

Extraperitoneal packing in unstable blunt pelvic trauma: A single-center study

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BACKGROUND:	Hemodynamically unstable pelvic fractures often require a multi-modal approach including both operative and endovascular management. While an important adjunct in hemorrhage control, time to angioembolization even at the most advanced trauma centers may take hours. Extraperitoneal packing (EPP) is a fast and effective procedure that can immediately address pelvic hemorrhage from the retroperitoneal space in severe pelvic injuries. The aim of this study was to evaluate the efficacy of early EPP, looking at 24 hours and overall mortality, and the hemodynamic impact of EPP in unstable blunt pelvic trauma.
METHODS:	All trauma patients admitted to an urban Level I trauma center were evaluated from 2002 to 2018 in a retrospective single-center comparative study. Inclusion criteria were patients 14 years or older who sustained blunt trauma with pelvic fractures and hemodynamic instability. Exclusion criteria were a concomitant head injury (Abbreviated Injury Scale >3) and patients who underwent resuscitative thoracotomy. The patient population was divided into two groups: an EPP group and a no-EPP group. Propensity score matching was used to adjust for differences in baseline characteristics in the two groups: a one-to-one matched analysis using nearest-neighbor matching was performed based on the estimated propensity score of each patient.
RESULTS:	Two hundred forty-four patients presented hemodynamically unstable, with a pelvic fracture (180 no-EPP, 64 EPP). With propensity score matching, 37 patients in each group were analyzed. Survival within the first 24 hours was significantly improved in the EPP group (81.1% vs. 59.5%, $p = 0.042$) and we registered similar results in overall survival rate (78.4% EPP group vs. 56.8% no-EPP group, $p = 0.047$). Those patients who underwent early EPP ($n = 64$) were associated with a significant improvement in hemodynamic stability, with a pre-EPP mean arterial pressure of 49.9 mm Hg and post-EPP mean arterial pressure of 70.1 mm Hg ($p < 0.01$).
CONCLUSION:	Extraperitoneal pelvic packing is an effective procedure that can be performed immediately, even within the trauma bay, to improve hemodynamic stability and overall survival in patients who sustain severe blunt pelvic trauma. The early use of EPP can be life-saving. (<i>J Trauma Acute Care Surg.</i> 2020;88: 597–606. Copyright © 2020 American Association for the Surgery of Trauma.)
LEVEL OF EVIDENCE:	Therapeutic, Level III.
KEY WORDS:	Extraperitoneal pelvic packing; pelvic fracture; blunt pelvic trauma; hemodynamic instability; propensity score.

The management of hemodynamically unstable patients with pelvic fractures still remains a clinical challenge. A multidisciplinary approach including operative management and endovascular interventions has improved patient outcomes, but hemorrhage remains the main cause of death with a mortality rate higher than 40%.^{1–3}

The most recent guidelines suggest using angiography and embolization to control pelvic bleeding after trauma, with a success rate ranging from 80% to 100% for arterial hemorrhage when used in combination with pelvic stabilization.^{1,4,5} However, bleeding associated with pelvic fractures is arterial only in 15% to 25% of cases, compared with 80% which is venous or from fracture fragments. In this latter case, angioembolization (AE) does not have the same success rates.⁶ Best clinical practice, as suggested by the 2019 “Western Trauma Association algorithm for Management of Pelvic Fracture with Hemodynamic Instability” and the most recent guidelines from World Society of Emergency Surgery about pelvic injuries, seems to be a complementary association of packing, resuscitative endovascular balloon occlusion of the aorta (REBOA) and endovascular procedures.^{1,5} At the same time, interventional radiology is not immediately available in every hospital. The time

required to set up the interventional radiology suite and mobilize the specialized personnel needed may be excessive. Early access to hemostatic resources has been associated with reduced mortality, but even in Level 1 Trauma Centers, it can take anywhere from 60 minutes to 90 minutes to 3 hours from admission to hemostasis: delays have been associated with an increase in mortality.³

Extraperitoneal pelvic packing (EPP) has been identified as a technique to control bleeding in hemodynamically unstable patients with pelvic fractures.^{1,4,7} It is a quick and effective procedure. In experienced hands, EPP can be performed in less than 20 minutes in either the operating room (OR) or emergency department (ED). Extraperitoneal pelvic packing was originally described in Germany in 1994, with subsequent demonstration of a significant reduction in mortality compared with patients managed without pelvic packing.⁸ Its most important role may be in controlling venous bleeding.⁹

In recent years, REBOA has emerged for temporary bleeding control in patients in “extremis”: it is an endovascular technique proposed as an alternative to control pelvic bleeding—when placed Zone 3—and animal models have shown REBOA can effectively control pelvic arterial hemorrhage.^{10,11} However, REBOA is not universally available. In addition, while REBOA helps control shock in bleeding patients, it is associated with complications like ischemia-reperfusion injury, vascular injury, and amputation. Its role must be evaluated by future studies.¹²

The aim of this study was to investigate the global efficacy of EPP in patients in hemorrhagic shock after pelvic trauma. Our hypothesis was an increase in survival rate after introduction of EPP in the management protocol: the primary endpoint was mortality, at 24 hours and overall, the secondary endpoint was the hemodynamic impact of the procedure.

METHODS

With more than 800 trauma activation patient per year, Niguarda Hospital Trauma Center is the largest level I trauma

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center in Italy. Data from all trauma activation patients are collected in Trauma Registry.

All trauma patients sustaining blunt trauma with a pelvic fracture and hemodynamic instability from 2002 to 2018 were studied. Demographic data, mechanism of trauma, systolic blood pressure (SBP), mean arterial pressure (MAP), Injury Severity Score (ISS), need for damage control laparotomy, type of pelvic fracture, associated extra-pelvic injuries, head, chest, abdomen and extremities Abbreviated Injury Scale (AIS) (1998 version) score, EPP-related infections, length of stay in intensive care unit (ICU), length of hospitalization, 24-hour and overall mortality were evaluated.

Hemodynamic instability was defined as an SBP less than 90 mm Hg despite pelvic binder, adequate fluid resuscitation (1,000 mL of intravenous crystalloids as stated by Advanced Trauma Life Support—ATLS manual) and transfusion of 2 units or greater of packed red blood cells (PRBCs).¹³ The pattern of pelvic fracture was classified according to Tile and Young & Burgess classifications. Exclusion criteria were a concomitant severe brain injury (AIS brain >3), patients who underwent resuscitative thoracotomy, penetrating trauma, and younger than 14 years (Fig. 1).

Until 2009, the management of patients sustaining pelvic ring fracture and hemodynamic instability was compression with a pelvic binder at the level of the greater trochanters, laparotomy for a positive Extended-Focused Assessment with Sonography for Trauma, external fixation placed at the anterior inferior iliac spine, and AE for persistent instability or positive contrast-enhanced computed tomography for arterial bleeding (Fig. 2A).

In 2009, early EPP was introduced in the treatment protocol. Patients with pelvic fracture and persistent hypotension despite pelvic binder (placed after primary survey in ED or even in pre-hospital setting by EMS personnel) and two units of 0-negative PRBCs had immediate EPP (if needed within the trauma bay), followed by external fixation and AE when indicated by the presence of persistent hemodynamic instability or positive contrast-enhanced computed tomography. In particular, angiography was performed with contrast extravasation demonstration at the post-EPP imaging. If confirmed as a clear arterial bleeding, also AE was performed. Embolization procedures were performed alternatively with coils, gelatin sponge, or microspheres depending on the pelvic bleeding (Fig. 2B).

The surgical technique for EPP is performed via a vertical or transverse incision. The fascia is divided vertically. Afterward, two to three pads are placed on each side of the bladder neck below the pelvic brim in order to achieve a direct compression of the bleeding site. Fascial and skin incisions are closed.² Extraperitoneal packing was even performed in the ED/trauma bay, if the patient was deemed too unstable to be transported to the OR, from 2014 to 2018.

Based on the different treatment protocols adopted before and after 2009, the sample was split into a no-EPP and an EPP group. Data were recorded in a computerized spreadsheet (Microsoft Excel 2016; Microsoft Corporation, Redmond, WA) and analyzed with statistical software (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY). Propensity score matching (PSM) was performed to adjust for differences in the baseline characteristics in the two groups.

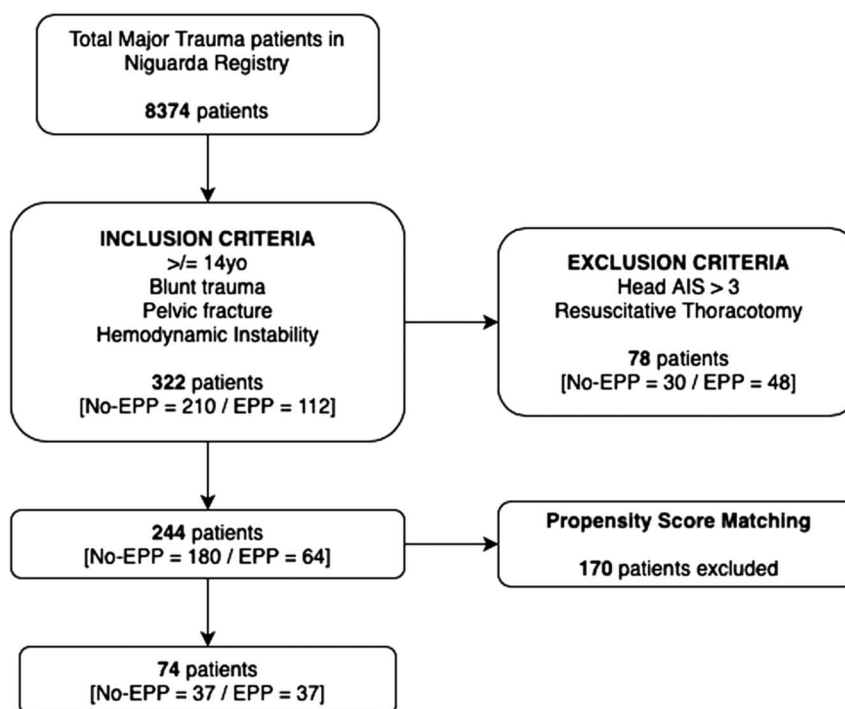


Figure 1. Flow Diagram of population selection.

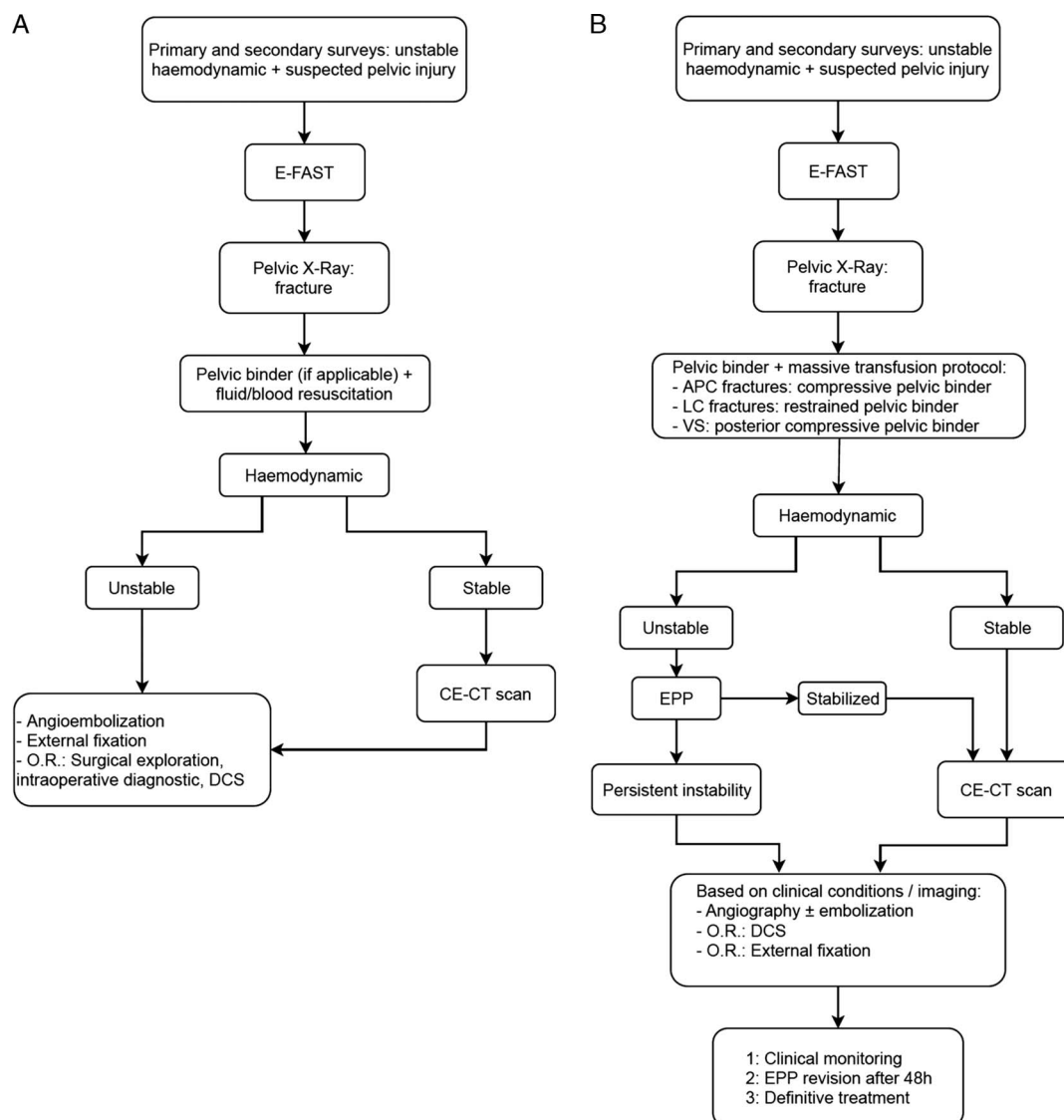


Figure 2. Management algorithm of hemodynamically unstable patients A) until 2009; B) from 2009 onward.

A one-to-one, nearest neighbor, logistic regression matching model was built setting the maximum tolerated difference between matched subjects (caliper) at 0.1 standard deviation (SD). Age, ISS, damage control laparotomy, abdominal and extremities injuries AIS score were selected as potential confounders and entered in the model. Graphical (histogram of propensity score, dotplot of standardized differences) and mathematical (standardized differences) balance diagnostics were evaluated after matching for an accurate assessment of the goodness of our model.

The distribution of the sample per each variable of interest was assessed with Shapiro-Wilk test. Differences in proportions were evaluated with Pearson's χ^2 or Fisher's test, whereas independent samples Mann-Whitney test and Wilcoxon signed-rank test for repeated measurements were used to compare continuous variables.

A *p* value less than 0.05 was considered statistically significant.

Collection of data for the Niguarda Hospital Trauma Center Registry had been approved by the local ethical committee.

RESULTS

During the study period 8,374 major trauma patients were admitted to Niguarda Hospital Trauma Center. Three hundred twenty-two patients presented hemodynamically unstable, with a pelvic fracture. Utilizing the aforementioned exclusion criteria, 244 patients were selected from the registry, 180 of whom were in the no-EPP group, and 64 in the EPP group.

The most frequent mechanism of trauma was motor vehicle crashes (43.8%) and almost two thirds of the study population were men (65.7%). Tile C was the most common pattern of pelvic fracture and was present more frequently in the EPP group (82.8% vs. 53.9%; *p* < 0.001). The MAP was significantly higher in the no-EPP group (81.25 mm Hg vs. 49.92 mm Hg; *p* < 0.001). Patients in the EPP group sustained more severe

TABLE 1. Demographic, Trauma-Related Data and Comparison Between No-EPP and EPP Groups

Variables	No-EPP (n = 180)		EPP (n = 64)		p*
	Number/Mean	%/SD	Number/Mean	%/SD	
Sex					0.225
Male	122	67.8	38	59.4	
Female	58	32.2	26	40.6	
Age	39.14	18.98	53	19.81	<0.001*
ISS	25.07	14.81	43.25	10.14	<0.001*
Mechanism of trauma					<0.001*
Road accident	130	72.2	17	26.6	
Fall	23	12.8	27	42.2	
Pedestrian	—	—	16	25	
Cyclist	—	—	4	6.3	
Work accident	11	6.1	—	—	
Domestic accident	7	3.9	—	—	
Sport accident	6	3.3	—	—	
Crime	3	1.7	—	—	
Type of pelvic fracture (Tile)					<0.001*
A	35	19.4	1	1.6	
B	48	26.7	10	15.6	
C	97	53.9	53	82.8	
MAP in ED**	81.25	20.35	49.92	17.12	<0.001*
Associated extrapelvic injuries AIS ≥ 3†	98	54.4	56	87.5	<0.001*
AIS, 98 (median/IQR)					
Head	0	2	0	2	0.1
Chest	2	3	3	2	0.063
Abdomen	0	2	3	2	<0.001*
Extremities	3	1	5	0	<0.001*
Outcome					<0.001*
Survived	161	89.4	44	68.8	
Dead	19	10.6	20	31.3	

*Significant value.

**First measurement.

†All patients sustaining abdomen, chest and extremities critical injuries.

abdominal and extremities injuries ($p < 0.001$ for both). Further characteristics of the sample are summarized in Table 1.

Looking specifically at eligible EPP group, we registered 34 extraperitoneal pelvic packing performed in the OR from 2009 to 2014, before protocol changed and other 30 were performed directly in ED.

Thirty-seven couples of patients were eligible after PSM. Graphical assessment of balance before and after matching is

displayed in Figure 2. For a more objective evaluation of balance diagnostic, we computed standardized differences of the selected confounders. For all covariates we observed a small effect size, defined by a standardized difference value below 0.2 after matching (Table 2).

A total of 24 of 74 patients died: 7/37 (18.9%) patients in the EPP group died in the first 24 hours, compared with 15 (40.54%) of 37 patients in the no-EPP group ($p = 0.042$). Only

TABLE 2. PSM Detailed Balance

	Means Treated		Means Control		SD Control		Std. Mean Diff.	
	Before	After	Before	After	Before	After	Before	After
Propensity	0.619	0.597	0.137	0.585	0.246	0.167	3.036	0.073
Age	53.338	51.162	39.022	49.919	18.870	21.725	0.721	0.063
ISS	43.108	44.622	25.144	43.216	14.721	13.869	1.774	0.139
Abdominal AIS	2.369	2.676	1.294	2.405	1.538	1.739	0.690	0.174
Extremities AIS	4.938	4.919	3.333	4.919	1.073	0.277	6.628	0.000
DC laparotomy	0.415	0.378	0.161	0.378	0.369	0.492	0.512	0.000

DC, damage control; Std, standard; Diff, difference.

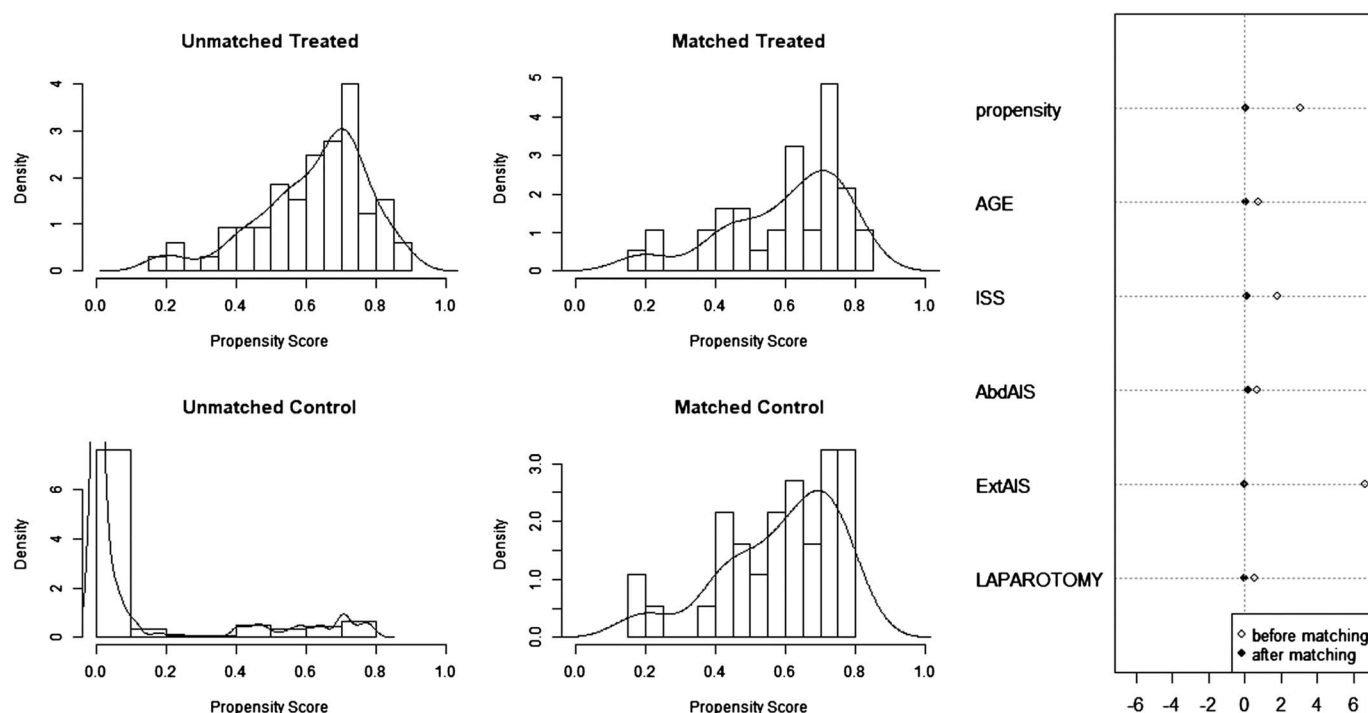


Figure 3. (A) Histograms of propensity score; (B) Dotplot of standardized differences.

one patient per group died after 24 hours, with an overall mortality rate of 21.6% for the EPP group, in contrast to 43.2% in the no-EPP ($p = 0.047$). Both patients died in ICU from septic complications (Fig. 3).

The time from ED admission to the start of the hemostatic procedure was significantly shorter in the EPP group with a mean time of 49.43 minutes ($p < 0.001$). Both length of stay in ICU and total length of hospitalization were longer in the EPP group ($p = 0.02$ and 0.012 , respectively). No differences between the two groups were observed in terms of number of diagnostic angiograms performed, the number of patients who had embolization and those treated with external fixation. Although not statistically significant, EPP patients surviving at least 24 hours received a lower mean amount of PRBCs (8.08 vs. 11.28) compared with those in no-EPP group. They also had lower Revised Trauma Score values (5.28 vs. 6.06). Details are reported in Table 2.

Considering the whole EPP subset (64 patients), we evaluated the hemodynamic improvement before and after EPP was performed. The comparison between repeated measurements of preprocedural and postprocedural SBP (65.87 ± 21.5 vs. 94.25 ± 32.54 ; $p < 0.001$) and MAP (49.92 ± 17.12 vs. 70.05 ± 25.07 ; $p < 0.001$) demonstrated a highly significant increase in blood pressure after EPP (Table 3).

Five (7.8%) of 64 patients in our series developed pelvic infection. This condition was defined as a microbiological contamination of the pads used for packing—routinely sent to laboratory for microanalysis when removed at surgical packing second-look (after 48–72 hours, depending on patient physiological condition)—associated with at least one of the following criteria: leukocytosis ($>15,000$), fever ($>38^\circ\text{C}$), and/or elevated C-reactive protein (>10 mg/L). In addition, no difference was

noticed matching patients who sustained EPP in OR versus ED setting. Patients sustaining infections from any clearly recognizable focus were excluded from this calculation.

In the whole EPP sample, the mean probability of death estimated by Trauma ISS system was 55.78%. Twenty of 64 patients died with an observed death rate of 31.25%. This leads to an absolute difference of 24.53% between estimated and observed mortality.

DISCUSSION

In 2015, an American Association for the Surgery of Trauma multinational trial surveyed the methods used in clinical practice of bleeding control, in order to determine any difference in mortality or patient outcome.¹⁴ In North America, the most common therapeutic approach was pelvic AE and stabilization of the fracture. In some trauma centers, EPP has emerged as an alternative to control the bleeding, and recently REBOA has been considered as a “bridge-technique” to control pelvic hemorrhage.^{15,16} World Society of Emergency Surgery (WSES) guidelines suggest EPP should always be considered, as first step of a multimodal approach followed by temporary mechanical stabilization or AE.

Our study demonstrates that EPP is an effective technique to manage pelvic fractures with hemodynamic instability. This is the largest series of EPP in Europe. EPP was associated with reduced mortality, improvement in blood pressure and was performed more quickly when compared with AE. Thus, EPP should be considered as a first choice, potentially life-saving procedure in patients not responding to pelvic binder and initial resuscitation.

TABLE 3. No-EPP and EPP Groups Comparison After Propensity Score Matching

Variables	No-EPP (n = 37)		EPP (n = 37)		p
	Number/Mean	%/SD	Number/Mean	%/SD	
Sex					0.326
Male	27	73	22	59.5	
Female	10	27	15	40.5	
Mechanism of trauma					<0.001*
Road accident	27	73	9	24.3	
Fall	9	24.3	15	40.5	
Pedestrian	0	0	9	24.3	
Cyclist	0	0	4	10.8	
Domestic accident	1	2.7	0	0	
ICU-LOS (days)	12	17.25	30.35	35.57	0.02*
Length of hospitalization	33.65	34.97	64	55.79	0.012*
No. angiography	21	56.8	21	56.8	1
No. embolization	8	21.6	6	16.2	0.147
No. external fixations	21	56.8	27	73	0.223
Time to emergency procedure (min)**	155.9	95.11	49.43	24.97	<0.001*
SBP in ED	82.95	27.9	65.73	17.79	0.004*
HR in ED	97.32	30.53	105.03	22.83	0.332
No. PRBCs <24 h	11.28	10.18	8.08	6.74	0.368
RTS	6.06	1.69	5.28	1.98	0.077
Probability of death (TRISS)	50.69	31.75	57.02	31.12	0.333
Deaths ≤24 h	15	40.54	7	18.92	0.042*
Total deaths	16	43.24	8	21.62	0.047*

*Significant value.

** Time elapsed from the admission in ED to the end of the emergency procedure.

ICU-LOS, length of stay in ICU; HR, heart rate; RTS, Revised Trauma Score; TRISS, Trauma and Injury Severity Score.

We utilized PSM, one of the most reliable statistical methods to minimize selection biases. Since its first description in 1983, PSM has progressively gained popularity in the scientific literature.¹⁷ It is largely based on a logistic regression model whose outcome expresses the probability of receiving a specific treatment, mimicking a quasi-randomization.

The comparison between EPP and no-EPP revealed significant differences in early and total deaths. We observed a mortality rate of 18.9% in the EPP group in the first 24 hours and 21.6% overall, compared with an early mortality rate of 40.54% and an overall of 43.2% in the no-EPP group. Moreover, patients in the EPP group had a shorter time to start of the hemostatic procedure, measured as the time from the ED admission to the end of the emergency procedure, with a mean time of 49.43 minutes compared with 156 minutes in the no-EPP group ($p < 0.001$). We compared pre- and post-procedural hemodynamic condition in the EPP Group. Packing was effective in improving SBP and MAP, with highly statistical significance ($p < 0.001$).

Our results are similar to others already reported. An American Association for the Surgery of Trauma (2016 plenary paper by Burlew et al. reviewed an 11-year patient series (128 EPPs performed) with an overall mortality rate of 21%, and a previous paper from our group demonstrated a 20% mortality within 24 hours and a higher overall mortality (28%, 7/25) compared to our current data.^{9,17,24} Li et al.¹⁸ compared 29 patients treated with EPP with 27 treated with AE: they observed a mortality rate with packing of 13.8% (4/29), compared to 18.5% in patients treated with endovascular procedure. More recently,

Magnone et al.¹⁹ reported a 30% mortality with EPP at 24 hours, higher than our series.

We also demonstrated a significant improvement both in SBP and in MAP after EPP. Studies by Tötterman et al.²⁰ and Jang et al.²¹ also reported increases in SBP of 19 mm Hg ($p < 0.001$) and 51 mm Hg ($p = 0.002$), respectively. These results demonstrated pelvic packing is effective increasing blood pressure, allowing a definitive or temporary hemodynamic stabilization in badly hypotensive patients.

In our series, we also observed in the EPP group a transfusion requirement of 8.08 units, compared with the no-EPP group requirement of 11.28 units. These results were not significant, probably due to the small size of our population; further study would be necessary to demonstrate if EPP reduces transfusion requirements.

Delay in hemostatic procedures for life-threatening pelvic hemorrhage is associated with increased mortality. Angioembolization seems to take much longer than EPP. Osborn et al.⁷ reported a mean time to EPP of 44 minutes from the ED admission, compared with a mean of 130 minutes to the AE suite. Similar timing was seen in a Korean study by Jang et al.,²¹ with mean time of 55 minutes to perform EPP compared with 194 minutes for no-EPP procedure. Similar results were also seen in a Chinese series (77 minutes to packing and 102 to AE) and in the recent Italian study by Magnone et al., with a reported time to pelvic packing treatment of 63 minutes.^{18,21,25} Tesoriero et al.,³ observing all the endovascular procedure performed, reported a median time to angiography of 286 minutes

at Shock Trauma Center in Baltimore. In our center, until 2014, EPP was performed in the OR. We have recently done EPP in the ED in patients with refractory hypotension. This may reduce the time to hemostasis. Finally, in our study, EPP was demonstrated as a safe procedure with the least number (5/64, 7.8%) of EPP-related infections in the medical literature. Thus, it seems EPP is not only safe and effective, but also much faster than all the other possible treatment options.

Intelligent care of patients in hemorrhagic shock from pelvic fracture bleeding may vary from institution to institution. Adjuncts, such as AE and use of REBOA, although potentially quite useful, may not be available in every institution. These adjuncts may not be instantly available as is needed for patients with life threatening hemorrhage. Extraperitoneal packing has the advantage of being able to be performed quickly and in any OR. The surgical technique is not particularly difficult. General surgeons should be able to perform it with a little additional training.

However, in institutions where AE is immediately available, the role for EPP may be substantially complementary to endovascular one, just prior—especially if performed in ER—in a multidisciplinary management of pelvic trauma. Resuscitative endovascular balloon occlusion of the aorta can achieve temporary stability as a bridge to AE, similar to EPP. Strategies, such as having acute care surgeons trained in vascular intervention, may make AE more readily available. Recent data suggest that surgeon performed trauma vascular intervention statistically significantly reduces time to start of intervention for time sensitive conditions.²² Thus, each institution will need to tailor care for these patients in a manner that maximizes use of local resources and expertise.

This study has several weaknesses. First, it is a retrospective analysis of data. Second, there may be a bias in the long period of observation (2002–2009 and 2009–2018). During this time, there have been several other modifications in the management of these patients. Our resuscitation strategy evolved from crystalloids to PRBCs, a new Massive Transfusion Protocol has been developed and we have started performing EPP, when necessary in the ED, not just in the OR. However, EPP has been identified as a key part in the new protocol, and it would seem to have a clear role in the increased survival rate and in the hemodynamic improvement observed.

We studied a large population: only Moskowitz's study in 2018 has more patients treated with EPP and no center in Europe has a comparable population.²³ By using the Propensity Score Analysis, we were able to obtain a quasi-randomization selection of patients, matching principal confounder factors and obtaining a statistically significant result.

CONCLUSION

Extraperitoneal packing is an effective procedure that improves hemodynamics and overall survival in patients who sustain severe pelvic blunt trauma. Extraperitoneal packing is safe, easy-to-perform by surgical personnel and faster than any other therapeutic option. The early use of EPP is lifesaving.

In view of its immediate effect, EPP can be the first step of a multidisciplinary management of pelvic ring disruptions: it

could be a time-gaining “bridge technique” for a subsequent diagnostics and hemostatic procedures.

Other studies are needed to understand if new techniques, such as REBOA, have the same role in bleeding control as EPP or if they are only alternatives for settings where packing cannot be performed.

AUTHORSHIP

S.F., S.G., S.G., S.C., F.S., T.M.S., and O.C. participated in the study conception, study design, and analysis of data. S.F., S.G., S.G., T.M.S., O.C. contributed to the drafting of the article. All authors participated in critical revisions.

DISCLOSURE

The authors declare no funding or conflicts of interest.

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DISCUSSION

JOERGEN JOAKIM JOERGENSEN, M.D. (Oslo, Norway): I want to thank the AAST for the privilege of discussing this interesting paper, and Dr. Frassini and his group for submitting the manuscript in a timely manner.

The authors are presenting a single center retrospective study over 17 years from 2002 to 2018 comparing outcomes of the 64 patients undergoing EPP in the ER after the procedure was implemented in 2009, with all the 180 other unstable pelvic fractures admitted during the same study period.

Since these two groups of patients were not comparable, they performed a propensity score matching, yielding a total of 37 patients in the EPP and 37 patients in the non-EPP group. A comparison of the matched groups revealed a significant survival benefit in the EPP group of 81 percent versus 60 percent in the no-EPP group; however, the numbers are small.

The authors conclude that EPP can be safely and effectively performed in the ER, and that it is an effective tool in achieving hemostasis. The authors suggest EPP as the procedure of choice for damage control in pelvic bleeding. I have several questions to the authors.

Question Number 1: The authors describe that implementation of the updated massive transfusion strategies occurred during the same time period as they started performing EPP; yet they report no data on resuscitation or physiology except systolic blood pressure. Please present data on fluid resuscitation and physiology.

Question Number 2: The authors describe hemodynamic instability as a requirement for inclusion in the study. The way I read the paper, all included patients after 2009 fulfill the criteria

for EPP. How many of the patients in the no-EPP group were treated after 2009, and why didn't they undergo EPP, since they fulfilled the inclusion criteria?

Question Number 3: The authors' protocol mandates packing after as little as two units of packed red blood cells. Our experience is that more blood products are needed to catch up with the decompensation caused by the tissue injury per se in patients with major pelvic fractures, also in patients without significant bleeding sources identified on subsequent CT scans.

One plenary session paper four years ago from Dr. Gaski from our institution demonstrated the virtually vanishing need for EPP due to improved resuscitation protocols in patients who would previously have been packed.

It raises the question about whether some of the existing protocols with mandatory EPP after transfusion of two units of packed red blood cells are too aggressive. Please comment.

Question Number 4: The authors claim causality between the packing procedure and hemodynamic improvement as well as increased survival. What in the presented data provides support to your conclusions?

And the last question: The authors describe that they performed logistic regression analysis to identify eventual independent predictor of mortality. What did the logistic regression analysis show?

Again, I want to thank for the privilege of the podium, and congratulate the authors on a well-presented study. Thank you.

ASSAD TAHA, M.D. (Boston, Massachusetts): I commend you on this, you know, tackling this difficult problem. Going forward, I think it would make more sense to use both REBOA and pre-peritoneal packing, and if you have capacity in the emergency room, that would be ideal, especially if you, in a situation where you can't transfer the patient, that will be the best.

And my question is do you have any complications from the EPP, doing it in the ER?

CLAY COTHREN BURLEW, M.D. (Denver, Colorado): I want to congratulate you. I believe this is the largest series out of Europe, and I really appreciate your very clear protocol and indication for performing pelvic packing. I have two questions.

The first, what do you think the role of external fixation is in these patients, and does it facilitate your packing and your outcomes?

And secondly, you are much braver than we have been, doing pelvic packing in the emergency room.

Which patients do you decide to pack in the emergency room versus in the operating room?

Excellent job.

SIMONE FRASSINI, M.D. (Milan, Italy & Baltimore, Maryland): First I want to thank Dr. Joergensen for discussing the paper, and the audience for all the questions. I'll address point by point, starting from the audience questions. About Dr. Taha's question, about the complications in the packing and the possibility to use REBOA together with packing; I think this one is a valid point of view and in the future should be reality also in our extra-American setting. But for now, we don't have in our institution any kind of emergency endovascular facility such as REBOA. So, our protocols started from the packing and for now this technique is the only available. We are thinking and we are working on the implementation of REBOA, but right

now we still don't have, and so our protocol is only including packing. About complications, we are working on a paper, looking at complication rate in the packing procedure performed in the emergency department versus the operating room. There is not increase in infections performing in ED, and we are demonstrating how it is absolutely safe from the infections point of view. In addition, there were not any other kind of complications doing this kind of surgical procedure in the emergency department instead of the operating room.

Looking at Dr. Burlew's comments about inclusion criteria and the location we normally decided to perform packing,

it is our protocol: in case of a clear pelvic fracture with unstable hemodynamic condition—demonstrated after the primary survey and pelvic x-ray—it is mandatory to perform the packing, even directly in ED. Then, if the hemodynamic has improvement, more imaging technique can be performed in order to understand which is the most appropriate emergency treatment. Then, in our setting, External Fixation—and generally all the orthopedic traumatic treatment—has a fundamental role but subordinate to surgical control of bleeding. It's a crucial part of Damage Control Surgery, but temporary after hemodynamic resuscitation with Packing and eventually transfusions.