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Haemodynamics as a determinant of need for pre-hospital application of a pelvic circumferential compression device in adult trauma patients

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ABSTRACT

Introduction: Pelvic ring fractures are common following high-energy blunt trauma and can lead to substantial haemorrhage, morbidity and mortality. Pelvic circumferential compression devices (PCCDs) improve position and stability of open-book type pelvic fracture, and can improve haemodynamics in patients with hypovolaemic shock. However, PCCDs may cause adverse outcomes including worsening of lateral compression fracture patterns and routine use is associated with high costs. Controversy regarding indication of PCCDs exists with some centres recommending PCCD in the setting of hypovolaemic shock compared to placement for any suspected pelvic injury.
Objective: To assess the need for PCCD application based on pre-hospital vital signs and mechanism of injury.
Methods: A retrospective cohort study was conducted in a single adult major trauma centre examining a 2-year period. Patients were sub-grouped based on initial pre-hospital and emergency department observations as haemodynamically normal (heart rate <100 bpm, systolic blood pressure ≥100 mmHg and Glasgow Coma Scale ≥13) or abnormal. Diagnostic accuracy of pre-hospital haemodynamics as a predictor of pelvic fracture requiring intervention within 24 h was assessed.
Results: There were 376 patients with PCCD in-situ on hospital arrival. Pelvic fractures were diagnosed in 137 patients (36.4%). Of these, 39 (28.5%) were haemodynamically normal and 98 (71.5%) were haemodynamically abnormal.
The most common mechanisms of injury were motor vehicle collision (57.7%) and motorcycle collision (13.8%). Of those with fractures, 40 patients (29.2%) required pelvic intervention within 24 h of admission; of these, 8 (20%) were haemodynamically normal and 32 (80%) were haemodynamically abnormal. As a test for pelvic fracture requiring intervention within 24 h, abnormal pre-hospital haemodynamics had a sensitivity of 0.80 (95% CI 0.64-0.91), specificity of 0.32 (95% CI 0.27-0.38) and negative predictive value (NPV) of 0.93 (95% CI 0.88-0.96). Combined with absence of a major mechanism of injury, normal haemodynamics had a sensitivity 1.00, specificity 0.51 (95% CI 0.36-0.66) and NPV of 1.00 for pelvic intervention within 24 h.
Conclusion: Normal haemodynamic status, combined with absence of major mechanism of injury can rule out requirement for urgent pelvic intervention. Ongoing surveillance is recommended to monitor for any adverse effects of this change in practice.

Introduction

Fractures to the pelvic ring are common following high energy blunt trauma, occurring in 8% of major trauma patients and 15.7% of patients with an injury severity score >15 ([1]). These injuries can cause substantial haemorrhage [2–4], with overall mortality reported at 14–18% [1,3,5,6]. In patients with unstable fractures, mortality can be as high as 42% [5].

The clinical assessment for pelvic fracture can be difficult and unreliable, missing 11% of fractures on clinical examination and patient symptoms alone [7]. Historically, examination for pelvic instability was conducted by 'springing' of the pelvis to assess for

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instability in compression and distraction [8,9]. This method of clinical assessment of pelvic stability is no longer in common practice, having been shown to have poor sensitivity (26%) for detecting unstable pelvic fracture [10]. Furthermore, there were concerns of potential for clot disruption that could cause further bleeding [11].

As such, pre-hospital providers must now rely on other methods of clinical assessment such as patient complaints of pain in the region, visual inspection for obvious deformity or a high index of suspicion. Pain free active hip flexion can exclude pelvic fractures, but this is suitable only among awake and cooperative patients [12]. Even in experienced, physician-lead services, clinical assessment has been shown to miss 31% of pelvic fractures [13].

In 1995, Routt et al. described using a circumferential sheet that would theoretically reduce the potential space for pelvic haemorrhage prior to definitive repair [14]. This then led to the development and introduction of formal pelvic circumferential compression devices (PCCDs) [15]. PCCDs have been shown to improve the position and stability of open-book type pelvic fractures, providing significant reduction in measured pubic symphysis diastasis [16–20] and improvement in patient haemodynamics following their application [20].

Though effective, the placement of PCCDs has the potential to cause adverse outcomes including low-pressure necrosis to underlying soft tissue. [18,21–24] In the acute stage, a tightly placed PPCD could lead to worsening of lateral compression fracture patterns [25,26] with potential for damage to underlying structures including vessels, bowel, bladder and sacral nerve roots [27]. In addition, the routine placement of PCCDs is associated with a cost ranging between $87USD to $134USD for two market-leading devices [28–30]. A misplaced binder may exacerbate a pelvic fracture if there is an injury through the iliac crest. When placed too high, it may obstruct access for abdominal examination and laparotomy [31].

In Victoria, Australia, Clinical Practice Guidelines for paramedics recommend the use of a PCCD in any suspected fracture of the pelvis [32] whereas both the National Institute for Health and Care Excellence (NICE) and the Faculty of Pre-Hospital Care (FPHC) recommend the placement of PCCDs in patients with a mechanism suggestive of pelvic fracture *and* signs of hypovolaemic shock [33,34]. In addition, the FPHC suggest there is a limited patient group in whom a PCCD may be considered unnecessary given normal haemodynamics, no distracting injury, and no pain on clinical assessment of the pelvis [34]; this recommendation is based on studies which have primarily focused on the use of physical examination rather than haemodynamics to detect fracture of the pelvis in alert patients [7,35].

The aim of this manuscript was to assess the need for application of a PCCD in patients with normal pre-hospital vital signs.

Patients and methods

Study design & setting

A retrospective cohort study was performed of consecutive major trauma patients presenting to a single adult major trauma centre (MTC) over a two-year period (July 2014 to June 2016 inclusive). The study was conducted at The Alfred Hospital, an adult major trauma centre in the state of Victoria, Australia. The centre receives over 8000 trauma admissions annually. The Alfred Trauma Registry (ATR) prospectively records pre-hospital and hospital data on all major trauma patients, and a subset of minor trauma patients. Emergency medical service (EMS) care in this setting is provided by Ambulance Victoria, which operates a two-tiered response system involving advanced life support and mobile intensive care ambulance (MICA) paramedics. The PCCD in use by Ambulance Victoria is the SAM Sling® (SAM Medical Products, Newport, OR, USA). The Alfred Hospital Ethics Committee granted ethics approval for this study.

Study population

Cases were identified from the ATR as having a PCCD in situ on arrival at the MTC. Patients were excluded if they were under the age of 18 years, or had been transferred from another facility to ensure that only PCCDs applied pre-hospital were considered.

Data extraction

Data on patients meeting the inclusion criteria was extracted from the ATR; this included patient age, initial heart rate (HR) and systolic blood pressure (SBP) recorded by EMS and on arrival to the Emergency Department (ED), and injury severity score (ISS). Further data were collected from the administrative database of electronic health records, and radiological data extracted from the Alfred Health Picture Archiving and Communication System (PACS); this data included Glasgow Coma Scale (GCS) recorded by AV and in the ED, mechanism of injury, report of computed tomography (CT) scans, and timing of pelvic interventions including angio-embolization, external fixation, or open reduction and internal fixation (ORIF).

Exposure variables

Following data collection, patients were categorised based on initial recorded observations both at the scene and immediately on arrival in the ED, as haemodynamically normal (HN) or abnormal (HA). For the purpose of this study, haemodynamically normal was defined as all of the following criteria: $HR < 100$ bpm and $SBP \geq 100$ mmHg and $GCS \geq 13$. This definition was chosen arbitrarily in order to maximise the sensitivity to rule out a serious pelvic injury. Based on initial CT findings, patients were categorised as those with a pelvic fracture and those without. The Young and Burgess classification system [36] was used to further describe patients who had pelvic ring fractures.

Major mechanism of injury was defined as any of the following: motor vehicle collisions (MVC) >60kph, vehicle rollover, ejection from vehicle, entrapment, collision with a heavy goods vehicle, motorcycle or cyclist impact >30kph, fall from height >3 m, fall from horse, crush injury, pedestrian impact and recreational vehicle collision.

Outcome measures

The primary outcome measure for this study was pelvic fracture requiring intervention within 24 h. Secondary outcome measures included the presence of pelvic fracture, anterior or posterior pelvic ring disruption, and pelvic bleeding or pelvic haematoma on CT scan.

Statistical analysis

Statistical analysis was performed using Microsoft Excel for Mac 2011 (Microsoft Corp. Washington, USA) and SPSS Statistics for Macintosh 24 (IBM Corp. Armonk, NY). Data were compared using the independent samples *t*-test for normally distributed continuous variables. Pearson's chi-square was used for categorical variables and Fisher's exact test was used if counts were less than five. Statistical significance was defined using a $p\text{-value} < 0.05$. Cases with missing data were analysed using pairwise deletion. Diagnostic accuracy was evaluated by calculation of sensitivity,

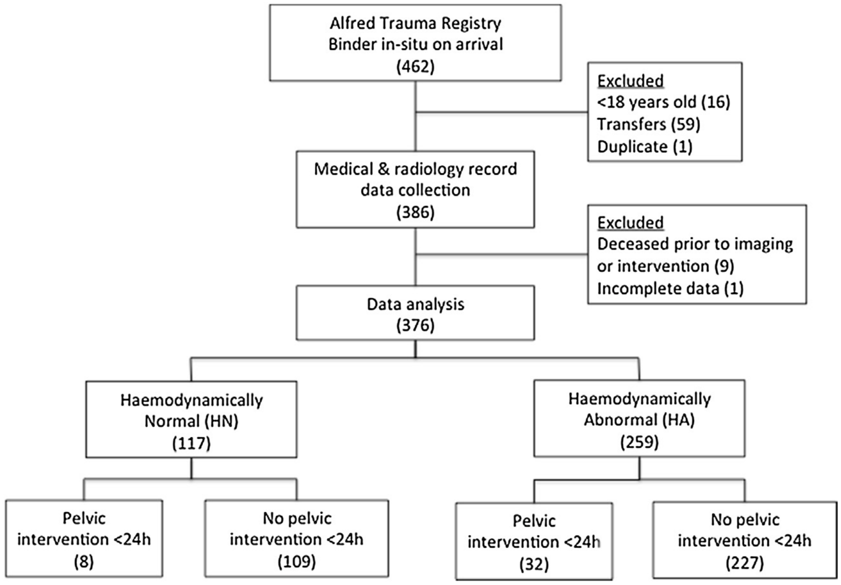

Fig. 1. Study Design Diagram.

specificity and negative predictive value with confidence levels reported as estimates of precision.

Results

There were 462 patients identified from the Alfred Trauma Registry as trauma patients presenting with a PCCD in situ over the two-year study period. Of these, 76 patients were excluded (16 patients were <18 years of age, 59 were transferred from another facility and 1 was a duplicate record). The remaining 386 patients were eligible for study inclusion and data collection from electronic medical and radiology records. There were 9 patients that died either in the Emergency Department, the Intensive Care Unit or the Operating Theatre and did not have imaging performed. These patients were also excluded due to lack of data regarding pelvic injury or intervention. Finally, one patient was excluded due to having no available data in medical or radiology records. The remaining 376 patients were included in the analysis (Fig. 1).

The mean age of the patient group was 43.8 years (SD 18.7 years). 265 (70.5%) were male. Among these, 160 patients (42.6%) had abnormal initial pre-hospital haemodynamics, 208 (55.3%) were haemodynamically normal and 8 patients (2.1%) had no pre-hospital haemodynamics available. Patient haemodynamics on presentation to the ED showed 161 (42.8%) normal and 215 (57.2%) abnormal. Overall there were 117 (31.1%) and 259 patients (68.9%) with normal and abnormal haemodynamics at any stage, respectively. Table 1 demonstrates differences in variables between these two groups.

Pelvic fracture was diagnosed in 137 patients (36.4%) overall. Of these, 39 (28.5%) were haemodynamically normal and 98 (71.5%) were haemodynamically abnormal.

There were 9 patients (6.6%) that had active pelvic bleeding related to their fracture and pelvic haematoma was seen in 38 (27.7%) of the patients with pelvic fracture. There were 87 patients who had fractures to the pelvic ring and classification of these fractures are described in Table 2. Of these, 68 (78.2%) were classified as Lateral Compression (LC) type fractures, 8 (9.2%) as Anteroposterior Compression (APC) type fractures, 5 (5.7%) as Vertical Sheer (VS) type and 6 (6.9%) as Combined Mechanism (CM). The most common mechanisms of injury in those with pelvic fracture were MVC (57.7%), motorcycle collision (13.8%), fall ≥3 m and pedestrian impact (both 7.3%).

There were 40 patients that required pelvic intervention within 24 h of admission, 8 (20%) were haemodynamically normal and 32 (80%) were haemodynamically abnormal. The most frequent intervention was external fixation (31 patients – 27 haemodynamically abnormal and 4 haemodynamically normal), followed by angio-embolization (13 patients – 9 haemodynamically abnormal and 4 haemodynamically normal), open reduction and internal fixation (ORIF) (6 patients – 3 in each group) and pre-peritoneal packing (6 patients - 5 haemodynamically abnormal and 1 haemodynamically normal). The most common mechanisms of injury for patients requiring intervention were MVC (54.3%), motorcycle collision (17.1%) and pedestrian impact (11.4%)

The sensitivity of abnormal haemodynamics at any time-point pre-hospital for urgent pelvic intervention was 0.80 (95% CI 0.64-0.91), specificity was 0.32 (95% CI 0.27-0.38), negative predictive value (NPV) was 0.93 (95% CI 0.88-0.96) and positive predictive value (PPV) was 0.12 (0.10 – 0.14). Similar calculations were performed for the secondary outcome measures of presence of pelvic fracture, pelvic bleeding or haematoma, and anterior or posterior pelvic ring disruption (Table 3).

In combination with the absence of a major mechanism of injury (Table 1), diagnostic accuracy of abnormal haemodynamics was calculated giving sensitivity 1.00 (95% CI 0.03–1.00), specificity 0.51 (95% CI 0.36 – 0.66), NPV of 1.00 and PPV of 0.04 (95% CI 0.03 – 0.06) to predict injury requiring pelvic intervention within 24 h.

Using haemodynamic status alone, false negatives (haemodynamically normal patients who required pelvic intervention within 24 h) were compared to true positives (haemodynamically abnormal patients who required pelvic intervention within 24 h). False negatives were found to be older (mean age 61.9 vs. 38.7 years; $p = 0.002$), and involved in a bicycle collision, fall ≥ 3 m, or recreational vehicle collision as their mechanism of injury ($p = 0.025$).

Discussion

Haemodynamic status alone was inadequately sensitive to confidently exclude serious pelvic pathology. This is despite our study's conservative definition of haemodynamically normal (HR < 100, SBP ≥ 100 mmHg and GCS ≥ 13), intended to maximise sensitivity. In combination with the absence of a major mechanism of injury (defined as MVC >60kph, vehicle rollover,

Table 1
Variables for haemodynamically normal and abnormal patients.

	Haemodynamically Normal (n = 117)	Haemodynamically Abnormal (n = 259)	p value
Age[a]	45.7 (SD 17.8)	43.01 (SD 19.1)	NS
Male Sex	91 (77.8%)	174 (67.2%)	0.04
Pre-hospital GCS			<0.001
≥13	114 (97.4%)	167 (64.5%)	
9-12	0	21 (8%)	
≤8	0	37 (14%)	
Unknown	3 (2.6%)	34 (13.1%)	
ED GCS			<0.001
≥13	115 (98.3%)	148 (57.1%)	
9-12	0	9 (3.5%)	
≤8	0	71 (27.4%)	
Unknown	2 (1.7%)	31 (12.0%)	
Pre-hospital HR[a]	79 (SD 11.3)	103 (SD 23.5)	<0.001
<100		117	108
≥100	0	151	
ED HR[a]	78 (SD 11.0)	106 (SD 23.5)	<0.001
<100	117	90	
≥100	0	169	
Pre-hospital SBP[a]	130 (SD 19.9)	115 (SD 29.7)	<0.001
≥100	116	177	
<100	0	83	
ED SBP[a]	140 (SD 20.5)	128 (SD 29.3)	<0.001
≥100	117	208	
<100	0	51	
ISS[b]	15 (IQR 9-22)	26 (IQR 14-35)	<0.001
Mechanism of Injury[c]			<0.001
MVC (Major)	40 (34.2%)	129 (49.8%)	
MVC (Minor)	9 (7.7%)	13 (5.0%)	
Motorcycle (Major)	14 (12.0%)	25 (9.7%)	
Motorcycle (Minor)	7 (6.0%)	5 (1.9%)	
Recreational Vehicle	1 (0.9%)	3 (1.2%)	
Cyclist (Major)	7 (6.0%)	2 (0.8%)	
Cyclist (Minor)	3 (2.6%)	1 (0.4%)	
Pedestrian Impact (Road)	5 (4.3%)	13 (5.0%)	
Pedestrian Impact (Train)	0	2 (0.8%)	
Fall ≥3 m	14 (12.0%)	18 (6.9%)	
Fall <3 m	5 (4.3%)	5 (1.9%)	
Fall from Horse	6 (5.1%)	7 (2.7%)	
Falling Object	1 (0.9%)	3 (1.2%)	
Crush injury	3 (2.6%)	3 (1.2%)	
Unknown	2 (1.7%)	30 (11.6%)	

NS - Denotes not statistically significant.
[a] Denotes mean value.
[b] Denotes median (IQR).
[c] Major mechanism of injury was defined as MVC >60kph, vehicle rollover, ejection from vehicle, entrapment, collision with a heavy goods vehicle, motorcycle or cyclist impact >30kph, fall from height >3 m, fall from horse, crush injury, pedestrian impact and recreational vehicle collision.

Table 2
Young-Burgess Classification of Pelvic Fractures.

Young-Burgess Classification	Haemodynamically Normal (% of class)	Haemodynamically Abnormal (% of class)	Total (% all pelvic ring fractures)
LC I	8 (23%)	27 (77%)	35 (40%)
LC II	10 (36%)	18 (64%)	28 (32%)
LC III	1 (20%)	4 (80.0%)	5 (6%)
APC I	1 (20%)	4 (80.0%)	5 (6%)
APC II	0	0	0
APC III	0	3 (100%)	3 (3%)
VS	2 (40%)	3 (60%)	5 (6%)
CM	0	6 (100%)	6 (7%)

LC – Lateral Compression Type.
APC – Anteroposterior Compression Type.
VS – Vertical Sheer Type.
CM – Combined Mechanism Type.

ejection from vehicle, entrapment, collision with a heavy goods vehicle, motorcycle or cyclist impact >30kph, fall from height >3 m, fall from horse, crush injury, pedestrian impact and recreational vehicle collision), the sensitivity and NPV of haemodynamics improves to 100% (Table 4). Using haemodynamic status alone, there was a significant difference in age between the true positive and false negative groups, perhaps due to the reduced capacity for physiological compensation and therefore change in haemodynamic values in elderly trauma patients [37]. However, sub-groups of injury mechanism were small and further validation using larger sample sizes and ongoing surveillance is recommended.

Table 3
Diagnostic accuracy of haemodynamic instability for pelvic injury.

Primary Outcome	Sensitivity (95% CI)	Specificity (95% CI)	NPV (95% CI)	PPV (95% CI)
Pelvic Intervention within 24 hours	0.80 (0.64 – 0.91)	0.32 (0.27 – 0.38)	0.93 (0.88 – 0.96)	0.12 (0.10 – 0.14)
Secondary Outcomes	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**NPV (95% CI)**	**PPV (95% CI)**
Pelvic Fracture	0.72 (0.63 – 0.79)	0.31 (0.26 – 0.38)	0.65 (0.57 – 0.72)	0.38 (0.35 – 0.41)
Pelvic Bleeding / Haematoma	0.71 (0.55 – 0.84)	0.31 (0.26 – 0.37)	0.89 (0.83 – 0.93)	0.11 (0.09 – 0.14)
Anterior or Posterior Pelvic Disruption	0.84 (0.69 – 0.93)	0.32 (0.27 – 0.37)	0.94 (0.88 – 0.97)	0.14 (0.12 – 0.16)

Table 4
Test Characteristics of Haemodynamics and Non-Major Mechanism of Injury.

	Pelvic Intervention	No Pelvic Intervention	
Haemodynamically Abnormal	1	23	PPV (95%CI) 0.04 (0.002 – 0.23)
Haemodynamically Normal	0	24	NPV 1.00 (0.83-1.00)
	Sensitivity (95%CI) 1.00 (0.05 – 1.00)	Specificity (95%CI) 0.51 (0.36 – 0.66)	

Objective clinical examination findings are essential for clinical decision rules as reliability of clinical assessment for pelvic injury can be variable. A 2004 meta-analysis found sensitivity of clinical examination to detect pelvic fracture ranged from 59 to 100% and specificity from 71 to 100%, with a pooled sensitivity and specificity both of 90% for the 12 included studies [7]. These studies were, however, evaluating hospital-based clinical assessment for pelvic injury and so are unlikely to have reproducible results when applied to pre-hospital clinical examination. At the scene of an incident, there may be distracting factors for both patient and practitioner that would affect the accuracy of their initial assessment. A 2016 study by Yong et al. examined the pre-hospital assessment for possible pelvic injury in an experienced, physician-led team with clear standard operating procedures for the use of PCCDs. They report low sensitivity (69%) for clinical detection (and therefore PCCD placement) of pelvic fracture in their study population [13]. They also found that in their population, missed pelvic injury was more likely in the haemodynamically normal patient. Our results demonstrate a potential 20% of serious pelvic injuries would have not received a PCCD if the treatment decision had been based on haemodynamics alone. Given the importance of early identification and management in such injuries, this supports current practice of liberal placement in any suspected pelvic injury.

The cost for all PCCDs used for our study population was USD $24,440 per year. The cost for all patients with normal haemodynamics who did not require pelvic intervention within 24 h was an estimated $7085 per year. For patients with a “minor” mechanism of injury and normal haemodynamics, the cost was $1610 per year though this was likely an underestimation of patients with less severe injuries that would not have been included into the registry and therefore this study. This costing suggests that even overall, PCCDs are not a significant expenditure, and even less so for the small group of patients who did not receive any benefit from its application. In lower income settings, where formal PCCDs may be considered too costly, external pelvic compression can be placed using a sheet to form a pelvic wrap [38]. This has been shown to anatomically reduce pubic symphysis diastasis in pelvic ring disruption, though this approach may not be as efficacious as purpose-built PCCDs [19,39].

The use of PCCDs in the management of the adult major trauma patient is certainly an area requiring further investigation. While cadaveric research has demonstrated their efficacy with regard to anatomical reduction of open-book pelvic fractures [16–20], there is only limited evidence to show clinical improvement as a consequence of this. Standard thinking has been that anatomical reduction leads to decreased pelvic volume and therefore less potential space for bleeding to occur. Stover et al. in their cadaveric study measuring pelvic volume using mathematical formulae before and after reduction of the pubic symphysis concluded that the true pelvis is best described as a hemi-elliptical shape. As such, changes in radius (by increasing or decreasing symphysis diastasis) have relatively little effect on measured pelvic volume and therefore “factors other than absolute change in volume must account for clinically observed effects of emergent pelvic stabilization” [40]. Tan et al. demonstrated a significant improvement in haemodynamics at two minutes following application of a PCCD to patients with unstable pelvic fracture on plain x-ray and signs of hypovolaemic shock [20]. This was a small cohort of patients with no control group and as such the perceived benefit may have been due to multiple factors including on-going fluid resuscitation. Fu et al. demonstrated in their small, retrospective study, a reduction in blood transfusion requirement, intensive care and hospital length of stay in patients with a PCCD placed for both stable and unstable pelvic fracture prior to transfer to a major trauma centre [41]. Without a control group or randomisation it is possible that these benefits may have been secondary to other factors such as the capabilities of the transferring institutions.

This study is limited by its single-centre, retrospective design. Being a single-centre study limits the external validity of our results. Variation in prevalence of pelvic injury due to differences in population demographics, geography and road safety legislation will affect variances in the NPV accordingly. Accurate extraction of data from scanned ambulance case sheets and electronic medical records can be challenging due to missing or ambiguous entries and can lead to inaccuracies in some aspects of collected data. In the case of our study, the primary data point affected by this was mechanism of injury, as it is documented in a subjective fashion, and could lead to bias when categorising the mechanism for analysis. It is also impossible to determine retrospectively the clinical reasoning for placement of a PCCD in cases with normal haemodynamics. One of this study's strengths is that, whilst the design is retrospective, the haemodynamics data used for our comparative groups were collected prospectively for the Alfred Trauma Registry and data for the primary outcome measure is taken directly from operative records, again recorded prospectively which limits measurement bias. Another strength is the liberal definition of haemodynamically abnormal, which maximised sensitivity of the test. Our primary outcome measure of any pelvic intervention within 24 h is also a broad definition in order to capture all patients with an injury that may have benefitted from a PCCD, but decreases NPV by increasing disease prevalence.

Further direction for research should consider which patients truly benefit from PCCD placement; whether they instil a clinical benefit in resuscitation, and if so, what the mechanism may be; which fracture patterns benefit most and which lead to adverse outcomes; and whether haemodynamically normal patients benefit from them in other ways such pain relief and reduction in fracture site bleeding during transport. With further investigation it may also be possible to develop a simple, reliable decision aid for the appropriate placement of a PCCD using a combination of haemodynamics, patient age, and mechanism of injury, including specific diagnostic groups. Ongoing surveillance of patients that are transported to the ED with a pelvic fracture, but without a PCCD is essential to assess the risk-benefit profile of PCCDs.

Conclusion

Haemodynamic status alone was insufficiently sensitive to exclude pelvic fracture requiring urgent intervention. When combined with absence of a major mechanism of injury, normal haemodynamics preclude the need for PCCD application. Ongoing surveillance of this practice is recommended to monitor for any adverse effects.

Declaration of Competing Interest

None of the authors have any conflict of interest to declare for this manuscript.

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