Effectiveness and complications of Pelvic Circumferential Compression Devices in patients with unstable pelvic fractures

A systematic review of literature

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Abstract

Background: Pelvic fractures can cause massive hemorrhage. Early stabilization and compression of unstable fractures is thought to limit blood loss. Reposition of fracture parts and reduction of pelvic volume may provide hemorrhage control. Several non-invasive techniques for early stabilization have been proposed, like the specifically designed Pelvic Circumferential Compression Devices (PCCD). The purpose of this systematic review was to investigate current evidence for the effectiveness and safety of non-invasive PCCDs.

Methods: To investigate current literature the search string: **"***pelvi* AND fract* AND (bind* OR t-pod OR tpod OR wrap OR circumferential compression OR sling OR sheet)*" was entered into EMBASE, PubMed (Medline), PiCarta, WebofScience, Cochrane Online, UptoDate, CINAHL, and Scopus. All scientific publications published in indexed journals were included.

Results: The search resulted in 16 included articles, none of which were level I or II studies. One clinical cohort study (level III) and 1 case-control study (level IV) were found. These showed a significant reduction of pelvic volume after applying a PCCD, without an effect on outcome. Other included literature consisted of 4 case series (level V). One biomechanical analysis of fractures in human cadavers showed pelvic stabilization and effective volume reduction by PCCD when applied around the greater trochanters. Finally, 7 case reports (level VI) and 3 expert opinions (level VII) were identified. These case reports suggested complications such as pressure sores and nerve palsy.

Conclusion: PCCDs seem to be effective in early stabilization of unstable pelvic fractures. However, prospective data concerning mortality and complications is lacking. Some complications, like pressure sores have been described.

Introduction

The pelvis is comprised of a bony ring, made up by the sacrum and 2 fused bone planes on each side, consisting of the ischiac, iliac and the pubic bones. Distortion of this ring due to fractures may lead to extensive hemorrhage, pelvic instability and organ damage (e.g., urinary bladder). Blood loss can occur from several sources, like venous plexus lesions, bleeding fracture sites and, less common, arterial injuries. Life threatening bleeding from arterial origin may occur in 5% to 20% of patients.[3, 8, 11] Theoretically, the reduction of pelvic fracture fragments diminishes the pelvic volume, thereby reducing the potential space for bleeding. Moreover, a reduction of fracture surfaces may reduce bony bleeding.[8,9] Unstable pelvic fractures should be considered as life threatening at all time, and constitute a high incidence of mortality causes in polytraumatised patients.[29]

During resuscitation of polytraumatised patients, priority is given to preventing and treating the lethal triad; hypothermia, acidosis, and progressive coagulopathy.[12, 27-29] In this context, the most efficient resuscitative measure to reduce blood loss in pelvic fractures is early cessation of bleeding. Application of a non-invasive pelvic circumferential compression device at the scene of the accident is frequently applied as early fracture fixation. With a PCCD in place, patients can be transported to a trauma centre, where definitive stabilization of the pelvis can be performed by the application of a pelvic C-clamp, operative placement of an external fixation device, or coiling of an arterial hemorrhage.

Several non-invasive stabilization methods have been developed over time. Ways to reduce hemorrhaging from pelvic fractures date from as early as 1974 with the introduction of the Medical Anti-Shock Trouser (MAST) or Pneumatic Anti-Shock

Garment (PASG).[2, 18] Randomized trials revealed no survival benefit from these devices.[20, 21] Several complications, like abdominal compartment syndrome and pressure sores have been reported.[1, 6] Moreover, these devices severely limited the surgical access to the abdomen, groin and upper legs. Overall, these limitations have rendered their use obsolete.

Circumferential compression can be achieved by using a simple bed sheet, tightened around the pelvis, or by using a specially designed commercial device. These pelvic circumferential compression devices (PCCDs) were first described in 1999.[30] The use of PCCDs in the initial care for pelvic fracture patients is currently incorporated in the Advanced Trauma Life Support guidelines, as put forward by the American college of Surgeons.[27] PCCDs are easy to use, can be applied quickly, thereby significantly contributing to survival of severely injured patients. However, evidence for the effectiveness for this treatment modality is scarce.

The purpose of this systematic review was to make an inventory of the current evidence for the use of PCCDs in patients with unstable pelvic ring fractures, both in terms of biomechanics (fracture reduction) and clinical efficacy (haemostasis, clinical applicability, and patient outcome in the initial treatment).

Materials and methods

In order to investigate the effectiveness of PCCDs in the initial treatment of unstable pelvic fractures, a systematic review of literature was performed. For this, a systematic search of relevant databases in medical literature was used.

Search strategy

Using the search string "pelvi* AND fractur* AND (bind* OR t-pod OR tpod OR wrap OR circumferential compression OR sling OR sheet)" all relevant literature investigating the effectiveness of PCCDs were retrieved. Relevancy on achieving reduction of fracture parts or symphysic diastases, or on obtaining clinical improvement in patients that sustained an unstable fracture of the pelvic ring was assessed.

The search string was used for retrieving manuscripts from EMBASE, PubMed (Medline), PiCarta, WebofScience, Cochrane Online, UptoDate, CINAHL, and Scopus. Subsequently, the abstracts of all hits were reviewed in order to assess whether the article was eligible. Scientific articles in any language, published in indexed journals, pertaining all levels of evidence concerning effectiveness, safety and biomechanics of PCCDs were considered eligible. Duplicate hits were filtered and references were hand screened to find relevant articles not identified by the initial search string. Inclusion criteria were scientific articles concerning the use of PCCDs or sheets in either clinical patients or in an experimental setting. Exclusion criteria were articles classified as product advertisements without scientific value or articles describing invasive compression devices. Included articles were analyzed and divided by design, research question and evidence level (Table 1). Results classified as product advertisements were excluded after hand searching references, because no scientific merit can be derived from these papers.

Results

The search strings used resulted in 176 hits. After comparison and removal of duplicate manuscripts, 100 manuscripts remained. After reading all abstracts, 16 relevant articles concerning the use of PCCDs were identified (Table 2). Screening the references of these articles yielded 1 additional publication. In total, 17 articles concerning the use of PCCDs were included in the review. These consisted of 3 biomechanical laboratory studies, 2 clinical studies, 1 experimental in vivo study, 1 case series, 7 case reports describing complications and adverse outcome of PCCDs, and 3 expert opinions. Four of the included articles discuss some form of experimental PCCD, while 5 articles investigate specially designed and commercially used PCCDs. Seven articles discuss the use of a bed sheet wrapped around the pelvis, and one biomechanical study compares the bed sheet to the commercially available T-POD®. The main results and corresponding level of evidence are depicted in Table 2. Below, all studies will be discussed by order of level of evidence.

The search resulted in only one level III study. In a prospective study, Krieg et al., investigated the effectiveness of an experimental PCCD (prototype SAM Sling) in reducing partially stable and unstable pelvic fractures.[16] Thirteen adult patients were included into this 16 month trial, which was performed in two level 1 trauma centers. PCCDs were applied in the emergency department and time between fracture and PCCD was on average 4.3 hours (range 1-10 hours). Pelvic fractures were confirmed on AP X-rays. A second AP X-ray was made upon application of a PCCD and finally a third radiograph was made after definitive stabilization. Reduction of the pelvic ring was assessed by measuring the change in horizontal and vertical position of the femoral heads. Horizontal translation was defined by coronal plane reduction and vertical displacement was used to assess the quality of anatomical reduction. PCCD placement significantly reduced the horizontal displacement by 9.9±6.0% in the 8 externally rotated fractures, which was comparable to definitive stabilization. Vertical displacement was reduced from 12.5±10.0mm to 7.4±7.6mm. Definitive stabilization further reduced vertical displacement to 3.8±4.0mm. For the 5 internally rotated fractures, PCCD application decreased the horizontal displacement by 5.3±4.9%. Upon definitive treatment, this was further decreased by 1.9±7.2%. Vertical displacement was on average over 50% less than in the group of patients with externally rotated fractures, and was not significantly affected by PCCD application or by definitive stabilization. Six patients were initially treated by wrapping a bed sheet around the pelvis and 2 patients had received PASG in the field. No effect on outcome is mentioned. Overall, this study showed a good effect for reducing horizontal displacement, comparable with definitive treatment, without investigating the effect on outcome.

A retrospective clinical study by Croce et al. was the only level IV study retrieved.[7] In a period of 10 years, 186 patients with structural and hemodynamically unstable pelvic fractures were enrolled. These had received emergent pelvic fixation by means of a PCCD (T-POD; N=93) or had underwent emergent external pelvic fixation (N=93). PCCD application significantly reduced the transfusion requirements in the first 48 hours after injury compared with the controls. Moreover, the number of pneumonias, as a marker for infectious complications was significantly lower in the PCCD group. The length of hospital stay and mortality was similar in both groups.

Five level V studies were found. In three studies the biomechanical properties of PCCDs were investigated using a biomechanical model in human cadavers. Bottlang et al[4] investigated the most effective application site of an experimental PCCD for reducing open book type fractures in 7 non-embalmed human cadavers. Using 180N of tension, their PCCD was applied to the greater trochanters, the midpelvis or around the iliac crests. A complete reduction was best achieved when the PCCD was applied at the greater trochanter level. For this, a tension of 177±44N and 180±50N was needed for Young and Burgess type II and III anterior-posterior compression fractures, respectively. This result was compared with the use of the pelvic C-clamp and the anterior external fixator. The stability provided by the PCCD was comparable with stability provided by the posterior pelvic C-clamp. However, the PCCD provided only one-third of the flexion-extension (horizontal displacement) stability and one-tenth of the internal/external rotation stability compared with a regular external fixator applied on the anterior iliac wing. Safety of using a PCCD was investigated by assessing the risk in terms of internal rotation of one hemi pelvis and increase in pelvic inlet area. This was not significant and the authors therefore stated that no risk of over-reduction in lateral compression fractures existed.

In a second study, Bottlang et al. evaluated pelvic reduction with respect to strap tension and the strap application site.[5] The effect of circumferential compression on intra-peritoneal pressure and skin–strap interface pressure was also measured. Reduction of the unstable pelvic fracture by PCCD application at the level of the greater trochanters was characterized by an intra-peritoneal pressure increase of 6.2±5.8mmHg (0.825±0.771kPa) and a strap–skin interface pressure of 24mmHg (3.192kPa). This is consistent with the PASG, which could be left in place safely for 48h without resulting in soft tissue damage.[2]

The third biomechanical study was performed by DeAngelis et al.[9] They created rotationally unstable pelvic fractures (Tile B1) in 12 non-embalmed human cadavers by sectioning the pubic symphysis and all anterior SI ligaments on the left side of the pelvis. Effects on symfysic diastases throughout the study were measured using standardised X-rays. First, a circumferential bed sheet (8'' diameter) was placed around the pelvis and greater trochanters and held in place with a clamp. After removal of the sheet, the original diastasis was recreated and a trauma pelvic orthotic device (T-POD®) was applied following the manufacturer's instructions. This process was repeated in 12 specimens. The bed sheet was able to reduce the diastases by an average 21.9mm and reduced diastases to normal (<10mm) in 17% (2 of 12) of cadavers. The T-POD reduced the diastases by an average 32.2mm and reduced diastases to normal in 75% of cadavers (9 of 12). The authors therefore conclude that the T-POD® is more effective in reducing pelvic diastases and thus volume than a simple bed sheet.

Critique; all measurements first sheet, then tpod. Ook aanbrengen en effect onder direct voelen aan de symfyse, dus weinig te zeggen over effect in de kliniek.

The fourth level V study is a case series performed by Nunn et al.[22] Herein, 7 patients with hemodynamically unstable pelvic fractures were initially treated using an improvised PCCD made of a cotton draw sheet. In a variety of fractures and associated injuries, all patients were described as seeming to have an excellent response to initial fluid therapy. However, all patients continued to need fluid resuscitation upon application of the PCCD. Three patients became hemodynamically unstable while undergoing further diagnostic examinations. So, although a transient effect of PCCDs was reported, patients did need continued fluid resuscitation. However, definitive treatment could be delayed and further diagnostics or interventions like laparotomy could be performed.

The fifth level V study was performed by Jowett et al[15] , who investigated the pressure characteristics of the Pelvic Binder® as a measure for the risk of developing pressure sores. The pressure exerted on the skin by a Pelvic Binder at the anterior superior iliac spine, the greater trochanters and the sacrum was measured in 10 healthy volunteers. The mean pressure was found to be 17.0, 13.4, and 11.1kPa, respectively. Since tissue damage is believed to occur when pressures of more then 9.3kPa are sustained continuously for more than 2 to 3 hours[13] their results suggest that PCCDs may not be suited for prolonged use.

Further reports on clinical efficacy of PCCDs are based upon case reports. In total, 7 level VI studies were found.[17, 23-26, 31, 32] Two reports claim adequate anatomic reduction of dislocated pelvic fractures with application of circumferential sheets,[23, 26] and two reports claim stabilization of hemodynamic instability in patients sustaining unstable pelvic ring fractures.[31, 32]

Reports on adverse outcome and complications have also been published. Krieg et al. reported on a 15 year old girl who sustained bilateral sacroiliac joint injuries, symphysic disruption, and bilateral rami fractures.[17] She was hypotensive (55/30mmHg) and tachycardic (120 beats/min). A PCCD was applied (SAM Sling, The Seaberg Co., Newport, OR). Within 48 hours, she received 14 liters of fluid, and developed edema. The patient developed skin necrosis over the area of PCCD application, specifically at the greater trochanteric region, which required several debridements and split skin grafts. The case presented by Schaller et al. also developed skin necrosis within 10 hours after application of a bed sheet.[24] Another patient sustained bilateral nerve palsy within 16 hours of application of a bed sheet. Motor function of the tibialis anterior, extensor hallucis longus and extensor digitorum longus was absent, but eventually returned to normal.[25]

Three reports contain only expert opinions, while no patients are presented.[10, 14, 30] Some authors describe techniques of application of PCCDs, especially improvised devices, ie sheets.

Discussion

Pelvic fractures are life-threatening injuries.[29] Reduction and stabilization lead to haemostasis. Early intervention may decrease blood loss, resulting in reduced morbidity and mortality. A method of early fracture stabilization that has been increasingly used in recent years is the use of non-invasive Pelvic Circumferential Compression Devices. These devices are well suited for use in the acute (out of hospital) phase of resuscitation, as they can easily be applied at the accident scene. Effects of these devices may be more effective in pelvic fracture patients than minimally invasive techniques like the C-clamp that can only be used in the in-hospital setting.

The aim of the current literature review was to gather the current evidence concerning the use of PCCDs. In total, 17 articles were found, none of which were level I or II (Table 2). The majority of reports were case reports, in which mainly instructions on how to use improvised PCCDs were described. Level III and IV evidence does exist, reporting effective fracture and pelvic volume reduction by PCCDs. Experimental studies, performed on human cadaveric specimens, also provide evidence of effective pelvic reduction and stability in several types of unstable pelvic fractures.[4, 5, 9] The fractures studied in these experimental studies were artificially inflicted. Fracture patterns occurring in vivo may show greater variation, and/or may involve more ligament disruptions. Therefore, results cannot be directly related to clinical effectiveness. A retrospective case-control study by Croce et al. suggests less blood loss upon application of a PCCD compared with invasive pelvic stabilization, resulting in lower transfusion requirements. However, this did not result in a statistically significant reduction in mortality rates. The number of pneumonias was, however, lower in the PCCD group.

Other factors, like advancements in pre-hospital life support protocols and quality of clinical resuscitation and intensive care treatment can obviously bias results. The main findings concerning efficacy of the use of PCCDs are summarized in Table 2. Results on studies of differences between the use of specially designed PCCDs or improvised devices like bed sheets have not been published.

Another aspect concerning the use of PCCDs that remains unresolved is whether the use of PCCDs in general, or a type of PCCD device in particular, is contra-indicated in certain fracture subtypes. Overall, it is insufficiently established whether PCCDs can be safely used on all types of pelvic fractures.

Certain risk factors have been described, mostly in case reports. Skin pressure exerted upon application of a PCCD following instructions of the manufacturer may exceed the safe threshold for developing skin necrosis. It is unclear from current data if a protocol can be developed for safe use of PCCDs in terms of pressure sore risk.

Conclusions

The currently available literature on PCCDs in patients with suspected pelvic fractures indicates a reduction of blood loss, and does not show life threatening complications associated with the PCCD use. Despite the absence of level I and II evidence for the clinical effectiveness of PCCDs, publications so far (level III-V) report that PCCDs are effective in reducing fractures and associated hemorrhaging. The nature, severity, and rates of PCCD related complications are not fully known. The effectiveness and safety of PCCD use in individual fracture types, also remain to be determined. Cases published do suggest a certain risk of skin damage and possible damage to internal organs after the use of a PCCD. The authors therefore state that prospective randomized clinical trials should be performed in order to further assess clinical relevance and safety of these devices. Information resulting from such level II studies may facilitate the development of an evidence based guideline for safe and effective use of PCCDs.

Conflicts of interest:

All authors state that no conflict of interest, neither financial nor personal, exists.

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Table 1. Level of Evidence[19]

Type of study	Level of evidence	Studies included
Systematic review with or without meta-analysis	I	0
Randomised controlled trials	II	0
Cohort studies	III	1
Case–control studies	IV	1
Case series	V	5
Case reports	VI	7
Opinion	VII	3

Table 2. Overview of the included publications showing the study design, level of evidence, type of PCCD used, fracture type(s) discussed and outcome measures used

Reference	*Design*	*Level of Evidence**	*N of cases*	*PCCD*	*Fracture type(s)*	*Outcome measure(s)*	*Clinical outcome*
Bottlang et al., 2002[4]	Case series Biomechanical cadaver study.	V	7	Experimental sling (50mm wide)	Y&B type II/III AP compression, 50 and 100mm diastases	• Most effective application site • Pelvic stabilization • Safety	Stability provided by PCCD comparable with C-Clamp
Bottlang et al., 2002[5]	Case series Biomechanical cadaver study.	V	7	Experimental sling (50mm wide)	Partially stable/ rotatory unstable fractures (OTA 61-B1 and 61-C1) with 50 and 100mm diastases	• Most effective application site • Pelvic reduction • Effect on intraperitoneal pressure • Strap-skin interface pressure	No risk for overcorrection or unstable correction
Croce et al., 2007[7]	Retrospective case-control study	IV	186	T-POD	Anterioposterior II and III fractures	• Transfusion requirement • Outcome	No significant difference in outcome (*i.e.*, mortality, hospital stay, morbidity) after T-POD versus external fixation Transfusion requirement lower (resuscitative, 24h, 48h) after T-POD versus external fixation
DeAngelis et al.[9]	Case series Biomechanical cadaver study.	V	12	Sheet vs T-POD	Rotationally unstable (Y&B APC II/ Tile B1)	• Pelvic reduction • Difference between T-POD and sheet	T-POD more effective in reduction than sheet. (21.9 vs 32.2 mm reduction).
Eastridge, 2007[10]	Opinion	VII	NA	Unknown	None	None	

Higgins, 2006[14]	Opinion	VII	NA	Sheet	None	None	
Jowett & Bowyer, 2006[15]	In vivo experimental Healthy subjects,	V	10	Pelvic Binder	None	• Skin pressure • Risk of pressure sores	Risk of pressure sores with use longer than 3 hours
Krieg et al., 2005[17]	Case Report	VI	1	SAM Sling	Tile C	• Pressure sores	Pressure sores after using PCCD
Krieg et al., 2005[16]	prospective clinical trial,	III	13	Experimental binder (15cm wide)	Internal and external rotation fracture patterns (OTA class 61-B1 and 61-C1)	• Reduction pelvic displacement	• Significant reduction of pelvic volume, comparable to definitive stabilization • No significant effect on outcome (*i.e.*, mortality, hospital stay, morbidity)
Nunn et al., 2006[22]	Case series	V	7	Sheet	Various, hemodynamically and anatomically unstable	• Hemodynamic stability/ fluid resuscitation requirement	Transient positive effect on fluid resuscitation requirement
Routt et al., 2002[23]	Case report	VI	1	Sheet	Tile A	None	
Schaller et al., 2005[24]	Case report	VI	1	Sheet	Anterior-posterior compression type II	Complication rates	Pressure sores after using bed sheet
Shank et al., 2003[25]	Case report	VI	1	Sheet with lower extremity wrap	Tile B	Bilateral peroneal nerve palsy	Bilateral nerve palsy after using bed sheet

Simpson, 2002[26]	Case report	VI	2	Sheet	Ota61b/c	Reduction symphysic diastases and pelvic inlet	
Vermeulen, 1999[30]	Opinion	VII	NA	Experimental sling	Not identified	• Stability • Time to application	
Ward, 1997[31]	Case Report	VI	1	Pelvic stabilizer	Open book with symphysic diastases 7.5cm and bilateral SI disruption (TileC)	Hemodynamic stability	Improved hemodynamic stability
Warme, 2002[32]	Case Report	VI	1	Sheet	Tile C, caudal displacement of right hemipelvis	Hemodynamic stability	Improved hemodynamic stability

* level of evidence, according to Table 1.

Y&B, Young and Burgess; OTA, Orthopedic Trauma Association; AP, Anterior-posterior; PCCD, Pelvic Circumferential Compression Device