Preperitoneal pelvic packing reduces mortality in patients with life-threatening hemorrhage due to unstable pelvic fractures

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BACKGROUND: A 2015 American Association for the Surgery of Trauma trial reported a 32% mortality for pelvic fracture patients in shock. Angioembolization (AE) is the most common intervention; the Maryland group revealed time to AE averaged 5 hours. The goal of this study was to evaluate the time to intervention and outcomes of an alternative approach for pelvic hemorrhage. We hypothesized that preperitoneal pelvic packing (PPP) results in a shorter time to intervention and lower mortality.

METHODS: In 2004, we initiated a PPP protocol for pelvic fracture hemorrhage.

RESULTS: During the 11-year study, 2,293 patients were admitted with pelvic fractures; 128 (6%) patients underwent PPP (mean age, 44 ± 2 years; Injury Severity Score (ISS), 48 ± 1.2). The lowest emergency department systolic blood pressure was 74 mm Hg and highest heart rate was 120. Median time to operation was 44 minutes and 3 additional operations were performed in 109 (85%) patients. Median RBC transfusions before SICU admission compared with the 24 postoperative hours were 8 versus 3 units ($p < 0.05$). After PPP, 16 (13%) patients underwent AE with a documented arterial blush.
Mortality in this high-risk group was 21%. Death was due to brain injury (9), multiple organ failure (4), pulmonary or cardiac failure (6), withdrawal of support (4), adverse physiology (3), and Mucor infection (1). Of those patients with physiologic exhaustion, 2 died in the operating room at 89 and 100 minutes after arrival, whereas 1 died 9 hours after arrival.

CONCLUSIONS: PPP results in a shorter time to intervention and lower mortality compared with modern series using AE. Examining mortality, only 3 (2%) deaths were attributed to the immediate sequelae of bleeding with physiologic failure. With time to death under 100 minutes in 2 patients, AE is unlikely to have been feasible. PPP should be used for pelvic fracture–related bleeding in the patient who remains unstable despite initial transfusion. (*J Trauma Acute Care Surg.* 2017;82: 233–242. Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic study, level IV.

KEY WORDS: Trauma; pelvic fracture; preperitoneal pelvic packing; hemorrhage; angioembolization.

Despite advances in the care of the critically injured patient, mortality rates for patients with hemodynamic instability due to pelvic fractures remain greater than 30% in modern series,[1–8] with up to one third of patients dying due to uncontrolled hemorrhage.[9–13] The most recent analysis, a multicenter observational study by the American Association for the Surgery of Trauma (AAST), reported a 32% mortality rate for complex pelvic fracture patients who presented in shock.[14] The majority of trauma centers in that study, and in the United States, emphasize angioembolization (AE) for primary hemorrhage control.[14–16] Although AE is effective in controlling arterial sources of hemorrhage, it does not address the venous or bony hemorrhage within the pelvis.[17] Ideally, diagnostic angiography of the pelvis would be performed in a hybrid operating room (OR) while addressing other sources of acute blood loss, as well as restoring pelvic bony stability, in the multiply injured patient. This, however, is not currently a reality in many trauma centers. Additionally, time to arterial hemorrhage control using AE, even in the most advanced Level I trauma centers with hybrid facilities requires 3 to 5 hours to accomplish, particularly on nights and weekends.[18,19]

Preperitoneal pelvic packing (PPP) combined with external fixation (EF) has been advocated to rapidly arrest hemorrhage, facilitate other emergent operative procedures, and provide an efficient use of AE.[19–26] We implemented PPP because despite protocolized care using hemostatic resuscitation, pelvic stabilization, and emergent angiography,[27] patients continued to die acutely of hemorrhage. Several international studies have reported equivalence[24,28] or a reduction[29,30] in mortality in patients undergoing PPP compared with AE. The goal of this study was to evaluate the time to intervention and outcomes of an operative approach to hemorrhage from pelvic fractures. We hypothesized direct PPP results in a shorter time to intervention and lower mortality in our institution.

METHODS

Since September 2004, all patients at our American College of Surgeons-verified and state-certified Level I urban trauma

Submitted: August 31, 2016, Revised: October 25, 2016, Accepted: October 25, 2016, Published online: November 23, 2016.

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This study was presented at the 75th annual meeting of the American Association for the Surgery of Trauma, September 14–17, 2016, in Waikoloa, Hawaii.

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DOI: 10.1097/TA.0000000000001324

center (Rocky Mountain Regional Trauma Center at Denver Health) with persistent hemodynamic instability despite red blood cell (RBC) transfusion and a pelvic fracture underwent PPP/EF, according to our protocol (Fig. 1); local expertise with resuscitative endovascular balloon occlusion of the aorta (REBOA) was introduced to the protocol in January 2015. Indication for PPP is persistent systolic blood pressure (SBP) <90 mm Hg in the initial resuscitation period despite the transfusion of 2 units of packed RBCs. Initial stabilization of the pelvis is performed in the emergency department (ED) with pelvic sheeting or a binder. Skeletal fixation of the pelvis with an external fixator or pelvic C-clamp is done concurrent with PPP in the OR. Additional operative procedures, such as thoracotomy or laparotomy for hemorrhage, were performed at the initial PPP operation as indicated. Patients with prehospital arrest or those undergoing ED resuscitative thoracotomy were included for descriptive purposes but excluded from the analysis.

Our technique of PPP has been described previously.[20,31] Angiography is performed for ongoing pelvic bleeding, defined as (1) greater than 4 units of RBCs after the patient's coagulopathy is corrected or (2) ongoing hemodynamic instability despite PPP/EF. Restoration of coagulation is guided by thromboelastography (TEG).[32] Pelvic pack removal is performed at 24 to 48 hours once physiologic restoration is complete. Repacking of the pelvis is avoided due to infectious risks.

All patients undergoing PPP/EF have been prospectively followed since the initiation of PPP as our primary hemorrhage control technique for unstable pelvic fractures. The study period for this analysis encompassed an 11-year period from September 1, 2004, to September 1, 2015. An initial report on the first 5 and a half years of experience was published in 2011.[21] Patient demographics, admission physiology, transfusion requirements, need for angiography, and hospital course were reviewed. The Young and Burgess classification was used to categorize fracture patterns.[33] Normally distributed data are expressed as mean (standard error of the mean); non-normally distributed data are expressed as median (range). The Colorado Multi-Institutional Review Board approved this study.

RESULTS

During the 11-year study period, 138 (6%) consecutive patients in refractory shock underwent PPP/EF among 2,293 patients admitted with pelvic fractures. The majority (70%) of patients were severely injured men, with a mean age of 44 ± 2 years and mean ISS of 48 ± 1.2. The most common mechanism was motor vehicle collision (42), followed by an autopedestrian accident (37), motorcycle collision (27), fall (12), crush injury (9), and other (11).

Patients With Prehospital Arrest/ED Resuscitative Thoracotomy

Of the 138 patients who underwent PPP, 10 patients had prehospital arrest and/or underwent ED resuscitative thoracotomy. The majority (60%) of patients were men, with a mean age of 45 ± 4 years and mean ISS of 56 ± 4. Mechanisms of

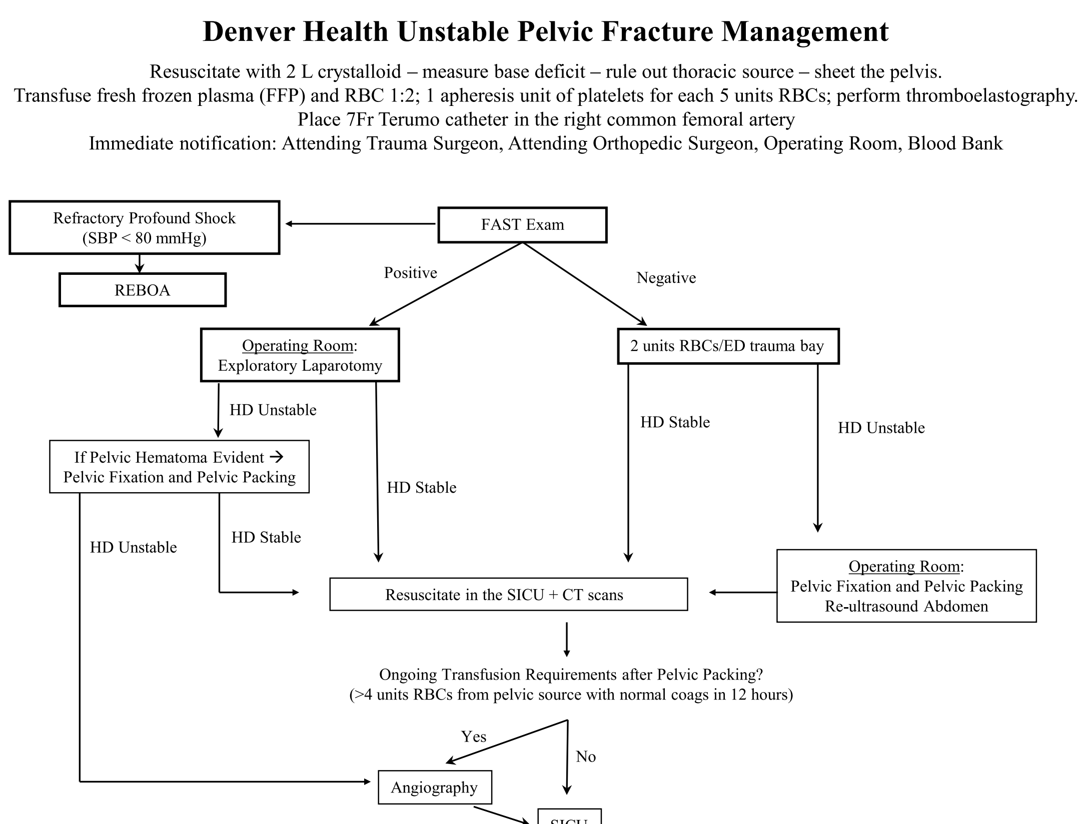

Figure 1. Management algorithm for patients with hemodynamic instability with pelvic fractures.

injury included autopedestrian accident (5), motorcycle collision (2), motor vehicle collision (1), fall (1), and bicycle crash (1). Plain radiographs were obtained in 7 patients; pelvic fracture classification included lateral compression (LC) III (4), LC II (2) and LC I (1) patterns. Survival rate to hospital discharge was 30%; all underwent EDT. Of those who died, one patient survived 11 days in the intensive care unit (ICU) only to succumb to multiple organ failure. The remaining six patients died within the first 24 hours. There was no significant difference in age, ISS, length of time in the ED, or number of RBCs transfused in the ED between survivors and nonsurvivors.

Hemodynamically Unstable Patients With Pelvic Fractures

For the remaining 128 patients, 70% were men with a mean age of 44 ± 1.7 years and a mean ISS of 48 ± 1.2. Pelvic fractures patterns included anterior posterior compression (APC) III (29), LC II (26), LC III (20), APC II (20), LC I (13), vertical shear (14), APC I (4), and CM (2). Of these, 18 patients had open pelvic fractures. In addition to their pelvic injuries, 43% of patients had associated head injuries, 65% thoracic injuries, 63% abdominal injuries, 70% extremity injuries, and 38% spine injuries. Mean ED SBP was 74 ± 2 mm Hg, and heart rate (HR) was 120 ± 2. Mean base deficit in the ED was 12 ± 5; however, 41 (32%) patients did not have an arterial blood gas recorded during this time. After the introduction of REBOA in January, 2015, three of seven patients undergoing PPP had a REBOA placed in the ED. Median time to operation was 44 minutes (range, 0–274) and an additional 3 ± 0.2 operative procedures were performed in 109 (85%) patients in addition to PPP/EF. Median blood transfusion requirements before SICU admission compared with the subsequent 24 postoperative hours were eight units versus three units ($p < 0.05$). Fresh frozen plasma (FFP)/RBC ratio was 1:2. Overall mortality for all 2293 pelvic fracture patients was 8%; in this group with refractory shock, there was a 21% overall mortality rate with 2% of the patients dying within hours of admission due to physiologic exhaustion.

Angiography and Therapeutic Embolization

During the study period, 35 (27%) patients underwent diagnostic angiography after PPP. Angiography was performed in 31% of patients during the first half of the study and 23% of patients in the second half of the study. Of these, 16 (13%) patients underwent AE with a documented blush; 19 (54%) of 35 patients undergoing diagnostic angiography had no evidence of arterial bleeding. The mean time to AE was 10 hours after admission (601 ± 200 minutes; range, 175–2280 minutes). Of those undergoing AE, pelvic fractures classifications were LC I (4), APC III (2), LC II (4), LC III (2), APC II (2), and vertical shear (2). Empiric embolization was performed in 7 of the 19 patients without evidence of a blush at angiography. One patient with empiric embolization of bilateral internal iliac arteries developed perineal necrosis (Fig. 2).

There were no significant differences in age, ISS, presenting hemodynamics (SBP, base deficit), or ED blood product transfusions between those who had an arterial blush at angiography (AE group) versus those that did not undergo AE (NA group). The only variable that reached statistical significance was a *lower* ED HR in the AE group compared with those patients not undergoing angiography (AE group 110 ± 6 beats/min vs. NA group 121 ± 3 beats/min; $p = 0.05$). The AE group did receive more RBCs and FFP pre-SICU admission (AE group 14 ± 2.5 units RBCs and 8 ± 1.6 units FFP versus NA group 9 ± 0.8 units RBCs and 4 ± 0.5 units FFP) and more RBCs and FFP in the subsequent 24 hours (AE group 8 ± 1.6 units RBCs and 5 ± 1.0 units FFP vs. NA group 3 ± 0.5 units RBCs and 2 ± 0.4 units FFP) than the NA group. No patient undergoing diagnostic angiography or AE died from acute blood loss or early physiologic derangements.

Figure 2. Perineal necrosis after empiric embolization of bilateral internal iliac arteries.

Pelvic Space Management and Complications

Most patients (84%) underwent a single operative packing of the preperitoneal space. Over the study period, 20 (16%) patients underwent repacking of the pelvis when returned to the OR; indication for repacking of the pelvis was persistent oozing deep in the preperitoneal space upon pack removal. All of the patients who had repacking of the pelvis occurred before July 2011. In these 20 patients, repeat packing was performed in one patient that returned to the OR within 12 hours, five patients returned to the OR between 12 and 24 hours, and 14 patients between 24 and 48 hours.

There were 15 (12%) pelvic space infections. Four infections (three polymicrobial, one Bacillus) occurred in patients with open fractures or those with perineal degloving injuries (n = 6); one patient underwent hardware removal 26 months postinjury. Four infections developed in patients with associated bladder injuries (*E. coli*, Candida, stenotrophomonas/Enterococcus/Candida, and Enterococcus/*E. coli*); none of these patients required hardware removal. Seven pelvic space infections occurred in patients without bladder or bowel injuries (Enterobacter/Enterococcus, Pseudomonas/Staphlycoccus, Staphlycoccus, MRSA, Enterobacter, Acinetobacter, and polymicrobial); two patients had hardware removed at 38 days and 16 months postinjury. There was a difference in pelvic space infection rates between those patients requiring repacking of the pelvis (9 [45%] of 20 patients) and those who had a single packing of the pelvis (6 [6%] of 108 patients).

Patient Outcomes

Overall, patients required 4 ± 0.3 units of PRBCs during their median ED course of 44 minutes. Median blood transfusion requirements prior to SICU admission compared with the subsequent 24 postoperative hours were eight units versus three units ($p < 0.005$). Transfusion of FFP to RBC ratio was 1:2. Patients required a mean of 12 ± 0.9 days of mechanical ventilation and remained in the surgical ICU for 15 ± 1.1 days. Overall length of hospital stay was 25 ± 1.7 days. Excluding those who died, patients required a mean of 14 ± 1.1 days of mechanical ventilation and had ICU and hospital lengths of stay of 17 ± 1.2 and 31 ± 1.8 days, respectively.

Overall mortality for all 2293 pelvic fracture patients during the study period was 8%, with 27 patients (21%) dying in this high-risk group of 128 patients. Fracture classification of those who died included LC II (7), LC I (7), LC III (5), APC III (4), APC II (2), APC I (1), and CM (1). Death was due to traumatic brain injury (9), multiple organ failure (4), withdrawal of support by family (4), pulmonary failure (3), cardiac failure (3), refractory metabolic collapse (3), and invasive Mucor infection (1). Of those three (2%) patients with physiologic exhaustion, two died in the OR at 89 min and 100 minutes after hospital arrival, whereas one died in the ICU 9 hours after arrival.

The three patients that died acutely of refractory metabolic exhaustion had significant physiologic derangements. The first patient was an 18-year-old woman who sustained an LC I fracture as well as a grade V liver and a grade V renal injury. In addition to PPP, she underwent nephrectomy and liver packing. She had a pH of 6.9 and a base deficit of 30 mmol/L and went into ventricular fibrillation in the OR 100 minutes after arrival; despite a resuscitative thoracotomy and heroic efforts she died. The second patient was a 42-year-old man transferred from an outside facility with an LC II fracture. En route via helicopter he was receiving his sixth unit of RBCs. In the OR, his blood pressure initially stabilized after PPP; laboratory results revealed a pH of 7.0, base deficit of 17, lactate of 23, and INR of 5.4. Soon thereafter, he arrested, 89 minutes after arrival. The third patient was a 48-year-old man with an APC III fracture who despite an apparent isolated pelvic injury developed an uncontrolled coagulopathy. He had a pH of 7.0, base deficit of 20, and his INR was 8.5. His TEG never normalized before his death in the SICU.

There were no differences in ISS, presenting SBP, presenting HR, ED base deficit, time in the ED before PPP/EF, RBC transfusion in the ED, or number of additional procedures performed between those patients who lived versus those who died. FFP/RBC transfusion ratios were similar between the two groups (alive group, pre-SICU transfusion ratio of 1:2 versus dead group ratio of 1:2; alive group, subsequent 24 hour transfusion ratio of 1:1.5 vs. dead group ratio of 1:1.1). There was a difference between the two groups in mean patient age (alive, 42 ± 1.7 years vs. dead, 53 ± 3.8 years), RBC transfusion pre-SICU admission (alive, 8 ± 0.6 units vs. dead, 16 ± 1.9 units) and in the subsequent 24 hours (alive, 3 ± 0.4 units RBCs vs. dead, 8 ± 1.5 units RBCs).

DISCUSSION

The purpose of this study was to evaluate the time to intervention and outcomes of an alternative approach to emergent AE for uncontrolled hemorrhage from pelvic fractures. Our group has had an interest in complex pelvic trauma since the early 1980s,[34] and we have critically reviewed our management over the past four decades. After that initial 1986 publication, we implemented a multidisciplinary clinical pathway in the 1990s which incorporated hemostatic resuscitation in a 1:1:1 ratio, pelvic stabilization, and emergent angiography.[27] Despite a marked reduction in mortality, we continued to have patients die acutely of hemorrhage. Having heard of its success in Europe, we adopted and modified the technique of pelvic packing combined with EF.[31] Patients with refractory shock, defined as persistent hypotension despite two units of RBC transfusion, were transported for PPP/EF. Median time to operation in this group was 44 minutes. After PPP/EF, there was a significant reduction in RBC transfusion in the 24 hours postoperatively compared to pre-SICU period. The 13% of patients treated with postpacking AE were temporized and resuscitated; AE was performed a mean of 10 hours after presentation. All-cause mortality in this multiply injured patient cohort was 21% with only 2% of the cohort dying acutely of physiologic exhaustion.

PPP as the first intervention for hemorrhage control in pelvic fracture patients with refractory shock has been advocated due to the recognition that 85% of the bleeding is not arterial.[17] Furthermore, PPP has the advantage of immediacy and rapidity of the procedure.[25,26,28] A small, quasi-randomized (based on time of day the patient presented) study of 56 hemodynamically unstable patients demonstrated a significantly faster time to operative packing and a shorter procedure duration compared with the angiography group.[28] A similar finding was reported in a small study of 24 patients from China; time to packing was 79 minutes, whereas time to angiography was 140 minutes.[24] Time to emergency angiography in a Korean evaluation of PPP was 194 minutes compared with 55 minutes with operative intervention.[3] Our group previously demonstrated that time to packing was significantly faster than time to angiography, with angiography taking three times longer despite interventional radiology availability at a Level I trauma center.[35] Our time to PPP in the current study, 44 minutes, is within the framework of these international publications. When compared with the time to angiography of 286 minutes[18] and 193 to 301 minutes[19] reported in the two most recent AE series, PPP is faster.

Timing to arrest of pelvic fracture hemorrhage is only one variable in the complex equation surrounding pelvic fracture management; the availability and location of angiography may also be a complicating factor. Ideally, a complex pelvic fracture patient in hemorrhagic shock is transported to a hybrid OR. This should be the standard for every Level I trauma center because it enables the clinicians to perform any operative or endovascular procedure warranted. Unfortunately, this is not a reality in many trauma centers; the ability to perform AE is often housed in interventional radiology which is geographically separate from the OR. In these scenarios, PPP affords one the ability to address pelvic hemorrhage while also addressing other needed urgent patient interventions, such as laparotomy, thoracotomy, fasciotomy, extremity vascular reconstructions, and fracture fixation. In fact, most patients in our study required at least three additional procedures at the time of the initial PPP/EF. Transporting a patient to the angiography suite limits or delays other essential operations.

There is a subset of patients that benefits from complementary AE. In our experience, 13% of patients underwent therapeutic AE after PPP/EF. This is not surprising because PPP may temporize arterial bleeding but does not directly address it, particularly as vasospasm resolves with resuscitation. PPP aids in stabilizing the patient to afford the time window for angiography to be performed. Time to angiography in this study, 10 hours after admission on average, is reflective of that stabilization period. Because AE was not considered a primary goal, and was only performed once the patient was transfused at least four units of RBCs postpacking, this is a descriptive variable rather than a recorded time to intervention variable. With a mean time to angiography of 10 hours, patients can undergo additional necessary operative procedures and even be transported to Level I trauma centers to undergo endovascular interventions. This stabilization after PPP is apparent in the transfusion requirements in the pre-SICU period compared with the 24-hour postoperative period. There was a significant reduction in the number of RBCs required after PPP/EF.

More recently, the reduction in mortality rates with PPP has been emphasized. In fact, our original impetus to change our pelvic fracture management algorithm[27] in 2004 was to lower our mortality rate further. Despite active involvement by the trauma and orthopedic services with clear protocols including pelvic stabilization and hemostatic resuscitation, as well as excellent angiographers, we still had patients that were dying on the angiography table. All of the comparative studies on PPP to date are small, single institution, internal analyses of available techniques. A single-center, longitudinal study identified a drop in mortality through three phases of management: 64% mortality during the preangiography phase, 42% in the angiography phase, and 31% in the PPP phase.[29] On multivariate analysis, PPP was a significant independent predictor for 24-hour survival. A similar reduction in mortality was identified with the institution of PPP, from 38% in the non-PPP group to a 14% mortality rate due to acute hemorrhage over a 3-year study.[3] Interestingly, those who died due to acute hemorrhage in the PPP group had actually undergone AE first only to require packing for ongoing hemorrhage and instability. In a propensity matched, comparative study of hemodynamically unstable pelvic fracture patients, mortality was significantly reduced with PPP compared with no-PPP (20% vs. 52%).[30] This cohort of patients was multiply injured, evidenced by an ISS > 40 for both groups and associated injuries in over 70%. Additional studies demonstrate mortality reduction rates of over 30% with PPP compared with AE but the findings are not significant due to small patient numbers.[24] Our own internal comparison of 20 patients undergoing PPP and 20 patients requiring AE demonstrated a faster time to intervention and a decrease in blood transfusions; mortality in the AE group was 30% with two patients dying of acute hemorrhage, whereas mortality in the PPP group was 13% and none died of acute hemorrhage.[35] Other groups report equivalent mortality rates between AE and PPP, but deaths due to exsanguination only occurred in the AE group.[28]

Because all of the aforementioned studies of PPP have an internal comparison of management strategies, what comparative group would provide a reasonable analysis to our single institution series on PPP? Because we have adopted PPP as our primary intervention for pelvic fracture patients with refractory shock, we felt that a comparison to the modern management of a similar group of patients in US trauma centers was appropriate. The recently published AAST prospective multicenter study is an evaluation of the current day management of pelvic fractures by 11 US trauma centers.[14] Of the 1,339 patients enrolled, only 178 patients met the criteria for shock defined as an SBP < 90 mm Hg, HR > 120, or BD > 6. Of these, 84% received at least one unit of RBC transfusion. Mortality in this group was 32% which is markedly higher than our reported mortality rate of 21% with PPP.

Is the comparison to the AAST multicenter study a good or valid one? First, contemporary prospective observational studies provide a benchmark of current practice standards. Second, our patients were more severely injured (Table 1). The AAST group we used for comparison was the 178 patients defined to be in shock: SBP < 90 mm Hg, HR > 120, or BD > 6. In reality, though, our study population consists of 128 patients who are in refractory shock despite two units of RBCs. This group appears to be a more physiologically deranged group with a higher ISS. The mean vital signs of the AAST group were a SBP of 91 mm Hg and HR of 116; the reported BD of 10 must

TABLE 1. Comparison of Available Demographics of the AAST Study Population[14] to This PPP/EF Study Population

	Denver Study of PPP/EF	AAST Study Population Patient Admitted in Shock
n (% of all pelvic fracture patients)	128 (6%)	178 (13%)
Age, y	44 ± 19	44 ± 20
Male, n (%)	90 (70%)	105 (59%)
ISS	48	28
Mechanism, n (%)		
Motor vehicle crash	41 (32%)	76 (43%)
Pedestrian vs. auto	32 (25%)	34 (19%)
Fall	11 (9%)	31 (17%)
Motorcycle crash	25 (19%)	28 (15%)
Crush	9 (7%)	2 (1%)
Other	10 (8%)	7 (4%)
SBP in ED, mm Hg	74 ± 18	91 ± 34
HR in ED, bpm	120 ± 23	116 ± 30
Base deficit	12 ± 5	10 ± 6
Patients requiring RBCs	128 (100%)	150 (84%)
Mortality, n (%)	27 (21%)	57 (32%)

Variables presented as mean ± standard deviation.

have been the primary determinant of the classification of shock in this group for the majority of patients. Our group had a mean SBP of 74 mm Hg and HR of 120. ISS was markedly different between the groups (AAST = 28 vs. our PPP group = 48); interestingly, the range of ISS scores for the AAST group was reported to be 17–38. Despite the differences in study population, the AAST study is the most current representation of modern day pelvic fracture management in the United States. As such, it is our best point of comparison despite the acknowledged limitations.

An alternate comparison is to a modern day series of pelvic fracture patients undergoing angiography.[18] Indications for angiography in this study included contrast blush on computed tomography (CT) scan (32%), pelvic hematoma (30%), and hemodynamic instability defined as a SBP < 90 mmHg (33%). With such a wide range on intervention "triggers", identifying a subset of this study group that is similar to our study population is critical. For those presenting with hemodynamic instability, mortality was 28% while those patients receiving a massive transfusion, defined as 10 units of RBCs in the first 24 hours, had a mortality rate of 41%. Our mean transfusion requirements in the PPP group were > 10 units of RBCs in the first 24 hours.

One of the difficulties of any analysis of pelvic trauma management is reflected in patient populations. Each study may have a slightly different interpretation of what constitutes hemodynamic instability or which patient should undergo an intervention for pelvic bleeding. For example, shock as defined by the AAST study was a slightly different population compared with our PPP group. Even when we compare our outcomes with PPP to our original report in 2001 on pelvic fracture management, the study populations are not comparable. The study population in the 2001 report had an ISS of 28, and only 52% had a SBP < 90 mm Hg. Additionally, mortality rates may be attributed to all causes of mortality versus only those related to acute hemorrhage. Only by delving into the specifics of the data on any one study will this become apparent. For example, our overall mortality rate was 21% but only 2% of the patient population expired in the first 24 hours due to adverse physiology. As is true in any series, overall mortality is multifactorial and the impact of early hemorrhagic shock can impact late causes of mortality, such as cardiopulmonary failure and MOF. Finally, as is true of many published series, this is a single institution's report and has the inherent limitations therein.

Our prospective observational study of patients with complex pelvic fractures permits one to reflect on the lessons learned. Technical aspects of the procedure are perhaps the easiest to incorporate. Early activation of the trauma and orthopedic teams is essential. Rapid transport to the operating room requires active involvement of both teams. External fixation before PPP provides stabilization of the bony pelvis, reduces the pelvic volume for packing, and permits removal of sheeting or binders that often can hinder a sterile procedure. The anterior bar of the external fixator should be rotated to permit access for the PPP incision and can be placed either high or low above this space. If an associated laparotomy is performed, the fixator bars should be positioned low across the pelvis to permit free access to the abdominal contents. Laparotomy incisions should be made separate from the packing space, optimally above the umbilicus to prevent entering the pelvic hematoma. Early recognition or concern for a urethral injury while in the ED is critical. Blood at the meatus, inability to pass the Foley catheter, or placement of the catheter through the urethral injury into the pelvic hematoma with decompression of frank blood should all herald the need for placement of a suprapubic (SP) tube. The SP tube should be placed at the time of PPP. It should ideally exit the fascia and skin through a separate stab incision, rather than through the midline, due to its long-term need. It should be placed after pack placement but before closure of the midline fascia. It may be necessary to delay positioning of the final anterior pack until after the SP tube is in place. Drainage of the bladder during this first exploration for PPP is imperative. Unpacking the pelvis to gain access to the bladder may result in recurrent bleeding, while allowing urine to leak through the urethral injury into the pelvic space is suboptimal; Foley decompression also permits accurate urine output recording to guide resuscitation. Division of labor by the available teams is a key component; with both the orthopedic and trauma teams able to perform PPP, the actual procedure can be relegated to the team with less urgent other necessary procedures. For example, if the patient needs a laparotomy, the trauma team does the abdominal exploration, while the orthopedic team performs PPP. If the patient needs bilateral fixation of lower extremity fractures with washout, the trauma team performs PPP, whereas the orthopedic team focuses below the inguinal ligament.

After PPP, some management principles have been gleaned. First, identifying associated injuries, which are common in these critically ill patients, is paramount; once the patient stabilizes, urgent CT scanning should be performed, ideally directly from the OR. Timing of diagnostic angiography is based on the number of RBCs transfused acutely; however, this count should start after the patient's coagulopathy has been corrected and should be due to a pelvic source. For example, a patient with an uncorrected TEG who also has significant chest tube output or oozing from their open abdomen via Jackson-Pratt drains in the temporary abdominal dressing is not necessarily the candidate for angiography. The patient with a normalized TEG who then receives more than four units of RBCs in the first 12 hours in the SICU without a clear extrapelvic source should undergo diagnostic angiography. If angiography is negative, empiric embolization of bilateral internal iliac arteries should be carefully weighed against the risks of pelvic claudication and perineal necrosis. In an attempt to limit the infectious morbidity of PPP, repacking of the pelvis should be avoided. Patients should not be returned for pack removal until they are physiologically replete and their coagulopathy resolved. Pack removal should involve the trauma team at a minimum so that bleeding may be controlled with direct ligation or topical agents as necessary. Rarely, large venous injuries are encountered at unpacking and may require reconstruction.

Finally, why are patients continuing to die in the immediate 24 hours after injury? Three (2%) patients' deaths were attributed to physiologic exhaustion with marked derangements in their laboratory values. With time to death under 100 minutes in two of those patients, AE is unlikely to have been feasible. The advent of REBOA may have been helpful to temporize the patient with pelvic hemorrhage as the predominant source. Early anecdotal experience with the use of REBOA has shown promise, particularly in this subset of patients; future reports will undoubtedly describe the role and limitations of this developing technology. Similarly, utilization of hybrid ORs only expands the available hemorrhage control options in the exsanguinating patient. Expanded training of trauma surgeons to perform endoluminal interventions would serve as a natural corollary.

PPP is advocated as the first-line treatment for pelvic fracture patients with persistent hemodynamic instability; multiple algorithms incorporating pelvic packing as the primary technique followed by postoperative AE when necessary have been published in the international literature.[13,24–26,30] Our study echoes these reports. PPP has a faster time to intervention for pelvic fracture related hemorrhage. Arterial bleeding was present in only 13% of patients, rendering angiography of limited utility. Outcomes with PPP appear to have a reduction in mortality compared with management schema that does not include PPP.

Despite this reduction in mortality, PPP should not be adopted for use in all pelvic fracture patients; this invasive procedure should be reserved for the patient in refractory shock despite hemostatic resuscitation. We feel this "trigger" for intervention for pelvic fracture–related bleeding, hypotension despite two units of RBCs, is a reasonable one. Would these patients have stopped bleeding if we had simply continued to transfuse them? That is hard to say. The mean transfusion was four units of RBCs in the ED, and the patients remained hypotensive. The "trigger" for angiography at other institutions includes a pelvic hematoma, a blush on CT scan in a stable patient, a SBP < 90 mm Hg regardless of transfusion requirements, or for the first unit of RBCs transfused.[18] A similar statement could be made of patients undergoing AE; perhaps they did not need the intervention and simply would have stopped bleeding. In the end, we feel we need a "trigger" to intervene for pelvic fracture–related bleeding and believe ours is a reasonable one. In our experience, only 6% of all patients with pelvic fractures required this life-saving intervention. PPP should be used for pelvic fracture–related bleeding in the patient who remains hemodynamically unstable despite initial blood transfusion.

AUTHORSHIP

C.C.B. participated in study design, data collection/analysis/interpretation, and writing. E.E.M. participated in data interpretation and critical revision. P.F.S. participated in data collection and critical revision. A.E.G. participated in data collection. A.E.W. participated in data collection. F.M.P. participated in data analysis and critical revision. C.J.F participated in critical revision. E.M.C. participated in critical revision. J.L.J. participated in critical revision. C.M. participated in critical revision.

DISCLOSURE

The authors declare no conflicts of interest.

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DISCUSSION

Dr. David A. Spain (Stanford, California): Pelvic binder-based treatment algorithms for patients with pelvic fractures, largely based on the work from Dr. Burlew's institution, combined with the principles of hemostatic resuscitation have really led to a dramatic decrease in our use of angio and embolization over the last ten years. So I have to admit, we've only done a handful of preperitoneal pelvic packing cases in unstable pelvic fracture patients where angio and embolization wasn't immediately available. But we have been impressed with the results in those few patients. So I have a couple of quick questions, Clay. Two of them get to that issue, the question of need versus use.

So we say we have persistently unstable pelvic fracture patients, but can you give me a little bit better idea of what you call "persistent"? My tolerance for a low blood pressure might be different than some of my partners. And you know, my tolerance today might be different than what it is tomorrow. Is this a couple readings of less than 90? Is this several readings over 10 minutes? What do you call persistent? Was this based on cuff pressures or did you use arterial lines in these patients? I think this is the same question we get in to with failure of non-operative management of splenic injuries—we don't all define failure the same way.

I think the same question applies to the use of angio and embolization later. You outlined it a little bit more in your presentation here but that same idea, how do you "pull the trigger" afterwards in terms of going to angio and embolization?

Just another couple of quick questions. You reported that the mean systolic blood pressure in the ER was 74. Was that arrival BP, the lowest BP or the average blood pressure for the patient during their duration in the ER? One minor thing, in the abstract you said that there was eight units of blood prior to pelvic packing but I think it's eight units prior to their arrival in the ICU which would make more sense.

And then the last question; you talked about it a little bit more in the discussion and that is the number needed to treat. I think one of the also important things we need to think about in these situations is also the number needed to harm. A significant number of patients in your group had pelvic infections. The majority of them had risk factors for pelvic infections, but a few didn't so there is some harm to this. Again, I think all of us would agree a live patient with a pelvic fracture is better than a dead patient without a pelvic fracture but I do think it's something we have to consider.

Now, lastly, I'd really like to congratulate Clay on an excellent presentation. This really represents another in a series from the group in Denver of thoughtful, consistent, and progressive evaluation of the care of severely-injured patients. And I would personally like to thank them for continually challenging us to do better for our patients.

Dr. Jeremy W. Cannon (Philadelphia, Pennsylvania): These patients have a lot of similarities to those with dismounted complex blast injury, which we see in the military, so your work has really inspired a lot of what we do in a forward environment managing those complex patients so I'd like to echo Dr. Spain's thanks. Thank you for keeping up this outstanding work.

Just a couple of practical questions. Do you keep these patients on antibiotics if they have no other indications for antibiotics? Secondly, what's your timing of pack removal?

And then, lastly, can you comment on the interesting results that Matt Martin has presented where he uses a preperitoneal balloon, like a preperitoneal hernia repair dissector balloon, to provide temporary occlusion?

Thank you.

Dr. Alicia Mangram (Phoenix, Arizona): Clay, a couple of thoughts. Bad pelvic fractures are one of those injuries that we all take care of, and you're sort of torn—where do I go? What do I do? OR pack, IR embolize.

When I look at the 44 minutes to the OR the first question that comes to my mind is did they go from the ER to the OR? Or did they go from the OR to CT to make sure there is are no other injuries and then to the OR? And if they did that 44 minutes, great; if not, I was wondering what was going on in those 44 minutes, trying to get to the OR?

And the second question, if you are concerned that there are other injuries—because it looked like you had opened the abdomen but closed the preperitoneal space and packed—are you packing and then throwing a few staples and then opening? And if so, why would you do that?

Lastly, the infection rate, are those superficial infections? Are you closing the skin? Or are those deep organ space infections where you are having to go back and drain or have IR put a drain?

I used a lot of lap sponges at first when I started to do the preperitoneal packing and then I switched to curlex, and I would have them tie the curlex together so that when they got to IR they didn't have those lap strings getting in the way, i.e. and the radiologist might not could see the blush due to radiolucency of lap sponge and that has worked really well. Tying the curlex, so when we pulled one out all the rest would come for fear of leaving one and not having that opaque string to help us.

But very, very nice presentation. Great work.

Dr. Christine Gaarder (Oslo, Norway): We have been packing pelvises since 1994 and we had in the beginning around 10 to 15 patients per year—approximately the same number per year of pelvic injuries.

What we presented here last year is that over the last few years we saw that with better resuscitation, better use of blood products early these patients, they tend to stabilize and they don't need packing of the pelvises.

We don't do more than zero to one packing per year anymore and we have reduced the rate of angiographies as well. They don't need that either because they actually stop bleeding.

Have you considered that your indication of two units of red blood cells is too low? That you should actually let them or catch up with them on resuscitation before you go to the OR?

I think the combination of two units of red blood cells and 44 minutes to get to the OR seems to me maybe you should reconsider what is the threshold for your indication for packing because it's an invasive procedure and none of us are able to see what kind of injuries we make to those patients during the packing.

Thank you.

Dr. Raminder Nirula (Salt Lake City, Utah): Clay, great work at pushing the envelope here. Two questions.

One, you had three patients that died of physiologic exhaustion and it sounds like two of them were really from bleeding from the pelvis and the other one was from the liver. Can you comment on whether or not you think those two cases died because you opened the retroperitoneum and you had persistent bleeding because you actually packed them?

And then the second question is do you have any more information about the pelvic sepsis in terms of in the cases where you had pelvic infections in terms of, you know, did it require hardware removal? How much of a morbidity really was this as a result of the procedure?

Dr. Clay Cothren Burlew (Denver, Colorado): Thank you very much. And first to my discussant, Dr. Spain, I appreciate your kind comments and let me see if I can address your questions in turn.

First, I think you bring up an excellent point, what is the trigger. And this was echoed by the statements from our colleague from Oslo. I think that it can be hard sometimes to make that clinical judgment. A single, systolic pressure less than 90 is not going to trigger me to pack the pelvis. If the patient receives a unit of blood and they respond and stabilize, they go to the CT scanner to delineate their injuries.

This is really the patient who comes in and has a systolic well below 90mmHg, and you give them blood and you are on that brink. These are the patients that come in once every month or two, and look at that pelvic film and the blood pressure, and you know that you're in trouble. Or you look at a degloving injury of the perineum along with a shear injury to the pelvis.

So an isolated pressure isn't it. We have said it is two units of blood and patients remain unstable despite this. And, as we noted, many patients received four units of blood in the emergency department before they arrived in the operating room. Few of these patients even had one blood gas in the emergency department, much less two that enabled one to determine a trend. Regarding your other questions about the systolic pressure of 74, that was the lowest pressure in the emergency department. And I agree, the eight units of transfused blood was actually prior to ICU admission, not prior to pelvic packing as that was the easiest break point in the patient's resuscitation. Angiography is performed after pelvic packing once coagulation is restored and the patient requires over four additional units of blood.

Regarding Dr. Mangram's questions and some of the other practical issues raised by others. I think all of us recognize that although 44 minutes may seem like a long time, if you're actually in the trauma bay that 44 minutes is pretty quick. In that time frame you are checking films and determining if they have other associated injuries, or if they need a tube thoracostomy to stabilize them.

Now we place our arterial sheath for blood pressure monitoring and potential REBOA early in their emergency department course. And the 44 minutes is an average; there are some patients who, with a systolic pressure of 50, the REBOA is placed and we are upstairs within 30 minutes, external fixator and pelvic packing done and we had our REBOA back out within an hour. So I think it just depends upon the patient where that 44 minutes is spent. And some do initially stabilize, and may undergo CT scanning, only to crump again.

Regarding the pelvic space, we keep this separate from the abdominal laparotomy. As far as tying the curlexes together, I think that's a terrific idea. Personally, that would require too many mechanistic things for me and I like a radiopaque marker because retained foreign bodies is problematic, but I think it's a great and inventive way to go about it.

Time to pack removal is empirically based upon our liver pack experience. We like to go somewhere between the 24 and 48 hour mark. The key, though, is you do not want to repack that pelvis, as I mentioned, because of the infection rate. So we really pause to make sure that that patient has restored physiology before we take them back, specifically that they are no longer coagulopathic. And then we take the time to unpack them carefully and control hemostasis within the pelvis in a variety of topical manners before we close them so that we do not have to repack them.

Patients do not get antibiotics for pelvic packs alone. The infection rates do, have some morbidity. The majority are deep space infections. We do close the skin but very few of these were superficial site infections. These patients typically undergo IR drainage of their abscess. Only three patients underwent an eventual hardware removal, anywhere between six weeks to two years later, speaking to Dr. Nirula's question.

Echoing a little bit on the question about needed to harm and infection rates, I agree with Dr. Spain. This is an invasive procedure. And I think that determining which really sick cohort would benefit from this is critical. But I also see mortality rates of 30 and 40 percent from excellent trauma centers, and I think that cutting down that mortality rate to the 20s is better.

And then, finally, the deaths, were they due to opening of the retroperitoneum, which as we were all taught, do not open the pelvic space, do not touch the pelvic hematoma. I emphasize, this is not a transabdominal procedure. And so by opening that retroperitoneum you pack it, into that closed space around the bladder, and close the fascia. If you leave the fascia open, and allow the blood to pour out then you do have a problem. But once you close down the pelvic space with the external fixator, you pack them, you close the fascia and skin, patients typically stabilize and it's pretty dramatic in my experience.

I hope I have answered all of your questions and thank you so much.