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Effect of a new pelvic stabilizer (T-POD®) on reduction of pelvic volume and haemodynamic stability in unstable pelvic fractures

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ABSTRACT

Background: Pelvic fractures, often the result of high energy blunt trauma, are associated with severe morbidity and mortality. A new pelvic stabilizer (T-POD®) provides secure and effective simultaneous circumferential compression of the pelvis.
Methods: In this study we describe 15 patients with a prehospital untreated unstable pelvic fracture with signs of hypovolaemic shock with the T-POD®. Before and 2 min after applying the T-POD®, heart rate and blood pressure were measured. An X-ray before and directly after applying the T-POD® was made to measure the effect on reduction in symphyseal diastasis.
Results: Application of the T-POD® reduced the symphyseal diastasis with 60% ($p = 0.01$). The mean arterial pressure (MAP) increased significant from 65.3 to 81.2 mm Hg ($p = 0.03$) and the heart rate declined from 107 beats per minute to 94 ($p = 0.02$). Out of ten patients in whom the circulatory response before and after the T-POD® was recorded, seven were good responders, one had a transient response and two responded poor.
Conclusion: In the acute setting, the T-POD® device has a clear compressive effect on the pelvic volume in unstable pelvic fractures. The T-POD® is therefore an effective and easy to use device in (temporarily) stabilizing the pelvic ring in haemodynamically unstable patients.
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Introduction

Pelvic fractures represent a significant challenge for physicians caring for the injured patient. Most pelvic fractures are the result of high-energy transfer from severe blunt trauma. Unstable pelvic fractures with haemodynamic instability are rare and have, besides a high morbidity rate, a high mortality rate.[8–11,17,18,20] An unstable pelvic fracture can be associated with significant bleeding, resulting in a hypovolaemic shock. Initial treatment is based on reduction of the pelvic volume, before operative stabilization of the pelvic ring is carried out. It is believed that by reducing the pelvic volume, a tamponade-like effect occurs.[9,13,18] Over the last few decades, the most used non-invasive method for reducing the pelvic volume has been the pelvic binder,[15] which is wrapped around the pelvis circumferentially. In the last years new pelvic circumferential compression devices have become available, which seem to be effective in early stabilization of unstable pelvic fractures[16]: the SAM Pelvic Sling® (SAM Medical Products) and the Trauma Pelvic Orthotic Device (T-POD®, Pyng Medical). The latter distributes the pressure by one traction cable, resulting in a greater reduction of the pelvic volume. Clinical studies on the compressive effect of the T-POD® have not been conducted yet. The aim of this study is to measure the effect of the T-POD® on reducing the pelvic volume and on haemodynamic stability.

Methods

During the period of 2004–2007, patients with a prehospital untreated unstable pelvic fracture, who presented on the emergency room of our level 1 trauma centre, were included in the study. Patients with a pelvic binder that had already been applied in the prehospital period by paramedics, were excluded. All pelvic fractures were classified, by AP pelvic film or computed tomographic scans of the pelvis, by one senior author (AvV) according to the classification of Tile.[17] Before and immediately (2 min) after applying the T-POD®, blood pressure and heart rate were measured. The T-POD® was applied around the pelvis at the level of the greater trochanters by one of the authors (ET or AvV). Just before application of the T-POD®, compression was given at the level of the great trochanters, and the legs were internally

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Table 1
Characterization of enrolled patient population (separate document).

Pat.	Age (years)	Sex	Mechanism of injury	ISS	Tile	GCS	MAP before	MAP after	HR before	HR after	SD before (mm)	SD after (mm)	Time accident - emergency room (min)	Fluids (in mL)	Other injuries	LOS (days)	Comorbidity
1	44	M	MVA	29	B1	13	51.3	91.7[G]	85	85	81.5	23	50	500	Extremity	11	Cardiac
2	28	M	MVA	16	C2	15	86.7	79.7[G]	80	80	5.5		60	1000	Extremity	10	
3	58	M	MVA	57	B3	15	60.7	82.3[T]	134	127	24		32	1000	Chest, abdominal, extremity, vertebra	72	Hypertension
4*	44	F	MVA	50	C1	3	72.3	53.7[P]	110	100	47.5		102	1750[C,H]	Brain, chest, abdominal, extremity	1	
5	36	F	Crushed by Object	18	B3	14	96.7	93.3[G]	92	85	14.5	11	67	1500[C]	Chest	10	
6	27	M	MVA	59	B3	15	70		120	100	48	10.5	37	1500[C]	Chest, abdominal, extremity	71	
7	48	M	Crushed by Object	20	C3	15	59	84.3[G]	90	90	25.5	11	70	1000	None	10	
8	58	M	MVA	38	B3	15	53.3	106.7[G]	90	80	112.5	8.5	47	2500[C]	Brain, abdominal, extremity	25	Hypertension
9	51	F	Crushed by Object	41	C2	15	60	86.7[G]	140	90	7	4.5	60	1000	Chest, abdominal, vertebra	21	
10	38	M	MVA	50	C1	3	81	94.7[G]	119	81	56.5	14	50	1000		34	
11*	55	M	MVA	27	B1	9			105	103	25	11.5	70	2000	Chest, abdominal, extremity	8	Cardiac
12*	37	F	Pedestrian vs Train	43	B3	3	26.3	39[P]	120	112	35.5	4	33	1250[H]	Brain, chest, extremity	1	Psychiatric
13	44	M	MVA	16	B1	15					25	12	65	1000	None	7	
14	17	M	MVA	17	B3	15					40	17	65	500	None	11	
15	20	M	MVA	38	C1	15	66.7	81			29.5	21.5	98	1000[C]	Chest, abdominal, extremity, vertebra	31	Psychiatric

* Patients who died, [G] = Good Response, [T] = Transient Response, [P] = Poor Response, [C] = including 500 cc colloid fluids, [H] = including 250 hypertonic saline.
ISS = Injury Severity Score, Tile = Tile Classification, GCS = Glasgow Coma Score on arrival on the emergency room, MAP = Mean arterial pressure in mm Hg, HR = Heart rate per minute,
SD = Symphyseal diastase before and after applying the T-POD®, LOS = Length of hospital stay, Fluids = Fluid resuscitation includes all fluids administrated prehospital and in the Emergency Room until application of the TPOD®.

Table 2
Clinical data before and after application of the T-POD® (mean and standard error of the mean).

	n	Before	After	*p*
Symphyseal diastasis (mm)	12	41.7 ± 8.6	12.4 ± 1.7	0.01
Mean arterial pressure (in mm Hg)	10	64.7 ± 6.4	81.2 ± 6.4	0.04
Good response	7	69.7 ± 6.8	91.0 ± 3.3	0.04
Transient response	1	60.7	82.3	–
Poor response	2	49.3 ± 23.0	46.4 ±7.4	0.8
Heart rate (beats per minute)	10	106 ± 6.8	93 ± 4.9	0.04
Good response	7	99.4 ± 8.2	84.4 ± 1.6	0.1
Transient response	1	134	127	
Poor response	2	115 ± 5.0	106 ± 6.0	0.07

rotated, though not tightened together (Fig. 3). The results were used to calculate the mean arterial pressure (MAP) and to define the circulatory response (good, transient, poor), according to ATLS® guidelines. The reduction of the pelvic volume was obtained by measuring the average of the upper and lower edge of the pubic symphysis. For this measurement a plain anteroposterior pelvic radiograph was made before and directly after (within 5 min) applying the T-POD® according to a standardized protocol.

All statistical analyses were conducted using SPSS 16.0 (SPSS Inc. Chicago, IL, USA). The paired-sample *t*-test was used to compare the signs and symptoms before and after application of the T-POD®. Incomplete data were discarded in the calculations. We investigated the influence of confounders using linear regression with forward and backward selection. The confounders considered were: age, mechanism of injury, ISS, time between accident and presentation in the emergency room, fluid resuscitation (including difference in crystalloids, colloids and hypertonic saline) and number of other sites with associated injuries.

Results

During the 4-year period 63 patients with an unstable pelvic fracture presented initially at our level 1 trauma centre. Of these, 15 consecutive patients (4 females), with a prehospital untreated unstable pelvic fracture, were included. The median age of the patients was 44 years (range 17–58) and the mean Injury Severity Score (ISS) was 35 (range 16–59). Nine patients suffered a pelvic fracture type Tile B (B1 = 3; B3 = 6) and 6 Tile C (C1 = 3; C2 = 2; C3 = 1). Three patients died, two patients due to severe haemorrhagic shock (one patient with concomitant multiple extremity injuries, the other due to severe thoracic and intra-abdominal bleeding). Both died within 6 h after arrival in our hospital. The third patient died after 8 days due to a septic shock. No cases of skin necrosis or compartment syndrome were observed during the TPOD® application (maximum 48 h, for definitive care).

Because of their critical haemodynamic condition, a second pelvic radiograph (within 5 min) could not be obtained in 3 out of 15 patients. Application of the T-POD® reduced the pubic symphyseal diastasis significant with 60% (range 24–92%, $p = 0.01$) (Tables 1 and 2, Figs. 1–3). In ten patients a complete circulatory response (MAP and heart rate before and after applying the T-POD®) was recorded. Among the other five patients at least one value was missing, which made an accurate calculation for these patients impossible. In seven patients a good response was seen. One patient had a transient effect, and in two patients no improvement of circulation was seen. Of the non-responders other bleeding sources (abdomen, chest, extremities) were present in both cases. The MAP increased significantly from 64.7 to 81.2 mm Hg ($p = 0.04$) and the heart rate declined significantly from 106 beats per minute (range 80–140) to 93 beats per minute (range 80–127; $p = 0.04$) (Table 1). No side effects of the T-POD® in this study were seen.

The confounders found to be most associated with the difference in heart rate, MAP, symphyseal diastasis were largely

Fig. 1. X-ray of the pelvis before applying the T-POD®.

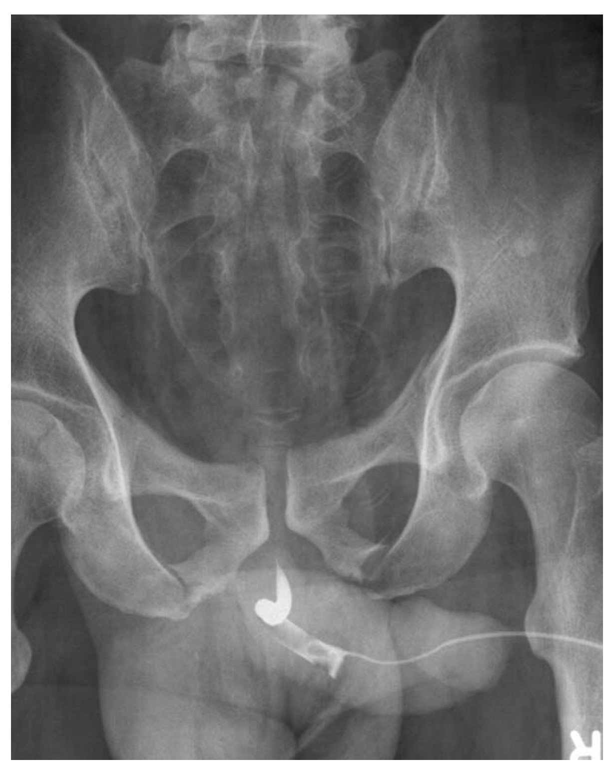

Fig. 2. X-ray of the pelvis after applying the T-POD® (same patient) combined with retrograde urethrography/cystography (no leakage).

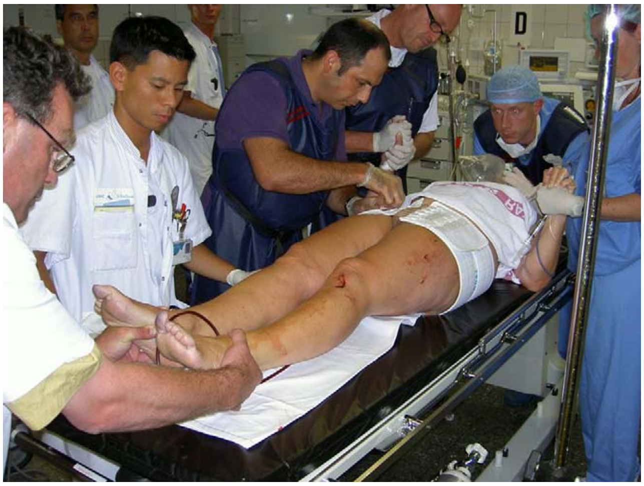

Fig. 3. Clinical application of T-POD®.

similar in forward and backward direction. Adjusting for these confounders showed that for heart rate and symphyseal diastasis, the effect of T-POD® remained statistically significant. For MAP, at least a trend was maintained (forward corrected *p*-value for the effect of T-POD® was 0.078, backward *p*-value was 0.027). For RR, the adjusted *p*-values for the effect of T-POD® were consistently non-significant.

Discussion

Our patient series is one of the first to demonstrate the effect of the T-POD® on haemodynamical stability in a clinical setting in a group of patients with prehospital untreated unstable pelvic fractures. We have found a statistical significant reduction of the symphyseal diastasis and significant positive changes in circulatory parameters. The treatment of unstable pelvic fractures is important, and research is difficult, because most patients with an unstable pelvic fracture also have other serious and complex injuries.[8,10,14,18]

The general treatment of unstable pelvic fractures is mainly based on quick stabilization of the pelvis. If the patient is haemodynamically normal at arrival, immediate definitive surgical treatment can be performed. Haemodynamical stability is important to prevent the lethal trias of hypothermia, metabolic acidosis and clotting disturbances.[19] Over the last decades the pelvic sling, an external fixator or the pelvic C-clamp[6] have been used for a quick stabilization of the pelvic ring. However, using these two invasive methods, takes considerable time and specific expertise. Additionally serious complications have been described in applicating the pelvic C-clamp: perforation of the os ilium, intrapelvic dislocation, haemorrhage and dislodgement of the pins into the greater sciatic notch.[1–3,7] The non-invasive methods for reducing the pelvic volume in an unstable pelvic fracture in the acute phase are safe, time efficient and technically easy to use.[3,5,12] Pelvic circumferential compression devices in the initial care for pelvic fracture patients is currently incorporated in the Advanced Trauma Life Support (ATLS®) guidelines.[4] The development of modern non-invasive methods, like the SAM Pelvic Sling® or the T-POD®, reduces the pelvic volume and symphyseal diastasis better than the traditional pelvic binders. The T-POD® is an easy and safe pelvic stabilizer, in one size and provides effective simultaneous circumferential compression of the pelvis with a specially engineered pulley system to ensure complete pelvic compression and stabilization, which may be used even single-handed with no straining. The costs in the Netherlands are around 95 euro (exl Tax), (weights 292 g measures 20 cm $\times$ 14 cm $\times$ 8 cm). In contrast to other Pelvic stabilizer the TPOD® is 100% radiolucent and CT and MRI compatible. The Sam Sling pelvic stabilizer is designed in that way that it cannot be overtightened. It is the only pelvic binder that will not allow a compression force greater than required to safely and effectively stabilize pelvic ring fractures. In the Netherlands the standard Sam Sling will cost around 70 euro (exl Tax, weights 257 g and measures 17.8 cm $\times$ 11.4 cm $\times$ 8.9 cm).

Prospective data on these pelvic circumferential compressions devices concerning mortality and complications is lacking, however some skin pressure sores due to these binders have been described.[16] In our case series we did not observe this complication.

DeAngelis demonstrated in a cadaver study, that the T-POD® had a better result on the reduction of symphyseal diastasis than the bed sheet pelvic binder.[5] Our study demonstrates the value of the T-POD® in the clinical setting; significant reduction of the symphyseal diastasis and significant improvement of circulatory parameters.

Several limitations hinder this study, the most important one having a selected patient population of prehospital untreated pelvic fractures, which could have biased our results. The time of measurement of the circulatory parameters is arbitrary and may also be influenced by the continued fluid resuscitation, according to ATLS® principles. In our opinion a clinical study without these influences may not be ethical and therefore not possible.[4]

A randomized controlled trial should be conducted to compare other measurements on symphyseal diastasis, circulatory parameters, need of transfusion, morbidity, and mortality. Prehospital use of the T-POD® should also be evaluated. It would be interesting to compare the effect of the T-POD® on the Tile B and Tile C fractures, as we believe that the greatest effect on haemodynamical stability can be reached in Tile B fractures. However, our study design was too small to demonstrate significant differences.

The T-POD® is a simple, safe, and easy to use pelvic binder with a clear compressive effect and a positive effect on the circulatory parameters. In our opinion the TPOD® is also suitable in a prehospital situation which can also be applied by paramedics upon suspicions of unstable pelvic lesions, at the accident scene to provide early stabilization within the "golden hour" and before patient transport, as well as by physicians at the time of hospital admission.

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