional trauma center opened in 2014, with plans to establish a total of 17 regional trauma centers in Korea by 2021. Several changes may be observed after the establishment of a trauma center, such as an increase in the volume of trauma cases in the center, trauma-dedicated resources, performance improvement programs, or the development of a regional trauma system.

The mortality rate of hemodynamically unstable patients with pelvic fractures remains greater than 30% despite advancements in the management of severely injured patients.(3-6) Furthermore, it is also one of the most frequent contributors to traumatic preventable death.(7) Therefore, management strategies for these patients including initial resuscitation, diagnosis, and therapeutic interventions are essential in reducing mortality. The majority of trauma centers emphasize angioembolization (AE) as an effective intervention to stop pelvic bleeding, although AE cannot address the venous or bony hemorrhage within the pelvis.(8, 9) However, the utilization of AE needs a proper facility, equipment, and human resources. It

is well known that time to hemorrhage control is related to mortality, but it typically takes around 2–5 hours before AE is performed in many centers.(5, 6, 10, 11)

Pre-peritoneal pelvic packing (PPP) with external pelvic compression reportedly stops hemorrhage and facilitates other emergent operative procedures.(9, 12) We included PPP and pelvic circumferential compression devices in the pelvic fracture management algorithm after the trauma center was established in 2014 and added resuscitative endovascular balloon occlusion of aorta (REBOA) to the management algorithm in 2016.(13) The aim of this study was to evaluate the time to intervention and the outcomes of hemodynamically unstable patients with pelvic fractures before and after the establishment of a trauma center and management protocol. We hypothesized the establishment of a trauma center, and protocols including interventions such as PPP and REBOA will shorten the time to intervention and lower mortality in our institution.

Materials And Methods

Setting

The Gachon University Gil Medical Center is a 1,500-bed teaching hospital in Incheon, South Korea that serves a population of 3 million people. The regional trauma center was established in 2014 in accordance with the trauma system development plan of the Ministry of Health and Welfare. Before 2014, the emergency center managed trauma patients without a dedicated trauma surgeon, trauma team, dedicated facilities, or protocols for the evaluation and management of pelvic injury. There were more than 3,000 trauma-related admissions, of which 500–550 patients presented with major trauma (injury severity score > 15). The regional trauma center is equipped with a trauma bay, 2 operating rooms dedicated to trauma, a 20-bed trauma intensive care unit, and a trauma angiography suite. Fourteen full-time trauma surgeons currently work at the center, and a team of emergency physicians, anesthesiologists, and orthopedic and neurosurgery consultants are available 24/7.

Study population

The study included hemodynamically unstable patients with pelvic fractures from January 2009 to December 2018. Hemodynamic instability was defined as having a systolic blood pressure (SBP) < 90 mmHg during the initial resuscitation period despite the transfusion of 2 units of packed red blood cells (pRBCs). We excluded patients who died in the emergency room (ER) or from out-of-hospital cardiac arrest, patients < 16 years old, patients without interventions to control pelvic bleeding, and those who received delayed interventions after treatment of other injuries. The outcomes of the enrolled patients were analyzed by time period; periods 1 and 2 were defined as before and after, respectively, establishment of the trauma center and protocols.

Protocol

During period 1, patients with pelvic injuries were initially evaluated and managed at the ER by emergency physicians. After evaluation and initial resuscitation, the general and orthopedic surgeons on call decided on further management plans. Angioembolization (AE) was mainly performed if extravasation of contrast was seen on computed tomography (CT). Pelvic circumferential compression devices or external fixations were not utilized in this period. There was no protocol for the management of bleeding pelvic fracture patients.

During period 2, severely injured patients were managed at the trauma bay by a trauma team utilizing dedicated facilities. Patients with bleeding pelvic fractures were managed according to a previously published algorithm (Fig. 1). Patients who tested positive for abdominal fluids on FAST were brought to the operating room for both laparotomy and pre-peritoneal packing (PPP). External fixation was performed following the operations, if available. If the patients remained hemodynamically unstable despite PPP, AE was then performed. For patients with negative FAST results, AE was attempted first. However, if AE was not immediately available, or the patient was hemodynamically unstable while waiting for AE, PPP was performed as a first choice. Since 2016, we implemented REBOA in the algorithm for extremely unstable patients.

Statistical analysis

Numerical data were presented as the means and standard deviations, whereas categorical data were presented as percentages. The univariate analysis was performed using the Student's *t* test and chi-squared test. Covariables with significance in the univariate analysis were analyzed in a multivariate regression model. Multivariable logistic regression was utilized to evaluate independent risk factors for mortality. Statistical significance was defined as $p < 0.005$. All statistical analyses were performed using SPSS version 20.0 (IBM Corp., Armonk, NY, USA)

Results

We extracted data from 1,469 patients with an AIS pelvis score over 1 point from the trauma center database. A total of 106 (7.2%) patients met the inclusion criteria of the current study (Fig. 2). The mean age of patients was 52.3 ± 19.8 years, and 53 (50%) of the patients were male. Demographic data indicated a mean SBP at ER admission of 83.5 ± 29.2 , the lowest SBP at ER of 60.4 ± 25.7 , a Glasgow Coma Scale (GCS) of 12 ± 4.2 , and ISS of 39 ± 11.3 . The basic demographics of the two groups were statistically similar (Table 1). The mean amounts of pRBC and fresh frozen plasma (FFP) transfusion for the first 24 hours were 16.4 ± 13.8 and 10.6 ± 10.4 , respectively. The mean amount of FFP transfusion for 24 hours was significantly increased from 7.5 ± 4.9 to 12.2 ± 12.1 in period 2 ($p = 0.028$). The mean time to intervention (for PPP, AE, or both) was 269 ± 132.4 minutes in period 1 and 147.2 ± 95.5 minutes in period 2 ($p < 0.001$). The mean time to AE only was also significantly shorter in period 2 ($p = 0.002$). The time to intervention decreased throughout the years (Fig. 3), and REBOA was performed only in period 2 for 10 patients (Table 2). Patients who underwent REBOA had lower SBP and higher lactate and ISS

compared to those who did not. In 8 patients, REBOA balloon was deployed in Zone 3. Seven patients survived for more than 24 hours and 3 patients were able to survive and get discharged (Table 3).

The overall mortality rate of the study population was 34.9%; from 47.2% in period 1, this decreased to 28.6% in period 2 ($p = 0.056$). The mortality rate associated with acute hemorrhagic shock also decreased from 33.3% in period 1 to 8.6% in period 2, and it was statistically significant ($p = 0.018$). There were no TRISS unexpected survivors (TRISS probability of survival < 0.5) in period 1, but there were 10 (24%) unexpected survivors in period 2 (Table 2). Patients who survived were found to be significantly younger (49.6 ± 20.1 vs. 57.4 ± 18.6 , $p = 0.046$) and have higher SBP (66.8 ± 23.6 vs. 48.4 ± 25.4 , $p = 0.001$), GCS, and TRISS, with lower ISS, lactate, base deficit, and transfusion amounts ($p < 0.001$) (Table 4).

A multivariate logistic regression analysis evaluated the independent risk factors for mortality as listed in Table 5. After adjusting for age, sex, base deficit, lactate, ISS, TRISS, and transfusion amounts, the following variables were found to be significantly associated with overall mortality: age (odds ratio, 1.19; 95% confidence interval [CI], 1.04–1.35), ISS (odds ratio, 1.16; 95% confidence interval [CI], 1.02–1.32), and period 1 (odds ratio, 13.4; 95% confidence interval [CI], 3.02–59.89).

Discussion

Trauma center establishment has been associated with reduced mortality in several studies, and it is mainly due to increased annual trauma volume, trauma-dedicated resources, and performance improvement program (PIP).⁽¹⁴⁻¹⁶⁾ Before the establishment of a regional trauma center, approximately 250 severely injured patients (ISS > 15) were admitted to our hospital annually. However, after the trauma center opened in 2014, more than 500 severely injured patients were managed annually. The volume of trauma patients and the rate of direct transportation increase year by year.⁽¹⁷⁾ Furthermore, the presence of human resources (trauma-dedicated surgeons, nurses, and a trauma program manager) and a PIP could influence resuscitation practice, time to intervention, and hemorrhage control modalities.⁽⁸⁾

Bleeding pelvic fractures are uncommon but are associated with significant mortality due to hemorrhagic shock. Before the establishment of a trauma center, hemodynamically unstable patients with pelvic fractures were managed mainly by an emergency physician at the initial resuscitation phase. After diagnosis of bleeding pelvic fracture was confirmed using imaging studies, general and orthopedic surgical services were contacted. In many cases, however, there were conflicts between departments when deciding on further treatment interventions. In one study, the application of a multidisciplinary clinical pathway with joint decision making between trauma and orthopedic surgeons resulted in improved outcomes in patients with pelvic fractures.⁽¹⁴⁾ Therefore, rapid hemostasis with appropriate treatment following a multidisciplinary algorithm involving hemostatic interventions is crucial. We implemented this pelvic fracture management protocol in 2014 shortly after the trauma center establishment.

The ATLS guidelines recommend that a pelvic binder (PB) should be used for the external compression of pelvic cavity when there are signs of a pelvic ring fracture.⁽¹⁸⁾ Studies have also demonstrated that

commercial PBs are more effective in controlling pelvic bleeding than a conventional “bed-sheet” compression.(19) In Korea, prehospital PB application is very rare, and our hospital used the conventional “bed-sheet” compression in a few cases until 2014. After the official approval of commercial PBs by the Ministry of Food and Drug Safety in 2013, we used these in the management algorithm for suspected pelvic fracture patients in 2014. External pelvic fixations are rarely used in this study because the orthopedic surgeons in our hospital prefer PB application over these. In a study comparing PB and external fixation in patients with pelvic fractures, those who underwent external fixation needed higher amounts of transfusion.(20) Thus, until now, we mainly utilize PB for external compression purposes in the algorithm for pelvic injury management.

AE has been used since the 1970s for hemorrhage control in patients with pelvic bone fractures. It has been proved to be effective and remains the most widely used hemostatic intervention. However, AE may not be an effective intervention to stop bleeding due to pelvic fracture, because approximately 80% of the bleeding is associated with bone or venous bleeding.(9) Venous bleeding cannot be managed by AE, so AE in hemodynamically unstable pelvic injuries results in poor patient outcomes with mortality rates greater than 40%.(9) In addition, the availability of AE varies by institution. AE requires specific facilities, equipment, and human resources, so some centers are unable to perform this technique. Even in centers that can perform AE, it might not be available immediately, specifically during nights or weekends, which can further increase the mortality rate.(11, 21) Several studies have reported that the time from ER arrival to AE takes at least 2 hours up to more than 5 hours.(22, 23) In our study, the time to AE only decreased from 269 minutes in period 1 to 181 minutes in period 2, but this waiting time is still too long for hemodynamically unstable patients.

PPP has been proposed as an alternative intervention to AE. PPP is a simple procedure, so it can be performed in the resuscitation room or operation room by a trauma surgeon within an hour of patient arrival. The time to PPP was 44–55 minutes in recent studies, and this is significantly shorter compared to AE.(5, 24) PPP could significantly decrease the time to intervention in our study also. Studies demonstrated that an implementation of clinical guidelines that include PPP for hemodynamically unstable patients led to a significant decrease in transfused blood products and in mortality.(5, 24) More recent studies have revealed that PPP is a safe and rapid intervention associated with significantly reduced mortality in hemodynamically unstable patients with pelvic fractures compared to patients managed by conventional intervention without PPP.(25, 26) Moreover, unstable pelvic fractures are often associated with intra-abdominal injuries. One study reported that a total of 34.3% of severe pelvic fracture patients had associated intra-abdominal injuries including bladder and bowel injuries.(27) In such cases, AE might delay abdominal exploration, or a laparotomy might delay hemostasis using AE. However, a midline laparotomy and PPP can be performed simultaneously with separate incisions, so it achieves hemorrhage and contamination control rapidly without concerns of cross-contamination in the retroperitoneal space from bowel injuries.(12) In this study, concomitant laparotomy increased in period 2 after inclusion of PPP in the management algorithm. In addition, laparotomy for the decompression of abdominal pressure in patients with suspected abdominal compartment syndrome was only performed in period 2. The World Society of Emergency Surgery (WSES) guidelines for pelvic fracture recommend that

PPP should always be considered in hospitals with no AE services and that PPP is an effective surgical measure for early hemorrhage control in hypotensive patients with bleeding pelvic disruptions.(18) Therefore, PPP is recommended as a first intervention for hemodynamically unstable patients (WSES grade IV) in the pelvic trauma management algorithm.(18)

REBOA has recently been reported as a viable alternative to performing an aortic cross clamp (ACC) through emergent thoracotomy.(28, 29) REBOA can be a “bridge” procedure in torso hemorrhages followed by an operation or AE. REBOA can be placed in Zone 1 (supra-celiac) or Zone 3 (infra-renal). Zone 3 REBOA can be optimal, especially for pelvic bleeding, because it can raise blood pressure and reduce arterial bleeding associated with pelvic injury while preventing ischemic insult on visceral organs on top of having a long occlusion time.(30) Although there is little evidence of mortality benefit in previous articles, the WSES guidelines suggest REBOA as an alternative to ACC and that Zone 3 REBOA should be considered to be a bridge to definitive treatment in hemodynamically unstable patients.(18) Our center has implemented REBOA in the pelvic injury management algorithm since 2016, and REBOA was performed in 10 patients; 80% of these were deployed in Zone 3 with 3 patients surviving and getting discharged.

The purpose of this study was to evaluate changes in outcomes after trauma center establishment and pelvic injury management protocol including PPP and REBOA. This study demonstrated significantly decreased time to interventions and mortality due to acute hemorrhage. We believe that these changes are due to (1) an attending trauma surgeon being a leader of multidisciplinary team; (2) management protocols including PB, PPP, and REBOA; (3) an increase in concomitant laparotomy; and (4) changes in blood product usage. We think these changes might not be achieved without the establishment of a trauma center with financial support in developing countries such as Korea.

This study has several limitations. The main limitations are its retrospective study design and small sample size due to the study being only from a single institute. These might have introduced bias. In addition, we investigated in-hospital mortality only, and these might have influenced our results. Finally, we could not evaluate the adherence of individual surgeons to the management algorithm. In the future, a well-designed multi-center prospective study with a larger sample size should be designed to analyze the relationship between trauma center establishment and patient outcomes.

Conclusion

The improved outcomes in hemodynamically unstable patients with pelvic fracture were achieved because of the establishment of a trauma center and multidisciplinary management protocols. Trauma center designation can advance the management of severe trauma cases such as pelvic fracture, especially in developing countries.

Abbreviations

ACC: Aortic Cross Clamping; AE: Angioembolization; CT: Computed Tomography; ER: Emergency room; FFP: Fresh Frozen Plasma; GCS: Glasgow Coma Scale; ISS: Injury Severity Score; PPP: Pre-peritoneal Pelvic Packing; pRBC: Packed Red Blood Cell; PIP: Performance Improvement Program; PB: Pelvic Binder; REBOA: Resuscitative Endovascular Balloon Occlusion of Aorta; SBP: Systolic Blood Pressure (SBP); TRISS: Trauma Injury Severity Score

Declarations

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Availability of data and materials

Data and materials can be made available to the public through direct requests to the corresponding author.

Authors' contributions

MAL and BCY had full access to all the data and drafted the manuscript. JNL, GJL, YEP, JHG and KKC participated in the study design and the education.

Ethical approval and consent to participate

This study was reviewed and approved by Gachon University Ethics Committee (approval number: 2020-471).

Consent for publication

All authors agree with the publication of this article

Competing interests

The author(s) declare no competing interests with respect to the research, authorship, and/or publication of this article.

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Tables

Table 1. General characteristics of all patients managed in the period 1 and period 2

	Total (N=106)	Period 1 (N=36)	Period 2 (N=70)	<i>p</i> value
Age	52.3 ± 19.8	51.2 ± 19.2	52.9 ± 20.3	0.667
Sex, male (%)	53 (50)	18(50)	35(50)	1
SBP upon ED arrival (mmHg)	83.5 ± 29.2	87.9 ± 25.5	81.2 ± 30.9	0.231
Lowest SBP at ED (mmHg)	60.4 ± 25.7	59.9 ± 25	60.6 ± 26.2	0.894
Hemoglobin (mg/dL)	10.9 ± 2.7	10.5 ± 2.2	11.1 ± 2.8	0.206
INR	1.71 ± 2.15	1.86 ± 2.45	1.65 ± 2	0.658
Lactate (mmol/L)	4.84 ± 3.19	4.26 ± 2.73	5.13 ± 3.37	0.161
Base deficit (mmol/L)	8.41 ± 5.81	7.93 ± 5.73	8.66 ± 5.89	0.546
GCS	12 ± 4.2	12.3 ± 3.9	11.8 ± 4.1	0.559
ISS	39 ± 11.3	38.1 ± 12.3	39.5 ± 10.9	0.55
TRISS	0.62 ± 0.32	0.67 ± 0.31	0.6 ± 0.32	0.267

SBP: systolic blood pressure, ED: emergency department, INR: international normalized ratio, GCS: Glasgow coma scale, ISS: Injury severity score, TRISS: trauma and injury severity score

Table 2 Intervention related data and outcomes for each period

	Total (N=106)	Period 1 (N=36)	Period 2 (N=70)	<i>p</i> value
Time to intervention (minutes)	188.9 ± 123.4	269 ± 132.4	147.2 ± 95.5	<0.0001
Time to AE only, N=79	221.6 ± 123.5	269 ± 132.4	181.9 ± 100.9	0.002
Time to PPP only, N=6	83.5 ± 30.5		83.5 ± 30.5	
Time to AE + PPP, N=21	91.6 ± 51.2		91.6 ± 51.2	
Laparotomy, n(%)	15 (14.2)	1 (2.8)	14 (20)	0.012
REBOA, n (%)	10	0	10 (14.3)	
pRBC for the first 4 hours (units)	7.5 ± 6.3	7.1 ± 5.3	7.6 ± 6.9	0.644
FFP for the first 4 hours (units)	3.3 ± 3.2	3.3 ± 2.7	3.3 ± 3.4	0.917
pRBC for the first 24 hours (units)	16.4 ± 13.8	13.1 ± 9.6	18.1 ± 15.4	0.08
FFP for the first 24 hours (units)	10.6 ± 10.4	7.5 ± 4.9	12.2 ± 12.1	0.028
Overall mortality, N (%)	37(34.9)	17(47.2)	20 (28.6)	0.056
24-hour mortality, N(%)	18 (17)	9 (25)	9 (12.9)	0.143
30-day mortality, N(%)	19 (17.9)	8 (22.2)	11 (15.7)	0.149
Mortality due to acute hemorrhage, N(%)	17 (16)	10 (33.3)	6 (8.6)	0.018
Unexpected survivor*, N	10	0	10	0.03

AE: angioembolization, PPP: pre-peritoneal packing, REBOA: resuscitative endovascular balloon occlusion of aorta, pRBC: packed red blood cell, FFP: fresh frozen plasma

*Unexpected survivor: Number of observed survivor among patients whose TRISS probability of survival < 0.5

Table 3 Characteristics and outcomes of patients underwent REBOA

	REBOA group (N=10)
Age	54.9 ± 18.4
SBP upon ED arrival (mmHg)	65.3 ± 18.3
Lowest SBP at ED (mmHg)	50.5 ± 7.2
Lactate (mmol/L)	7.86 ± 3.12
ISS	43.6 ± 10.4
REBOA deployment in Zone 3, N (%)	8 (80)
Death, N (%)	7 (70)
Death in 24 hours, N (%)	3 (30)
Death in 30 days, N (%)	4 (40)

REBOA: resuscitative endovascular balloon occlusion of aorta, SBP: systolic blood pressure, ISS: Injury severity score

Table 4 Comparison of the characteristic between survivor and non-survivor

	Survivor, N=69	Non-survivor, N=37	<i>p</i> value
Age	49.6 ± 20.1	57.4 ± 18.6	0.046
SBP upon ED arrival (mmHg)	87.5 ± 27.8	75.9 ± 30.7	0.59
Lowest SBP at ED (mmHg)	66.8 ± 23.6	48.4 ± 25.4	0.001
Lactate (mmol/L)	4.05 ± 2.54	6.28 ± 3.73	<0.0001
Base deficit (mmol/L)	7.29 ± 4.6	10.6 ± 7	0.004
GCS	13.5 ± 2.8	9.1 ± 4.8	<0.0001
ISS	36.3 ± 10.4	44.1 ± 11.3	0.001
TRISS	0.733 ± 0.028	0.417 ± 0.057	<0.0001
pRBC for the first 4 hours (units)	5.3 ± 4.3	11.4 ± 7.7	<0.0001
FFP for the first 4 hours (units)	2.4 ± 2.4	4.9 ± 3.8	<0.0001
pRBC for the first 24 hours (units)	11.8 ± 9.6	25.1 ± 16.4	<0.0001
FFP for the first 24 hours (units)	11.8 ± 9.6	16.2 ± 12.9	<0.0001
Period 1, N(%)	19 (27.5)	17(45.8)	0.056

SBP: systolic blood pressure, ED: emergency department, GCS: Glasgow coma scale, ISS: Injury severity score, TRISS: trauma and injury severity score, pRBC: packed red blood cell, FFP: fresh frozen plasma

Table 5 Logistic regression analysis of the independent risk factors of mortality

	<i>p</i> value	Odds ratio to mortality	95% confidence interval	
			Lower	Upper
Period 1	0.001	13.442	3.017	59.895
Age	0.011	1.185	1.040	1.351
Base deficit	0.775	0.973	0.808	1.172
Lactate	0.492	1.121	0.809	1.553
ISS	0.023	1.162	1.021	1.324

Figures

Figure 1

An algorithm for the management of pelvic fracture.

Figure 2

Flowchart of patient inclusion.

Figure 3

Time from ER to intervention throughout the study periods.