# Assessment of the efficacy of an elastic compression skirt (Jupystrap®) for pelvic girdle pain

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Conflicts of interest: Dr Philippe Nicolas is one of the founding members of PHILAU Sport and is the designer of the Jupystrap® device. PhilauSport provided, at no cost, all the Jupystrap® devices used during the course of the study.

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## Introduction

Pelvic girdle pain (also known as symphysis pubis dysfunction) affects 20 to 45% of pregnancies (1).This condition corresponds to the pain described during pregnancy affecting the anatomic region from the posterior iliac crest to the gluteal canal, and more specifically the sacroiliac joints. Conventionally, the pain is intermittent and is very often caused by simple, daily actions (walking, staying seated or standing for long periods of time) (2,3). This condition can be differentiated clinically from low back pain by the presence of a pain caused by palpation of the inferior segment and/or the pubic symphysis, and especially by latero-uterine pains along the round ligament path, from the inguinal region to the uterine horn.

This pelvic girdle pain may be associated with different factors(4):

- physiological ligament release due to the production of relaxine(5)
- mechanical action related to the foetus
- increased external rotation of the lower limbs while walking, related to a shift in the centre of gravity during pregnancy, leading to the internal rotator muscles being overworked, in particular the abductors.

Over the last few years, PHILAU Sport has developed a medical device (Shortystrap®) that is effective in the treatment of groin pain and pelvic muscle pain in athletes (6).In view of the clinical similarity between the functional complaint observed among high-level athletes and pelvic girdle pain, and based on the pathophysiological hypotheses for this condition, this company has developed a similar medical device that has been adapted to pregnant women, in the form of a skirt (Jupystrap®) for the treatment of pelvic girdle pain.

The aim of this study was to assess the efficacy of this device in a cohort of patients with pelvic girdle pain that has been authenticated by a doctor or a midwife.

## Materials and methods

This was a prospective, observational cohort study conducted between October 2013 and April 2015 at the Collège des Gynécologues from the town of Rennes and the Clinique Mutualiste de la Sagesse.

The inclusion criteria were:

- pregnant women 14 to 37 weeks of amenorrhoea (WA)
- singleton pregnancy
- adult patient capable of expressing her non-opposition to the study
- incapacitating pain in the pelvic area (pubic and/or inguinal)

The exclusion criteria were:

- multiple pregnancy
- History of osteoarticular surgery to the pelvis
- isolated low back or sacrum pain
- differential diagnoses of pelvic girdle pain:
    - risk of premature labour
    - appendicular syndrome
    - intestinal functional disorders
    - lower urinary infection

Adding an additional therapy for analgesic purposes during the study was an exclusion criterion.

All enrolled patients were provided with a Jupystrap® device correctly sized based on the manufacturer data (Figure 1). The Jupystrap® device was provided free of charge to the patient by PHILAU Sport.

The Jupystrap® device (Figures 2 and 3) is designed and manufactured in France with patent number (scope non-determined to date) of 1562088 filed on the 9 December 2015 by PHILAU Sport. This device is a certified medical device and CE standardisation was obtained on 18 January 2016.

The Jupystrap® device tends to reduce the mobility of the pelvis and the use of the internal rotator muscles. It limits the movement of the lower limbs and the activity of the abductor muscles.

This action is the result of:

- two diagonal elastic straps extending from hip to contralateral mid-thigh, made of neoprene
- a lower circular strap made of neoprene
- a Lycra skirt, the front belt of which is placed beneath the pregnant stomach
- four squares of neoprene, providing good stitching strength and an anti-slipping effect.

A questionnaire was completed at enrolment, including maternal characteristics, duration of the pain to date and intensity of the pain on a simple numeric scale (0 to 10). The patients completed a questionnaire online at the evalform.com website (personalised space dedicated to the study) at D1, D15 and D30. The intensity of the pain and the discomfort associated with the use of the skirt was recorded, using a simple numeric scale from 0 to 10. At D30, the satisfaction of the patient with respect to the device was also recorded using a scale from 1 to 5 (1 indicating not very satisfied at all, 5 indicating very satisfied). Finally, in order to assess the adduction effect of the device, the question was asked to patients in image form ("Do you feel it is indisputable that the Jupystrap® device brings the legs together inwards, as though you are walking on a tightrope?").

The statistics were performed using the R software environment (R-project.org). The paired Student's t-test was used for the qualitative variables and the chi-squared test for qualitative variables. A p value $< 0.05$ was considered significant.

## Results

Between 29 October 2013 and 7 April 2015, 48 patients were enrolled in the study. No exclusions needed to be made due to the addition of other analgesic medicinal and/or non-medicinal therapies.

Jupystrap® size was relatively evenly distributed in the cohort, from size 1 to size 7 (Figure 4).

The results of the questionnaire regarding maternal characteristics, and also the assessment of pain and satisfaction regarding efficacy of the device are recorded in Table 1.

95.7% of patients (n=46/48) felt indisputably the sensation of adduction of the lower limbs.

A side effect was reported for two of the patients, involving a rash due to irritation of the skin from contact with the neoprene. This side effects did not, however, lead to the withdrawal of these patients from the study. This was alleviated by adding clothing (leggings, stockings, etc.) to limit direct skin contact.

**Discussion**

The Jupystrap® support skirt provides a significant improvement in pelvic girdle pain between 14 and 37 WA with strong levels of patient satisfaction. This observational study conducted among 50 pregnant women presenting highly symptomatic pelvic girdle pain (mean SNS at enrolment: 7.58 (SD: 1.23)) shows a significant decrease in pain after the use of the Jupystrap® device, at D1, D15 and D30 with strong levels of patient satisfaction.
Although this was an observational cohort and not a case-control study, the cohort was representative of the various patient body shapes, since all the device sizes were represented in the cohort.

Pelvic girdle pain affects approximately 20 to 45% of pregnancies(1). The pain caused by this condition on a visual analogue scale is normally on average between 50 and 60 mm on a 100 mm scale (7). This condition, which occurs most commonly during the third trimester and sometimes as early as the second trimester, also has significant socio-economic consequences: increase in emergency consultations or consultations with different health professionals (physiotherapists, osteopaths, etc.), earlier and more frequent sick leave during pregnancy (8). This condition also raises the problem of more frequent consumption of analgesics and the exposure of the foetus to these analgesics during pregnancy.In particular, the latest scientific data regarding step I analgesics such as paracetamol, which are accessible for self-medication, suggest medium and long-term consequences for newborns (increase in the rate of cryptorchidism, reduced fertility later in life, increased risk of autism), especially in cases of prolonged use (9,10). Furthermore, although the functional prognosis is generally favourable post-delivery, some authors have found a postpartum decrease in mobility and an increase in comorbidities and depressive symptoms (11).

A number of alternatives to medicinal therapies have been proposed for the specific treatment of this condition (fitness exercises, yoga, pelvic support belt, osteopathic manipulations, cognitive behavioural therapies, etc.), but studies assessing their benefit provide only weak evidence or mixed results, and a meta-analysis performed in 2015 was not conclusive regarding their efficacy (12).Furthermore, physiotherapy and osteopathy sessions usually have only a temporary effect. The pelvic belts currently

being marketed (e.g. Physiomat®) have not, to our knowledge, been the subject of clinical studies specific to this condition or their assessment did not relate specifically to pelvic girdle pain (13).

## Conclusion

The Jupystrap® support skirt provides a significant improvement in pelvic girdle pain between 14 and 37 WA with strong levels of patient satisfaction. In order to confirm the efficacy of this device to a satisfactory level of scientific proof, it would seem to be necessary to perform an assessment using a controlled, randomised study versus placebo (Lycra skirt without elastic neoprene straps). Indeed, because this is a common disease with significant public health consequences, it is essential to rationalise the treatment of pelvic girdle pain and to assess objectively the medical devices being sold commercially for this indication without any scientific evidence.

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Figure 1: Table of choice of Jupystrap® size based on pelvis circumference

| SIZE | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| Circumference of pelvis-buttocks | 90/94 | 95/98 | 99/102 | 103/106 | 107/110 | 111/114 | 115/118 |

Figure 2: Representation of the mechanism of action of the Jupystrap® device

Figure 3: Appearance of the Jupystrap® device from the front and the rear


Figure 4 : Distribution of Jupystrap® sizes used in the cohort

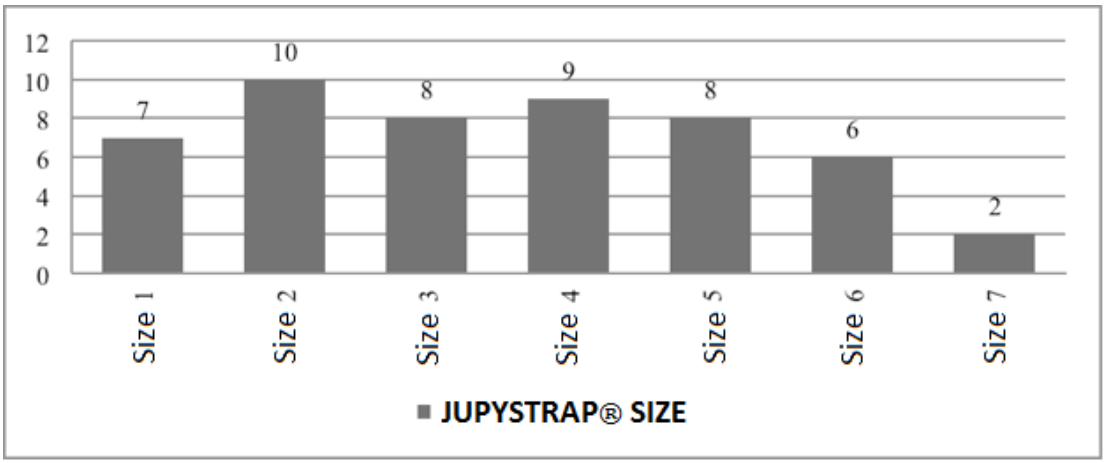


Table 1: Maternal characteristics (results expressed as mean and standard deviation or percentage)

| Characteristics | | *p* |
|---|---|---|
| **Age (years)** | 30.8 ± 4.53 | |
| **Body mass index (kg/m²)** | 25.9 (4.7) | |
| **Waist circumference (cm)** | 96.8 (10.1) | |
| **Circumference of pelvis (cm)** | 103.2 (10.4) | |
| **Jupystrap® device size** | 3.6 (1.7) | |
| **Gestational age when Jupystrap® device provided (weeks of amenorrhoea)** | 28.2 (5.5) | |
| **Duration of the pain to date (days)** | 8.6 (7.7) | |
| **Initial SNS without Jupystrap®** | 7.6 (1.2) | |
| **SNS at D1 after Jupystrap® provided** | 4 (2.1) | **< 0.0001** |
| **SNS at D15 after Jupystrap® provided** | 2.8 (2.1) | **< 0.0001** |
| **SNS at D30 after Jupystrap® provided** | 2.1 (2.5) | **< 0.0001** |
| **Discomfort associated with the use of Jupystrap® (scale from 0 to 10)** | 3.9 (2.3) | |
| **Assessment of satisfaction associated with the use of Jupystrap® (scale from 0 to 5)** | 4.1 (1.1) | |
| **Sensation of adduction of the lower limbs** | 95.8% | |

SNS = simple numeric scale (0 to 10)

## Figure and table legends

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