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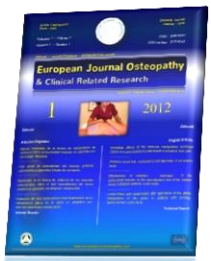

ORIGINAL ARTICLE

Assessment of Low Back and Pelvic Pain after applying the Pelvis Global Manipulation Technique in Patients with Primary Dysmenorrhea: A Pilot Study

Molins-Cubero S * [a,b] (PT, DO), Boscá-Gandía JJ [a] (PT, DO), Rus-Martínez MA [c] (PhD)

a Madrid Osteopathic School. Madrid. Spain.
b Clinic of Physiotherapy and Osteopathy S. Molins, Valencia. Spain.
c Department of Experimental Biology. University of Jaén. Spain.

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ABSTRACT

Introduction: Primary Dysmenorrhea (PD) is a common gynaecological disorder in women of childbearing age. The most common premenstrual symptom is pain in the lower abdomen, followed by low back and pelvic pain.

Objectives: We aim to assess the effect of global pelvic manipulation (GPM) on low back pain in subjects with PD through the evaluation of the: (i) self-perceived low back-pelvic pain; (ii) pressure pain threshold (PPT) in right and left sacroiliac joints (SIJ), and (iii) endogenous response of the organism to pain following catecholamines and serotonin release.

Material and Methods: A randomized, double-blind, controlled clinical trial was performed to evaluated the efficacy of the GPM in the treatment of women with PD. Twenty patients (n=20) with PD were screened, ten (n=10) belonged to the control group (CG) and ten (n=10) to the experimental group (EG). The low back-pelvic pain was measured using Visual Analogue Scale (VAS) scores, the PPT was determined with a digital algometer, and a blood test was performed to determine catecholamines (adrenaline, noradrenalin, and dopamine) and serotonin levels.

Results: A significant improvement of the PPT of both SIJ ($p = 0.001$) was observed in the EG, although there were no differences in the self-perceived low back-pelvic pain ($p = 0.129$). There was a non-statistically significant increase in serotonin ($p=0.447$) and dopamine ($p = 0.255$) levels, as well as a non-significantly decrease in plasma levels of adrenaline ($p = 0.819$) and noradrenalin ($p=0.218$) in the EG.

Conclusions: The bilateral GPM technique improves the PPT in both SIJ in patients with PD, but it does not affect the self-perceived low back-pelvic pain. The GPM also increases serotonin levels, but not significantly, although no changes are detected in the catecholamines plasma levels.

* Corresponding author: email: osteopasilvia@gmail.com (Silvia Molins) - ISSN on line: 2173-9242

INTRODUCTION

Primary Dysmenorrhea (PD) is a common gynaecological disorder in women of childbearing age[1,2], characterized by a number of symptoms that precede the menstruation. PD lasts between 48-72 h and it does not show any organic pathology. The most frequent symptom is pain in the lower abdomen, followed by low back and pelvic pain (fig. 1), although PD also shows other less frequent symptoms [3, 4]. This pain is described as a suprapubic pain, which radiates to both thighs, or to the lumbar-sacral region [1, 3-7], and it is sometimes accompanied by nausea and diarrhea.

PD affects 40-70% of women of childbearing age and is a repeated cause of absenteeism from work or school, thus interfering with daily life. In fact, PD is one of the most common gynaecological disorders in young women. However, to date there is any effective treatment for PD and women often tend to self-medication. Therefore, this problem should be addressed and new findings regarding aetiology and treatment for PD have recently been reported[3].

Medical treatment usually involves the administration of non-steroidal anti-inflammatory drugs (NSAIDs) and minor analgesics, since they are peripheral inhibitors of prostaglandin synthesis [8], which seem to be involved in the pathogenesis of PD [5]. The oral contraceptives are also proposed as pharmacological treatment, because they inhibit the ovulation and, consequently, the endometrium reduces the thickness thereby diminishing prostaglandins synthesis. Although its efficiency is about 90%, they show side effects [9].

In severe cases of PD, surgery intervention can be the best option, consisting of the resection of the pre-sacral plexus, denervation of the suspensory ligament of the ovary, and section of the uterus-sacral ligaments[10]. Also, alternative therapies have been reported to improve PD symptoms, including continuous low-level topical heat at hypogastric level [11], acupuncture [12], and transcutaneous electrical nerve stimulation (TENS)[13, 14]. However, these results are not conclusive enough to recommend a routinely use [15].

On the other hand, several works have analysed the efficacy of spinal manipulative therapy on subjects with PD [6, 16, 17]. In this sense, Boesler *et al.* indicated that both menstrual cramps and pain were relieved after high-velocity low-amplitude (HVLA) manipulation. Also Hondras *et al.* showed changes in pain, measured using Visual Analogue Scale (VAS) scores, after HVLA manipulation in women with PD.

Other studies have reported that manipulation at low dorsal, lumbar, and sacroiliac levels can modify plasma levels of some chemical mediators of pain[17-19] , however these results are inconclusive.

Based on the neurophysiological effects of spinal manipulation, consisting of decreased pain and gamma hyperactivity with consequent muscle relaxation, and added to the neurovegetative effect [20-22], this work is addressed to analyse the low back-pelvic pain, as well as several nociceptive biomarkers following the global pelvic manipulation (GPM) technique, bilaterally applied in patients with PD.

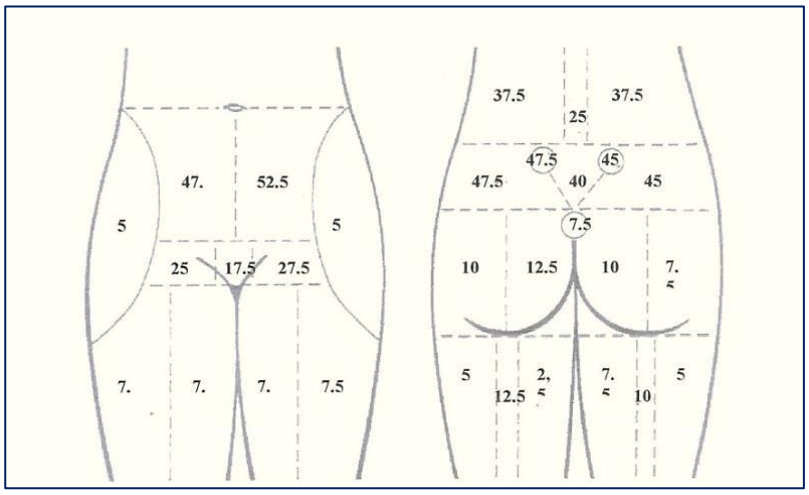

Figure 1. Distribution of pain in percentages in patients with pelvic instability suffering from dysmenorrhea (image taken with the consent of the author from the Thesis of Angel Burrel Botaya[6]: "Estabilidad sacroilíaca en dismenorreicas")

With this technique, we try to achieve a biomechanical effect in L5-S3 segments to relax muscles, fascias and ligaments, as well as affect the vegetative nervous system (VNS), particularly the hypogastric plexus, thereby improving uterine vascularization and regulating its contractions, responsible for ischemia and pain. In addition, we aim to examine the response of the pain inhibitory systems after spinal manipulation by measuring catecholamines and serotonin levels in plasma of women with PD.

MATERIALS AND METHODS

Design

A randomized, double-blind, controlled clinical trial was conducted.

Study Population

Twenty (20) women suffering from PD were included in the study and divided into two groups: Control Group (CG, n = 10) and Experimental Group (EG, n = 10). We collected medical records of patients from the Osteopathic Clinic of the main researcher, who suffered from low back pain and PD.

All patients had been diagnosed of PD by a gynaecologist, excluding any other gynaecological pathology. Inclusion criteria were the following: (i) aged between 18 and 40 years, (ii) regular menstruation, and (iii) patients who gave the informed consent.

Exclusion criteria were the following: (i) to have an intra-uterine device (IUD), (ii) to have secondary dysmenorrhea, (iii) to have been submitted to previous gynaecological interventions, (iv) contraindications to the GPM, (v) to have received osteopathic treatment in less of two months before the beginning of the study, and (vi) to have fear of GPM or blood test.

The sample size was calculated using the software "Tamaño de la muestra 1.1" ®, obtaining a sample of 10 subjects per group (control and experimental) as a pilot study.

Randomization

The assignment to one of the groups, CG or EG, was carried out by an Internet website (randomized.com), using a table of random numbers. The hypotheses and aims of the study were unknown for both the participants and evaluators.

Study Protocol

Patients, chose by the inclusion criteria, were cited in the clinic the first day of the menstrual cycle to begin with the measurement protocol and data collection, before they had signed the informed consent and filled the personal data form. The confidentiality of the data was guaranteed in accordance with Spanish Law 15/1999 on Data Protection. The process was conducted in a room equipped with a treatment table and temperature between 18 and 21 °C. All measurements were performed in both groups (CG and EG) before and after the intervention.

1. Evaluation of Low Back-pelvic Pain.

We used a Visual Analogue Scale (VAS) to measure the pain, since it is considered an effective, accurate, sensitive, easy to use, and reproducible method [24] to measure acute and chronic pain and its efficacy has been validated by several works [25-27]. The patient, seated on the treatment table, marks on the VAS the level that reflects the intensity of the low back-pelvic pain at that time. The result was expressed in millimeters (mm), ranged from 0 to 100 mm.

2. Assessment of Pressure Pain Threshold (PPT) in Sacroiliac Joints (SIJ)

We used a digital dynamometer (PCE, FM 200, China) to determine the PPT, defined as the point at which pain begins to be felt [28]. All measurements were expressed in kg/cm^2. We have previously validated the reproducibility of the pain location in the Posterior Superior Iliac Spine (PSIS) in patients with SIJ dysfunction [29].

The patient was placed in a sitting position on the treatment table, with feet on the floor and back straight. The evaluator behind the patient feels the PSIS and places the head of the algometer on the PSIS, perpendicular to the ground. The measurement is performed on each hemibody (fig. 2).

Figure 2. Measurement of the Pressure Pain Threshold (PPT) in right and left Sacroiliac Joints (SIJ) using algometry.

3. Blood extraction

Assessments were performed by an experienced nurse. The first blood extraction (pre-intervention) was performed on patient's right arm of CG and EG, and catecholamines (A1) and serotonin (B1) level were evaluated. The second blood extraction (post-intervention) was performed 30 min later on patient's left arm of both groups, also to measure catecholamines (A2) and serotonin (B2).

Blood samples were centrifuged for 10 min to separate plasma and serum following the method published by Schinelli Cubedu [10]. The tubes for analysis of catecholamines were frozen at -3 ºC until used, while tubes for determination of serotonin were refrigerated at 4 ºC. These tubes were insulating from light with aluminium, since light influences serotonin levels.

Catecholamines levels are commonly determined by radioenzymatic methods[30, 31], or by high-performance liquid chromatography with electrochemical detection [32, 33].

In this study, catecholamines were analyzed in plasma by high-performance liquid chromatography. For the determination of serotonin, we followed a modified Oishi [10] protocol in serum samples, which were then analyzed by high-performance liquid chromatography with electrochemical detection, following a modification of the method of Chaurasia [14].

4. Experimental Group Intervention. Bilateral Global Pelvis Manipulation (GPM) Technique

The GPM was carried out by an experienced osteopath in patients of the EG. The GPM is a semi-direct HVLA thrust technique that achieves a global opening of the SIJ and of the facet joint of L5 over S1.

Because it is a global technique, it is performed bilaterally. Its description[34,35] (according to Terramorsi) is as follows: the patient is placed in lateral decubitus position with the handle side up and pelvic obliquity, the lower limb in contact with the treatment table, is extended and the lumbar spine is in neutral position.

The osteopath performs trunk rotation and the patient interlaces her fingers while her hands rest on the side. The osteopath flexes the lower-top limb until perceiving tension at S2 level.

The osteopath stands in front of the patient, at the height of patient pelvis, looking to the patient head. The forearm contacts the SIJ and the iliac crest to bring tension to L5, the longer and lower arm of the SIJ.

The osteopath´s hand performs a small rotation and controls the patient chest. The slack reduction is done in three stages: (1º) to reduce the slack in the lumbar-sacral facet, the hand increases trunk rotation until perceiving tension in L5, (2º) to reduce the slack in the SIJ lower arm, the forearm pushes forward towards the lower arm to form a fold in this side, and (3º) to reduce the slack in the longer arm, the forearm pushes the bottom part of the SIJ towards the therapist trunk (in the direction of the longer arm).

These three reductions are kept while the osteopath adds compression to open the SIJ and puts the knee over the patient flexed knee to the Kick contact.

A thrust is performed increasing all parameters with the forearm and performing a compression towards the ground.

5. Control Group Intervention. Placebo.

The patients of CG received a placebo or sham procedure during two (2) min (estimated time to perform the bilateral GPM). The sham was performed by the osteopath, placing his hand on the hypogastric region of the patient, just above the pubic symphysis.

Statistical Analysis

The statistical analysis was performed using the SPSS Windows 17.0 software. The mean, standard deviation and 95% confidence interval (95% CI) were calculated for each variable.

The Kolmogorov-Smirnov test showed a normal distribution of all quantitative variables ($p > 0.05$).

The variables in both groups were compared using the Student's t test for quantitative variables and Chi square (X^2) for categorical variables.

An analysis of variance for repeated measures (ANOVA test) was performed using "time" (pre- and post-intervention) as intra-subject variable, and "group" (control or experimental) as inter-subject variable.

In variables in which statistically significant differences between groups at baseline were found, the pre-intervention value was included as a potential co-variable (ANCOVA) to adjust the effect [36].

RESULTS

In the EG, 7 women suffered PD between grades I and II (70%) and 3 patients had grade III (30%), whereas in the GC, all patients (n = 10) suffered PD between grades I and II (100%).

Table 1 shows the characteristics of the study subjects, attending study groups (EG and CG). When comparing both interventions, we detected a significant increase in the PPT of both right ($p = 0.001$) and left SIJ ($p = 0.007$) (table 2).

However, there were no significant differences in self-perceived low back-pelvic pain ($p = 0.180$).

Regarding the concentration of catecholamines (adrenaline, dopamine and noradrenaline) and serotonin in plasma, we observed a non-significant increase in levels of dopamine ($p = 0.795$) and serotonin ($p = 0.086$) in the EG after the intervention, while there was a non-significant decrease in adrenaline ($p = 0.932$) and noradrenaline ($p = 0.058$) level (table 2).

DISCUSSION

The GPM, bilaterally applied, exerts a statistically significant effect by improving the low back and pelvic pain, detected by an increase in the PPT of both SIJ, although it does not affect the self-perceived pain, determined with the VAS.

Several works have analysed the influence of spinal manipulation from T10 to L5, as well as at SIJ level on pain, measured with the VAS[17,35].

Contrarily to our results, Kokjohn *et al.*[17] concluded that spinal manipulation improves self-perceived pain in patients with PD.

However, Hondras *et al.*[37] obtained similar results to ours, showing that spinal manipulation failed to show a significant decrease in pain in these patients.

On the other hand, Boesler *et al.* found that spinal manipulation improves low back-pelvic pain (measured by electromyography of the lumbar musculature) associated with menstrual cramps and, therefore, the symptoms of dysmenorrhea[38]. This diversity of results can be motivated by the different intervention technique applied in each study and by the different spinal region manipulated[16]. It is worth noting that the pain suffering from these patients is complex due to its subjective and multidimensional nature. Therefore, we try to objectify a basically subjective phenomenon which shows a great individual variability. Given that a number of factors may influence this pain, it is crucial to find a representative study sample, as well as to standardize the variables in both groups[39].

VARIABLE		CONTROL			EXPERIMENTAL		
		PRE_I	POST_I	p-value	PRE_I	POST_I	p-value
PAIN	(VAS)	59.60 ± 27.87	59.40 ± 29.62	0.922	22.60 ± 10.46	16.85 ± 15.57	0.129
PPT_RS	(kg/cm^2)	1.37 ± 0.56	1.35 ± 0.56	0.179	1.64 ± 0.41	1.93 ± 0.46	0.004 *
PPT_LS	(kg/cm^2)	1.39 ± 0.42	1.27 ± 0.39	0.130	1.89 ± 0.44	2.03 ± 0.47	0.011*
ADREN	(ng/ml)	43.01 ± 5.82	42.51 ± 7.54	0.698	43.81 ± 9.07	42.99 ± 9.49	0.819
NORADREN	(ng/ml)	194.40 ± 38.59	227.50 ± 65.83	0.129	207.25 ± 100.2	181.11 ± 103.7	0.218
DOPA	(ng/ml)	76.10 ± 15.24	88.20 ± 21.17	0.193	61.0 ± 9.17	70.1 ± 20.45	0.255
SERO	(ng/ml)	115.19 ± 50.75	91.89 ± 37.57	0.135	57.13 ± 33.12	64.19 ± 43.43	0.447

Table 1. Pre- and post-intervention values in each group (control and experimental) for each variable.

CONTROL: Control Group; EXPERIMENTAL: Experimental Group; PRE_I: preintervention; POST_I: postintervention; p: p-value; VAS:Visual Analogue Scale; PPT_RS: Pressure Pain Threshold in the right Sacroiliac Joint; PPT_LS: Pressure Pain Threshold in the left Sacroiliac Joint; ADREN: Adrenaline plasma levels; NORADREN: Noradrenaline plasma levels; DOPA: Dopamine plasma levels; SERO: Serotonine plasma levels. Data are expressed as mean ± standard deviation. P values refer to the comparison between pre- and post-intervention values in each group by an ANOVA test ;* The statistically significant differences were expressed as *p<0.05.

VARIABLE		CONTROL	EXPERIMENTAL	p-value
PAIN	(VAS)	(- 0.2) ± 6.32 (95% CI - 4.32/4.72)	5.75 ± 10.88 (95% CI -2.03/13.53)	0.180
PPT_RS	(kg/cm^2)	0.02 ± 0.04 (95% CI - 0.11/0.05)	(- 0.29) ± 0.24 (95% CI -0.46/-0.11)	0.001 *
PPT_LS	(kg/cm^2)	0.11 ± 0.22 (95% CI - 0.04/0.27)	(- 0.13) ± 0.13 (95% CI - 0.23/-0.38)	0.007 *
ADREN	(ng/ml)	0.50 ± 3.9 (95% CI - 2.3/3.3)	0.82 ± 11.03 (95% CI -7.07/8.71)	0.932
NORADREN	(ng/ml)	(- 33.0) ± 62.67 (95% CI - 77.93 / 11.73)	26.14 ± 62.44 (95% CI -18.52/70.80)	0.058
DOPA	(ng/ml)	(- 12.10) ± 27.10 (95% CI - 31.48 / 7.28)	(- 9.1) ± 23.64 (95% CI - 26.01/7.81)	0.795
SERO	(ng/ml)	23.3 ± 44.85 (95% CI - 8.78/55.38)	(- 7.06) ± 28.1 (95% CI - 27.16 /13.04)	0.086

Table 2. Comparison between groups (control and experimental) for each variable from post- to pre-intervention.

CONTROL: Control Group; EXPERIMENTAL: Experimental Group; PRE_I: preintervention; POST_I: postintervention; P: p-value; VAS:Visual Analogue Scale; PPT_RS: Pressure Pain Threshold in the right Sacroiliac Joint; PPT_LS: Pressure Pain Threshold in the left Sacroiliac Joint; ADREN: Adrenaline plasma levels; NORADREN: Noradrenaline plasma levels; DOPA: Dopamine plasma levels; SERO: Serotonine plasma levels. Data are expressed as mean ± standard deviation (95% CI, confidence interval). P values refer to the comparison between pre- and post-intervention values in each group by an ANOVA test ;* The statistically significant differences were expressed as *p<0.05.

In this sense, the measurement instrument used, the VAS, has been considered one of the most reliable method for pain assessment[40]. As mentioned above, we have found a significant increase in the PPT of both SIJ after spinal manipulation. This means an improvement in pain and mobility of this joint, which is essential for the static and dynamic body adaptations and, therefore, the patients position is susceptible to be indirectly improved. In agreement with our results, previous works have shown that spinal manipulation improves the PPT in trigger points, suture points, and musculoskeletal points[41-45].

In this way, Legal[41] measured the PPT in the SIJ using the pressure algometry to analyse the relationship between the PPT of this joint and its mobility.

Burrel[6] related the low back-pelvic pain of dysmenorrhea with the SIJ and tested an improvement in the VAS after the application of the manipulation, a pelvic strap and exercises for 4 weeks. Our results showed the self-perceived SIJ pain also improved, but not in a significant way, probably due to the small sample size examined. Therefore, further investigation should be crucial to check if the GPM can improve low back-pelvis pain in patients with PD.

Concerning the endogenous response of the organism to the intervention, Degenhardt *et al.*[18] detected the concentration of five nociceptive biomarkers, including serotonin, in patients with low back pain after the application of the osteopathic manual therapy (OMT), without applying HVLA techniques. However, they did not find significant changes in serotonin levels in any study group. This result may imply that the effects of the OMT without applying HVLA techniques may not be mediated by the serotonergic pathway, but probably by endogenous opioids and cannabinoids.

In contrast, Skyba *et al.*[19] demonstrated in an animal model that joint manipulation increases the serotonin concentration, which can produce analgesia through the descending inhibitory pathway. Our initial hypothesis was that the GPM could activate the pain descending inhibitory pathways, increasing the levels of plasma catecholamines and serotonin. In this sense, our results showed no difference in catecholamine levels after intervention between CG and EG.

However, we detected an increase in serotonin levels in plasma of patients receiving the GPM, while there was a decrease in serotonin in patients receiving the placebo technique. Therefore, we infer that the GPM, despite having a strong influence on the pelvic structures, is not powerful enough to trigger the desired effect.

Nevertheless, given that this work is a pilot study, it would be of great interest to increase the sample size in order to further investigate the relationship between this type of manipulation and the increased levels of serotonin.

Study Limitations

We find some limitations in our study. As mention above, we detected significant differences in the pain measured with VAS at baseline in CG and EG. These results could be influenced if the patient had taken NSAIDs, which has been considered as a possible bias. This may explain why the EG showed lower baseline VAS values than patients of the CG, and thus, it would be difficult to reduce these initial potentially low values.

Furthermore, the measurement of plasma catecholamines and serotonin level is complex because they show a circadian rhythm, the first ones are very sensitive to both stress and the patient position, and the serotonin is influenced by the intake of certain food[46, 47]. For these reasons, our patients were placed in a sitting position and between each blood extraction they were at rest. Furthermore, the study was performed between 8 and 9 h pm to avoid influencing the initial levels. As mentioned above, emotional or physical stress can elevate catecholamines level; therefore, if a patient was afraid to manipulation or blood extraction and failed to

report such feeling, catecholamines levels may have been altered.

Based on the results obtained in this study, we understand that the GPM should be taken into account to treat gynaecological disorders such as PD, due to its observed effects on pain. However, it is also necessary to continue the research in this field in order to generalize the results and conclusions derived from this work.

CONCLUSIONS

The GPM, bilaterally applied, to women with PD significantly boosted the PPT of both SIJ, thereby improving pain and mobility of this joint. However, the GMP did not significantly influence the low back-pelvic pain, measured with the VAS. Regarding the levels of chemical modulators of pain (catecholamines and serotonin), we did not find significant differences in any biomarker, although we detected a non-significant increase in serotonin.

ETHICS RULES

Our study complies with the ethical standards established in the Declaration of Helsinki[48], and subsequent revisions.

CONFLICT OF INTEREST

The authors of the manuscript declare no conflict of interest.

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