



# European Journal Osteopathy & Clinical Related Research

Editorial – Original Articles

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2012

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Evidencias como Fuente de Excelencia  
en Osteopatía.

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Atlanto-Occipital Joint Manipulation and Suboccipital Inhibition  
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## PROGRAMA DO CONGRESSO

### 5 DE OUTUBRO DE 2012

8:30- ENTREGA DE DOCUMENTAÇÃO

9:00- PALESTRA 1

9:35- PALESTRA 2

10:10- PALESTRA 3

10:45- PAUSA BREVE

11:15- INAUGURAÇÃO OFICIAL.

11:50- PALESTRA 4

12:40- MESA REDONDA

13:15- PAUSA PRINCIPAL

15:15- PALESTRA 5

16:00- PALESTRA 6

16:35- PALESTRA 7

17:10- MESA REDONDA

17:45- ENCERRAMENTO

18:00- MOMENTO LÚDICO

18:30- PORTO DE HONRA

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9:35- PALESTRA 9

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11:50- PALESTRA 12

12:30- MESA REDONDA

13:00- ENCERRAMENTO

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# European Journal Osteopathy & Clinical Related Research



## EDITORIAL

### Evidences as a Source of Excellence in Osteopathy

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a. Editor of European Journal Osteopathy & Clinical Related Research

We present to the readers the new format of the journal previously known as Osteopatía Científica, which is transformed into an electronic journal, published in full text and free of charge in English and Spanish, with open access to facilitate the dissemination of research results performed in Osteopathy.

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Our magazine aims to contribute to the international development of Osteopathy, encouraging the dissemination of research results to generate evidence on the health problems associated with osteopathy. We are sure that in the future there will be more and more scientific discoveries that provide evidence in the field of the Osteopathy, which should consider the contributions of the multidisciplinary health sciences to provide appropriate diagnostic and therapeutic resources to all patients in any clinical perspective. We believe that research should be encouraged from the highest quality to produce results applicable to clinical populations. These results should be quickly disseminated among professionals involved in Osteopathy at no extra cost.

Excellence in Osteopathy could be achieved by obtaining evidence from rigorous studies, when their results reach clinicians effectively, and thus simply, quickly and without additional charges. In our opinion, this magazine under its new format can contribute to effective international dissemination of the results of research in Osteopathy.

Therefore, our efforts will be directed to achieve these objectives.

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# European Journal Osteopathy & Clinical Related Research



## ORIGINAL ARTICLE

### Immediate Effects of the Ashmore Manipulation Technique C5/C6, in Muscle Activity in patients with Mechanical Neck Pain

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## ABSTRACT

### Key Words:

*Manipulation, Spinal;  
Manipulation, Osteopathic;  
Electromyography;  
Neck Pain*

**Introduction:** The effects of spinal manipulation are not yet entirely clear. Previous studies have found both increased and decreased electromyographic (EMG) activity of muscles related to the level being manipulated, although few of them have considered the cervical region or symptomatic individuals.

**Objetives:** To determine the immediate effects of the C5/C6 (Ashmore) manipulation technique on bilateral EMG activity of the middle deltoid muscle at rest and in contractions.

**Patients, Materials and Methods:** A randomized, controlled, single blind, experimental study was conducted. A total of 30 individuals presenting with mechanical neck pain were assigned randomly to two groups: 15 formed the experimental group (EG), and 15 the control group (CG). All participants completed a data questionnaire and the NDI (Neck Disability Index), and underwent a vertebral artery and EMG evaluation before their participation. After C5/C6 manipulation in the intervention group and no manipulation in the control group, the EMG evaluation was repeated.

**Results:** All the variables were normally distributed, indicative of the total sample's initial homogeneity. Comparative post-intervention inter-group analyses showed statistically significant differences in the root mean square (RMS) values of the 30-s isometric bilateral EMG measurements of the middle deltoid muscle's activity.

**Conclusions:** C5-C6 spinal manipulation reduced EMG activity in the longer isometric contractions, but no changes were observed neither in the resting EMG values nor in the isotonic contractions performed.

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## INTRODUCTION

Spinal manipulation has been found to have different physiological effects. Among the most important are increased muscle strength<sup>1,2</sup>, the reduction of pain as evidenced by pressure pain thresholds<sup>3-5</sup>, changes in reflexes<sup>6</sup>, the capacity to change inhibitory neural processing and cortical motor control<sup>7,8</sup>, and control of the production of substance P or tumour necrosis factor<sup>9</sup>.

The musculoskeletal effects of spinal manipulation are not well understood<sup>10</sup>, although it is observed to cause facet joint cavitation, and to affect the mobility of the vertebral bodies and the reflex response of the muscles in the vicinity of the manipulation<sup>11</sup>.

The biomechanical changes caused by spinal manipulation are also considered to have the physiological consequence of affecting the inflow of sensory information to the Central Nervous System (CNS).

The procedure stimulates paraspinal muscle spindles and Golgi tendon organ afferents<sup>12</sup>. Small diameter sensory nerve fibres are probably activated, although this has not been demonstrated directly.

Therefore, one of the effects following spinal manipulation should be the capacity to alter central sensory processing by modifying the mechanical or chemical stimulation threshold of the paraspinal tissues<sup>6</sup> and the change in the excitability of alpha motor neurons<sup>13,14</sup>. Changes may occur both near and far from the location of the manipulation<sup>14</sup>.

There is an association between spinal manipulation and improvement of muscle function,<sup>15</sup> although this relationship is sometimes contradictory<sup>16,17</sup> and seems more evident in the lumbar than in the cervical spine<sup>18</sup>.

It has therefore been proposed to study the effects of cervical manipulation on non-spinal muscle electromyography (EMG) in symptomatic individuals (with neck pain)<sup>19</sup>. The purpose of the present study was to determine the immediate effects of the C5/C6 (Ashmore) manipulation technique on the resting and contraction bilateral EMG activity of the middle deltoid muscle in patients with mechanical neck pain (MNP).

## MATERIAL AND METHODS

### Design

The study design to evaluate the immediate pre- and post-intervention effects was experimental, randomized, single blind, and explanatory.

### Study Population

The participants were thirty (n=30) volunteers of both sexes who had presented Mechanical Neck Pain (MNP) in the last 6 months, aged between 22 and 45 years, divided into two groups: the experimental group (EG) (n=15; aged 22-42 years) received the Ashmore Technique, and the control group (CG) (n=15; aged 23-45 years) without intervention.

The volunteers were employees and students of FOP/UNICAMP recruited through in-campus posters and publicity. They all signed an informed consent form.

The exclusion criteria were: pathology of the vertebral artery (detected by screening<sup>20</sup>), severe osteoarthritis, osteoporosis, presence of a tumour, neck surgery, disk herniation in the neck, joint instability (torsion, fracture, or dislocation), cervical trauma, ingestion of analgesics in the preceding 24 hours, or receiving physiotherapeutic, osteopathic, or chiropractic treatment.

### Randomization

The distribution of patients to study groups was random, and it was generated by software - Microsoft Excel 2007® (Microsoft Corporation, Washington, USA).

### Assessments

We performed the following assessments:

1.- Neck Disability Index (NDI). The Neck Disability Index (NDI)<sup>21</sup>, translated into Portuguese and validated in Brazil<sup>22</sup>, was applied at the beginning of the evaluation.

2.- Electromyography (EMG). EMG was used to evaluate the activity of the (middle) deltoid muscle fibres before and after the intervention. We used a Myosystem-Br1 Electromyograph (DataHommis, Uberlândia, MG, Brazil) with active differential electrodes (silver bars 10mm apart, 10mm long, 2mm wide, gain of 20×, input impedance of 10 GΩ, and rejection rate of 130 dB at 60 Hz).

The device is designed in conformance with international standards, and was calibrated according to standard specifications<sup>23</sup>.

EMG activity was recorded with the subject seated comfortably in a chair in four situations: at rest for 5 s (with forearms and hands resting on the thighs), isotonic contraction (90° bilateral shoulder abduction, elbow flexed at 90° for 5 s), 5-s isometric contraction (maintaining the 90° abduction with a weight of 1 kg on the arm for 5 s), and 30-s isometric contraction (the same procedure but for 30 s).

To standardize the evaluation, the subjects received instructions from the evaluator as follows: before rests, "relax as much as possible"; before the isotonic contraction, "gradually separate the elbow from the body until it reaches shoulder height"; during the isometric contractions, "keep your position steady, don't move, you're doing good, hold on, ...".

The subjects rested for at least 30 s between evaluations. None of them made any mention of any pain during the evaluation or intervention. To analyze the EMG signals, we took their root mean square (RMS) values ( $\mu V_{RMS}$ ). The isotonic and isometric contraction measurements were divided into windows as follows: for the isotonic contraction, the beginning and end of the contraction were discarded; for the isometric contractions, we took one window at the initiation of the contraction and another at the end<sup>24</sup>. These evaluations have proven to have high reliability<sup>25,26</sup>.

### Experimental Group Intervention

The technique employed was that of Ashmore. This uses anterior and lateral glide, and the greater parameters of extension, ipsilateral lateroflexion, and contralateral rotation.

Adjustment is in the first part of the technique, followed by slightly increasing the tension to take up the soft-tissue slack, and the "thrust" is made in cervical rotation<sup>27</sup>.

According to Le Corre, this technique can be performed on the C3, C4 to C7, and T1 vertebrae in order to use the possibilities offered by the spine's biomechanics to minimize the maximum rotation and its impact on the vertebrobasilar circulation<sup>20,28</sup>. The technique was applied to the right side.

### Control Group Intervention

The individuals belonging to the CG underwent no intervention, only the vertebral artery test with the same waiting time as the other group.

### Statistical Analysis

Statistical analyses were performed using SPSS 16.0 (SPSS, Chicago, Ill). For the descriptive analysis, we calculated the mean and, as appropriate, the standard deviation, standard error, and/or 95% confidence interval.

The Kolmogorov-Smirnov test was used to evaluate the normality of quantitative data. Baseline characteristics were compared between groups using Student's *t*-test, the chi-squared test, and Fisher's exact test.

To analyze the principal effects of the intervention on the EMG, a two-way analysis of variance (ANOVA) was applied for independent samples with the groups (experimental and control) and the inter-subjects factor, and the moment (pre-post) and the intra-subjects factor.

The hypothesis of interest was the inter-group interaction. The analysis was performed for a confidence level of 95%, with values of  $p < 0.05$  being considered statistically significant. Intra-group effect sizes were calculated in terms of Cohen's *d*.

An effect size greater than 0.8 was considered large, of around 0.5 moderate, and of less than 0.2 small<sup>29</sup>.



VARIABLE	GROUP		p-Value
	EXPERIMENTAL (n=15)	CONTROL (n=15)	
AGE (years)	30,41 ± 4,76	30,78 ± 7,43	0,4
WEIGHT (kg)	65,55 ± 12,12	70,5 ± 16,55	0,3
HEIGHT (m)	1,7 ± 0,12	1,73 ± 0,23	0,4
BMI (kg/m <sup>2</sup> )	22,68 ± 2,81	23,58 ± 3,8	0,4
NDI	8,12 ± 3,4	7,8 ± 5,72	0,7

**Table 1. Demographic Results of both Groups.**

BMI: Body Mass Index; NDI: Neck Disability Index; The statistically significant differences were expressed as \* p<0.05.

VARIABLE (μV)	GROUP		ANOVA 2 way F (p-value)
	EXPERIMENTAL (n=15)	CONTROL (n=15)	
RMS resting Right PRE	1,7 ± 0,61	1,82 ± 0,62	0,01(0,9)
RMS resting Right POST	1,71 ± 0,65	1,71 ± 0,6	
RMS resting Left PRE	2,22 ± 0,9	2,46 ± 1,51	
RMS resting Left POST	2,21 ± 1,32	2,22 ± 1,2	1,52(0,28)
RMS isot Right PRE	96,87 ± 41,52	91,49 ± 34,20	<0,01(0,9)
RMS isot Right POST	90,52 ± 39,81	86,1 ± 26,78	
RMS isot Left PRE	95,32 ± 43,19	96,01 ± 47,02	
RMS isot Left POST	91,84 ± 47,29	89,42 ± 41,54	0,17(0,71)
RMS Isomet 5 seg Right PRE	90,01 ± 41,76	91,04 ± 33,88	<0,01(0,96)
RMS Isomet 5 seg Right POST	83,82 ± 36,23	85,43 ± 31,04	
RMS Isomet 5 seg Left PRE	83,66 ± 37,27	88,54 ± 38,62	
RMS Isomet 5 seg Left POST	81,44 ± 37,39	86,56 ± 42,86	0,05(0,84)
RMS Isomet 30 seg Right PRE	86,23 ± 33,23	81,67 ± 32,02	4,5(0,04)*
RMS Isomet 30 seg Right POST	81,82 ± 33,58	84,16 ± 34,34	
RMS Isomet 30 seg Left PRE	79,69 ± 32,08	84,50 ± 35,22	
RMS Isomet 30 seg Left POST	74,45 ± 33,56	88,93 ± 40,03	4,4(0,04)*
RMS INITIAL Isomet 30 seg Right PRE	92,23 ± 36,67	89,77 ± 33,02	<0,01(0,9)
RMS INITIAL Isomet 30 seg Right POST	92,07 ± 42,34	89,35 ± 32,67	
RMS INITIAL Isomet 30 seg Left PRE	87,56 ± 39,06	89,33 ± 42,43	
RMS INITIAL Isomet 30 seg Left POST	85,45 ± 44,78	99,67 ± 48,05	6,45(0,02)*
RMS FINAL Isomet 30 seg Right PRE	84 ± 33,67	81,54 ± 34,63	1,14(0,32)
RMS FINAL Isomet 30 seg Right POST	80,57 ± 34,05	80,38 ± 31,63	
RMS FINAL Isomet 30 seg Left PRE	76,6 ± 32,5	79,56 ± 31,02	
RMS FINAL Isomet 30 seg Left POST	70,03 ± 29,23	85,69 ± 31,01	8,9(0,01)*

**Table 2. Pre- Post-intervention Results of EMG variables**

RMS: Root Mean Square ; Data are expressed as mean ± (SD) standard deviation  
The statistically significant differences were expressed as \* p<0.05.

VARIABLE	GROUP	COHEN (d)
RMS resting Right	Experimental	-0,04
	Control	-0,13
RMS resting Left	Experimental	0,01
	Control	-0,17
RMS isotonic Right	Experimental	-0,16
	Control	-0,18
RMS isotonic Left	Experimental	-0,1
	Control	-0,16
RMS isometric 5 seg Right	Experimental	-0,18
	Control	-0,18
RMS isometric 5 seg Left	Experimental	-0,08
	Control	-0,08
RMS isometric 30 seg Right	Experimental	-0,11
	Control	0,07
RMS isometric 30 seg Left	Experimental	-0,10
	Control	0,07
RMS INITIAL isometric 30 seg Right	Experimental	0,01
	Control	0,01
RMS INITIAL isometric 30 seg Left	Experimental	-0,04
	Control	0,20
RMS FINAL isometric 30 seg Right	Experimental	-0,13
	Control	-0,05
RMS FINAL isometric 30 seg Left	Experimental	-0,21
	Control	0,19

Table 3. Results of Intra-group Cohen Index (d)

## RESULTS

There were no significant differences between the groups by sex, age, BMI, or NDI, nor in the pre-intervention values of the EMG variables, so that one could assume that the two groups could be compared in all the variables. The baseline data of each group are presented in Table 1.

**EMG.** The two-way ANOVA showed no effect on the short (5-s) activity, whether isometric or isotonic (Table 2). Differences were identified, however, in the longer-time deltoid activities. Thus, the total isometric activity showed a statistically significant lower bilateral electrical activity, with changes greater than 4 $\mu$ V. In the initial and final windows, the behaviour was more heterogeneous. Indeed, it was the CG which showed

the greater change in the RMS values, with these changes being more important on the left side. This behaviour is clearly distinct from a result of bilaterality, so that the capacity for any interpretation has to be questioned because of the high variability of the data for these variables.

Finally, although statistically significant differences were found, they constituted aspects of little clinical relevance since the corresponding effect sizes were close to 0. Even in the best of the cases they were low in magnitude, examples being the variables *RMS INITIAL Isometrics 30 s LEFT* (post-intervention increase in the CG) and *RMS FINAL Isometrics 30 s LEFT* (post-intervention decrease in the EG) (Table 3).

## DISCUSSION

Cervical manipulation at the C5/C6 level with leftwards rotation in the seated position was able to change muscle activity behaviour during contractions of long duration (30 s) in patients with MNP. Although bilateral, these changes were of low effect size, and lacked uniformity with respect to the window periods at the beginning and end of the contraction.

This behaviour contrasts with the homogeneity and absence of effects found in contractions of short duration (5 s), whether isometric or isotonic.

The results of this study are coherent with those in the literature on asymptomatic subjects, although, to the best of our knowledge, it is one of the first to evaluate the effects of cervical manipulation on EMG in patients with a pathology (MNP). Dunning et al.<sup>19</sup> performed a study that applied a C5/C6 cervical manipulation technique, evaluating the resting electrical activity of the biceps brachii in healthy subjects. They found increased bilateral EMG activity following the manipulation, as also has been reported in other studies<sup>10</sup>, contrary to the findings of the present study.

In contrast, Sterling et al.<sup>30</sup>, also observed a decrease in EMG activity of the neck flexor muscles following a C5/C6 joint mobilization technique. They explained this decrease as being a possible indirect effect of facilitation of the deep neck flexor muscles, leading to an improved motor pattern during the action of craniocervical flexion<sup>30</sup>.

This lack of uniformity in behaviour is also manifest in the lumbar spine, a region which has been investigated in greater depth, and with a greater diversity of research techniques, evaluation tools, and subjects than has the cervical spine<sup>2,17,18,31-33</sup>.

There are at least three proposed theoretical mechanisms of how spinal manipulation acts – as a mechanical arthrokinetic effect, as a neuroendocrine effect (e.g., endorphin release), and as a neurophysiological or reflex effect<sup>16</sup>.

Some authors have argued that changes in muscle activity after mobilization of the cervical spine can be explained by the reduction in pain, which has been associated with a sympathetic excitatory effect resulting in decreased muscle activity<sup>30</sup>.

These data are consistent with the hypothesis that spinal manipulation activates the descending inhibitory pathways through the midbrain periaqueductal gray area<sup>4</sup>, which also could be responsible due to the associated motor response to manipulation.

It was not possible to test these mechanisms in the present study because of the painlessness of the application of the protocols and the sample's low NDI values.

### Study Limitations

Although the 5-s and the 30-s results were consistent, it is possible to identify certain limitations and imprecisions in the study. The variability of the initial and final windows of the 30-s contractions reduced the power of the results to reject a null hypothesis, and the consistency of the negative results was limited (as in the CG). Several sample sizes are required to draw more decisive conclusions on these variables.

The diversity of the methods used in the literature makes it hard to draw stable conclusions that can be carried over to clinical practice, and limits the comparability of results between studies. The low NDI of our patients shows that in their cases the disease is not acute. It might be interesting to know what happens with spinal manipulation at different stages of MNP in the medium and long terms.

We propose long-term evaluation studies, including other variables as well as those of EMG, in different

conditions, and with larger samples, so as to achieve more consistent results.

## CONCLUSIONS

The Ashmore technique C5-C6 significantly reduced the bilateral EMG activity of the middle deltoids during 30-s isometric contraction, enhancing muscle recruitment and fatigue resistance, compared with the electrical activity in the control subjects, but no changes were observed neither in the resting EMG values nor in the isotonic contractions performed.

These changes were absent, however, in the shorter (5 s) activities, with small effect size.

## ETHICS RULES

This research meets the ethical standards established in the Declaration of Helsinki<sup>34</sup>.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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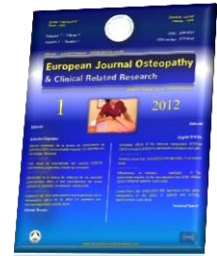
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# European Journal Osteopathy & Clinical Related Research



## ORIGINAL ARTICLE

# Atlanto-Occipital Joint Manipulation and Suboccipital Inhibition Technique in the Osteopathic Treatment of Patients with Tension-Type Headache

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## ABSTRACT

### Key Words:

Tension-type Headache;  
Manipulation, Osteopathic;  
Atlanto-occipital Joint

**Introduction:** The tension-type headache is extremely common, and has repercussions in both the work environment and the social life of the people who suffer from them.

**Objectives:** To evaluate the efficiency of two manual therapy treatments in patients with tension-type headaches.

**Material and Methods:** A random, double-blind trial was undertaken, with seventy-six (n=76) patients (81.6% women) diagnosed with tension-type headache ( $39.9 \pm 10.9$  years), distributed in four groups (n=19 each one), three experimental groups and one control group (without intervention).

Interventions in experimental groups included osteopathic manual therapy with: 1) Suboccipital soft tissue Inhibition Technique (SIT); 2) Occiput-Atlas-Axis global manipulation (OAA); 3) The combination of both (SIT+OAA). Treatments were applied during four sessions (one per week), with follow-up at 30 days. Patients were evaluated before and after treatment and during follow-up, by monitoring cervical mobility, the impact of pain and the frequency and intensity of the headache.

**Results:** The SIT group significantly improved the impact of the pain ( $p=0.02$ ). The OAA group and the SIT+OAA group, improved the headache impact and intensity ( $p<0.001$  to  $p=0.05$ ), and suboccipital flexion and extension ( $p<0.001$  to  $p=0.04$ ). The OAA group also improved cervical rotations ( $p=0.008$  to  $p=0.007$ ). The SIT+OAA group obtained significant results in the frequency and intensity of the pain ( $p<0.001$  to  $p=0.05$ ).

**Conclusions:** The three treatments applied were effective in the impact of headache and in pain intensity. The OAA treatment is the most effective in increasing cervical mobility, followed by the SIT treatment. The combined treatment SIT +OAA was the most effective in reducing the frequency and the intensity of the pain caused by tension-type headache.

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## INTRODUCTION

In 2004 the international headache society (IHS)<sup>1</sup> carried out a classification of primary and secondary headaches, as well as their characteristics. According to Felício et al.<sup>2</sup> between 22.65% and 30% of the population suffer from tension-type headaches (TTH), which have repercussions in the work and social environment, the daily life and the quality of life of those affected.

TTH is the most common form of headache and a health problem that has an important socio-economic impact. Furthermore, tension-type headaches provoke a high number of visits to diverse health professionals and generate a large number of medical prescriptions with high associated costs<sup>3,4</sup>. Stovner et al.<sup>5</sup> demonstrated that headaches occur during the most productive ages, between 20 and 50 years, causing an important reduction in the quality of life. Other studies<sup>6,7</sup> showed similar clinico-epidemiological characteristics.

Coupe et al.<sup>8</sup> measured the activity of the pericranial muscles using electromyography (EMG), after applying pressure to myofascial trigger points (TrP) in the neck and head, registering greater pain intensity and frequency in patients with TTH compared to patients of the control group. According to Serrano et al.<sup>9</sup> contracture of the pericranial musculature and stress both play fundamental roles, participating in the mechanisms of central and peripheral sensitisation, that can account for the painful pericranial hypersensitivity and a lowering of the pain threshold. Buchgreitz et al.<sup>10</sup> maintain that central sensitisation caused by experiencing prolonged periods of pain can cause this to become chronic.

Fernández et al.<sup>11</sup> demonstrated the association between trigger points in the trapezius muscles, the sternocleidomastoids and the temporal muscles, in patients with TTH with regard to the intensity and duration of the pain. In a later study, Fernández et al.<sup>12</sup> associated the cranio-cervical angle with the frequency

and duration of the pain and the presence of active suboccipital trigger points.

In a revision of the literature on the treatments for headaches, we have observed that the majority of the studies applied a combination of procedures or soft tissue techniques and manipulations,<sup>13-16</sup> but were unable to detect which of these was truly effective for this pathology. For this reason we determined to test the efficiency of manipulation of the occiput-atlas-axis (OAA) and suboccipital soft tissues inhibition technique (SIT), separately and in combination (SIT + OAA). The objective of this study was to evaluate the efficacy of the suboccipital inhibition technique (SIT) and occiput-atlas-axis manipulation (OAA) as treatments applied to alleviate pain, increase mobility and reduce the impact of pain in patients with TTH. Patients were further assessed one month after treatment ceased to determine whether the changes observed post-treatment were maintained.

## MATERIAL AND METHODS

### Design

This was a randomized, placebo-controlled, double blind, factorial study, with four groups. According to the Nquery program, the necessary number of subjects per group for an ANOVA of one inter-subjects factor with four groups, assuming a significance level of 5% for a high effect, is 19 subjects. The evaluations and clinical interviews were performed by an evaluator who had no knowledge of the studies objectives. All of the patients (experimental and control groups) were evaluated under the same conditions during all phases of the study.

### Study Population

A total of 76 patients, who had been referred by specialists from different fields, commenced the study and all of them completed it. They were diagnosed with frequent episodic TTH or chronic TTH. The other

criteria for inclusion or exclusion are shown in Table 1. The study was carried out between January and November 2010 at a specialised centre for headache treatment based in Valencia (Spain).

### Randomization

Patients were randomly assigned to the experimental or control group, which was double-blinded (neither patients nor therapist knowing to which group they were assigned). The randomization was performed with computer assistance by an assistant who had no relation to, nor knowledge of, the study or its objectives.

### Study Protocol

The protocol was performed as follows: (1°) Selection of the sample; (2°) Signature of informed consent; (3°) Randomization of patients to study groups; (4°) Preintervention assessments in the study groups; (5°) Interventions in the study groups (SIT, OAA, SIT+OAA, CONTROL - without intervention); (6°) Postintervention assessments in the study groups; (7°) Statistical Analysis and interpretation of data obtained.

### Experimental Group Interventions

We consider three experimental groups, each integrated by 19 patients and defined as: Suboccipital Inhibition Technique group (SIT) received Suboccipital Inhibition Technique; Occiput-Atlas-Axis group (OAA) who received the Occiput-Atlas-Axis manipulation technique; combined group (SIT + OAA) received both interventions, Suboccipital Inhibition Technique and also the Occiput-Atlas-Axis manipulation technique, in that order. During the treatment, four sessions were performed at seven day intervals. Each session had an approximate estimated duration of 20 minutes.

Prior to the intervention, a bilateral vertebral artery test was performed on the patients of all groups (including the control). Following treatment, the patient remained in the rest position on the treatment table for five minutes (10 minutes in the control group).

- Suboccipital soft-tissue Inhibition technique (SIT). The application of this technique produces an inhibition of suboccipital soft tissues. This tissue can respond to local stimuli produced by tension and messages from higher control centres, that are probably activated by pain or emotional stress<sup>16</sup>.

#### INCLUSION CRITERIA

- Be between 18 and 65 years of age
- Diagnosed with frequent episodic TTH and chronic TTH
- Have headaches on more than 1 day per month.
- Suffer from episodes of pain lasting between 30 minutes to 7 days
- Meet two of the following characteristics:
  - The pain is located bilaterally.
  - Pressing, non-pulsating pain.
  - Suffer mild or moderate intensity pain.
  - Headache is not aggravated by normal physical activity
- May suffer from photophobia, phonophobia, nausea or vomiting
- The headache may be associated with pericranial tenderness
- Suffer TTH for more than three months
- Be under pharmaceutical control

#### EXCLUSION CRITERIA

- Patients with infrequent episodic TTH and those patients with probable TTH in frequent and infrequent form.
- Headache that is aggravated by head movements.
- Metabolic disorders or musculoskeletal pathologies with symptomatology similar to headache.
- Previous neck trauma
- Vertigo, dizziness, arterial hyper/hypo tension
- Joint stiffness, atherosclerosis or advanced osteoarthritis
- Patients with cardiac devices
- Patients undergoing pharmacological adaptation
- Excessive emotional tension
- Neurological alterations
- Laxity of the cervical soft tissue
- Radiological alterations
- Generalised hypermobility or hyperlaxity
- Articular instability
- Pregnancy

**Table 1. Criteria for inclusion in this clinical study.** TTH Tension-type headache; Episodic TTH; Chronic TTH.

To perform the technique we use palpation of the suboccipital musculature to locate the posterior arch of the atlas. A deep, progressive, sliding pressure is applied. The objective is to release the spasms in the occipital muscles and soft tissues that provoke joint dysfunction in the occiput, atlas and also the axis.

The therapist sits at the head of the patient, placing their hands so that the occiput rests in the palms of the hands. With the hands in the correct position, upward pressure is applied to the atlas, the occiput being supported by the hands while the atlas is suspended by the finger tips. The pressure should be maintained for various minutes<sup>18-20</sup>.

- Occiput-Atlas-Axis global manipulation (OAA). This technique, first described by Fryette<sup>21</sup>, has been used in other trials<sup>22</sup>. It is employed to increase the range of motion of the joints between the occiput-atlas-axis, permitting the correction of a global dysfunction. It is a structural technique, applied bilaterally through a vertical line that passes through the odontoid apophysis of the axis, which uses neither flexion nor extension, and very little lateroflexión<sup>19</sup>

The osteopath stands on the side to be manipulated, their centre of gravity situated vertical to the area to be treated. The superior hand supports the head; the forearm is situated on the axis of the odontoid apophysis, and the head is then placed in right rotation. The inferior hand controls the opposing side of the head, on the side to be manipulated; the thumb rests behind the mastoid, the index finger rests over the temple, and the second finger rests in the direction of the internal angle of the eye. The ring finger, in metacarpalphalangeal flexion with phalanges 2<sup>a</sup> and 3<sup>a</sup> in extension, is placed below the chin. The forearm rests on the sternum of the patient with the elbow pointing toward the feet. The barrier to motion is located applying selective tension, and a high velocity manipulation is performed in pure rotation toward the side being manipulated without raising the head.

The rest position is the same for all groups, with the patient adopting the supine resting position, in neutral ranges of cervical flexion, extension, rotation and inclination. This allows the tissues to adapt to the changes they might have undergone, as well as to any temporary vasospasm that could have been produced following manipulation. Furthermore, this position produces a general relaxation of the cervical and suboccipital areas, eliminating the compression effects caused by gravity.

### Control Group Intervention

We do not apply any technique to the control group, but patients in the control group received the same assessments (impact of headache, goniometry, records), and the rest position was higher (10 minutes). Assessments were performed before the first session, at end of treatment and the follow-up at 30 days, as for all groups.

### Assessments and Variables

Following assignment to the corresponding group, individual clinical interviews were conducted that included the collection of socio-demographic data.

Subsequently, the evaluations described as follows were performed during three stages of the trial: at the beginning, at the end of the four week treatment period and at follow-up, 30 days after the end of treatment.

- Impact of Headache. The impact of headache using the Impact Ttest-6 (HIT-6) questionnaire, published by Ware et al.<sup>23</sup> evaluates the impact that headache has on the patient's work or daily activities. It demonstrates the effect that headaches have on a patient's normal daily life and their capacity to function. For the scoring interpretation of the Spanish version of HIT-6<sup>24</sup> the replies are classified: never (0 points), almost never (5 points), occasionally (10 points), frequently (15 points) and always (20 points). For a total of 48 points or less there is no functional limitation, between 50 and 60



points a visit to the doctor is recommended, between 50 and 54 there is some impact, between 55 and 68 the impact is moderate and for a score of over 60 the impact is severe.

**- Cervical Mobility.** Assessment of cervical segment mobility using the CROM goniometer. This is an easy-to-use, low cost evaluation method. The cervical range of motion (CROM) (Performance Attainment Associates. 958 Lydia Drive, Roseville, Minnesota, USA. 55113) combines a system of inclinometers and magnets arranged on a mainframe headpiece with a support to the bridge of the nose, that measures the degree of movement in flexion, extension, inclination and rotation. It also permits measurement of the range of movement of the suboccipital spine (C0-C1-C2). Different trials<sup>25-28</sup> have demonstrated the reliability of the instrument. In this trial we evaluated cervical movements of flexion and cervical and suboccipital extension, in addition to both rotations, with the aim of evaluating the possible limitation of mobility that might be suffered by patients with TTH. We had to bear in mind that this instrument incorporates a system of magnets and should not therefore be used on subjects fitted with devices such as pacemakers or defibrillators.

Prior to the trial, a pilot study was undertaken with two experienced evaluators and 12 subjects, who were evaluated for the range of mobility in suboccipital flexion and extension and the cervical spine's global range of motion, in addition to rotation to both sides. The global correlation between both evaluators in this trial was 0.98. The means obtained for the evaluators were 44.79 and 44.92 respectively.

**- Frequency and Intensity of the pain.** To evaluate the frequency and intensity of the pain we employed an easy to use daily register of scale - the visual analogue scale (VAS) - that can be analogical or visual and refers to the intensity of the pain felt by the patient at the time of the test.

### Statistical Analysis

The data was codified and analyzed using the statistics program SPSS for Windows (version 15.0).

Descriptive analysis of the sample in general and by groups was performed for absolute and relative frequencies, mean scores, standard deviation and the confidence interval. An ANOVA was performed during the pretest to confirm the homogeneity of the groups prior to starting treatment. This included the calculation and interpretation of the partial eta squared for the effect size index. In ANOVA-type analyses Levene's statistic is calculated to confirm the assumption about the homogeneity of variance. In those cases where the result was significant, the Welch, and Brown-Forsythe robust F tests were performed.

Likewise, the t-test for dependent samples was performed to compare the means of the pretest and post-test and of the pretest and the follow-up (separately for each one of the groups) and for the calculation and interpretation of the standardised mean change effect size. The Kolmogorov-Smirnov test was used in the t-tests separately, for each group, and each measurement, in order to confirm compliance with the assumption of normality. When this was not observed, the means were compared using the Wilcoxon signed-rank test. In order to check the association between qualitative variables the  $\chi^2$  test was applied, and for global associations in the ordinal variables the gamma coefficient ( $\gamma$ ) was used. The established level of significance in all the analyses was 5%. With regard to the effect size: 0.2-0.5 was considered small magnitude, 0.5-0.8 medium magnitude and >0.8 large magnitude.

## RESULTS

Of the 76 subjects in the sample, 62 were women (81.6%) and 14 were men (18.4%). The average age was 39.96 years (SD=10.93), ranging between 18 and 65 years. The time of evolution of the TTH for the whole sample varied from 1 to 53 years, with a mean of 10.98 (SD=11.78).

The patients feel pain in different areas of the head: 36.8% feel pain in the occipital zone, 34.2% in the interparietal zone and 29% in the frontotemporal zone. The moment of pain onset was variable: in 18.4% of the patients the headache began first thing in the morning, while in 44.7% of the patients the pain started

at any time during the day. For 6.7% headache onset was late in the day and 30.3% reported no fixed time for onset, with this being variable from day to day. On average the duration of the pain episodes was 1.43 days (SD=0.77).

100% of the patients suffered from bilateral pain. The patients reported a non-pulsatile pain in 81.6% of the cases and pulsatile in the remainder of the sample (18.4%); some 92.1% of the patients reported having medium intensity pain and 7.9% moderate pain. In 69.7% of the patients pain did not increase with physical activity; some 40.8% reported that they suffered pain on more than 15 days a month, whilst the rest said they had pain for less than 15 days.

With respect to the severity of the headache in the previous month, 50 patients (65.8%) suffered headaches of moderate intensity, 17 patients (22.4%) perceived them as severe and 9 patients (11.8%) as mild. Regarding the pain intensity, measured using the Visual Analogue Scale (VAS), the mean was situated at 6.58 (SD=1.73). A total of 42.1% of the patients have direct family members who experience headache.

51.3% of the patients reported that the pain was triggered by physical effort or by drinking alcohol, either together or in isolation. In 34.2% of the patients the pain was triggered by ingesting certain foods, such as chocolate, cheese or coffee.

As an aggravating factor, stress was considered to be the most important by 69.7% of the patients. In addition, job related factors aggravated the pain in 52.6% of the sample, whilst emotional, family and study-related factors affected 19.7%, 19% and 7.9% of the total sample respectively.

Depending on the activity to be performed, the impact of the pain was different: It was considered moderate by 72.4% of patients during the activities of daily living (ADL), by 61.8% during moderate-intensity

free time activities (FTA) and by 64.2% engaged in work-related activities.

With respect to the impact of the headache as evaluated with the HIT-6 questionnaire, the OAA group and the SIT + OAA group showed significant differences after treatment and in the follow-up with a large effect size.

In cervical mobility the results showed that suboccipital flexion obtained significant results in all of the experimental groups and in all the evaluations; suboccipital extension improved in the groups with a manipulation component (OAA and SIT+ OAA), with a greater effect size noted in the SIT+OAA group. Results for craniocervical flexion were positive in the SIT group with medium and large effect size, although this also occurred in the control group but with a smaller effect size.

Craniocervical extension improved in the manipulation group in both evaluations. The range of rotation to both sides improved significantly in both evaluations in the articulatory group. All the results relating to mobility are shown in Table 3.

In the register, the frequency of headache was statistically significant in the SIT+OAA group and the intensity improved in the follow-up for all groups, but had a larger effect size in the experimental groups (SIT, OAA, SIT+OAA) (Table 4).

## DISCUSSION

In our study the results confirm that TTH has specific pain characteristics that coincide with the IHS<sup>1</sup> classification as well as in aspects that influence TTH such as trigger and aggravating factors and having a family history of tension-type headaches<sup>29</sup>. The majority of sufferers are women, which coincides with all of the studies that were revised.<sup>30,31</sup> As with other studies, we

VARIABLE	STUDY GROUP			
	SIT	OAA	SIT + OAA	CONTROL
HIT-6				
Pre-treatment	59,21 (9,01)	60,32 (6,29)	60,68 (7,993)	58,11 (6,56)
Post-treatment	57,58 (7,87)	53,74 (6,19)	56,11 (8,432)	55,21 (7,85)
Follow-up	55,05 (7,42)	53,11 (6,33)	53,26 (7,362)	55,63 (8,05)
Pre-Post Treatment	t=0,88;p=0,39	t=3,98;p=0,001*	z=-1,99;p=0,04*	z=-2,247;p=0,02*
Effect size	0,18	1,00	0,55	0,42
Pre Follow-up	t=2,53;p=0,02*	t=5,47;p=0,000*	z=-2,92;p=0,003*	z=-1,5;p=0,13
Effect size	0,45	1,09	0,89	0,36

**Table 2. Results of the impact of pain with HIT-6 questionnaire**

The results are presented with the mean and standard deviation (SD); z Wilcoxon; t Student; \*  $p \leq 0.05$

have included patients with episodic and chronic TTH. Other studies were restricted to patients with episodic TTH,<sup>29,36</sup> whilst other authors only included patients suffering from chronic TTH.<sup>37</sup>

The pain, whilst characterised as covering all of the head like a "helmet," is localised principally in the occipital and interparietal zones and to a lesser extent in the frontal zone. In the study performed by Silberstein et al.<sup>38</sup> patients suffered from pain in the frontal region (95%), in the occipital zone (53%), in the interparietal zone (33.6%), and from pain throughout the head like a helmet (25.6%). The patients also reported one or more areas of pain. In our study we have analyzed the predominance of greater intensity, given that in tension-type headache pain is felt throughout the head with predominance in one particular zone, it being sometimes difficult to determine which area is the most painful.

According to the IHS<sup>1</sup>, TTH must present with two or more of the following characteristics: it must be bilateral, with non-pulsatile pressure; the headache must not increase during physical activity and should be of medium to moderate severity. The majority of the subjects of our study reported suffering from a bilateral pain and the greater part also reported that the headache was not pulsatile and that once established it did not increase during physical activity. In other

studies,<sup>29,38</sup> the incidence of bilateral pain had a lower percentage.

In contrast, with respect to the classification of the perceived severity of the pain (mild, moderate, severe), moderate was the answer given by the majority of the subjects of our study sample, which is similar to other studies<sup>38</sup>.

In the patients of our study, the pain became established in a variety of ways. This can be explained because it is the triggers, the aggravating factors and the situations of stress, and tension, produced during the course of daily life that provoke the headache. The associated symptoms are in the majority photophobia or phonophobia, pericranial tenderness and, to a lesser extent, nausea or vomiting. Other authors<sup>38,39</sup> obtained similar results in relation to these symptoms.

More than half the sample subjects have a direct family history of primary headaches. In the study by Matta and Moreira<sup>29</sup>, the family history of headache was 24% in a sample of 50 subjects, whilst in Holroyd et al.<sup>33</sup> it was 67% in a sample of 245 patients. The average age of the patients (39.7) usually coincides with the peak of commitments to work and family, resulting in greater stress due to the increased demands of both environments.



VARIABLE	STUDY GROUP			
	SIT	OAA	SIT + OAA	CONTROL
<b>Suboccipital Flexion</b>				
Pre-treatment	8,53 (5,12)	9,11 (3,48)	6,58 (2,27)	8,42 (4,75)
Post-treatment	12,68 (4,70)	15,26 (4,85)	11,47 (4,78)	9,68 (4,33)
Follow-up	12,11 (5,40)	12,00 (5,18)	10,89 (4,75)	9,32 (3,98)
Pre-Post Treatment	$z=-2,41$ ; $p=0,01^*$	$z=-3,63$ ; $p=0,000^*$	$z=-3,14$ ; $p=0,002^*$	$z=-1,39$ ; $p=0,16$
Effect size	0,77	1,69	2,06	0,25
Pre Follow-up	$z=-1,92$ ; $p=0,05^*$	$z=-2,74$ ; $p=0,006^*$	$z=-2,85$ ; $p=0,004^*$	$z=-0,59$ ; $p=0,55$
Effect size	0,67	0,79	1,82	0,18
<b>Suboccipital Extension</b>				
Pre-treatment	17,11 (10,33)	17,32 (9,92)	13,42 (7,14)	12,42 (6,38)
Post-treatment	17,37 (7,60)	23,53 (9,67)	19,84 (10,31)	14,74 (6,32)
Follow-up	19,32 (12,55)	21,26 (10,27)	20,11 (12,21)	12,16 (5,33)
Pre-Post Treatment	$z=-0,58$ ; $p=0,56$	$z=-2,86$ ; $p=0,004^*$	$z=-3,68$ ; $p=0,000^*$	$z=-2,71$ ; $p=0,007^*$
Effect size	0,02	0,60	0,86	0,34
Pre Follow-up	$z=-0,28$ ; $p=0,77$	$z=-2,09$ ; $p=0,04^*$	$z=-2,86$ ; $p=0,004^*$	$z=-0,36$ ; $p=0,72$
Effect size	0,20	0,38	0,90	0,04
<b>Cervical Flexion</b>				
Pre-treatment	49,26 (12,88)	52,42 (10,23)	52,89 (12,63)	50,63 (11,34)
Post-treatment	60,26 (11,78)	54,68 (10,06)	53,74 (11,11)	54,99 (11,02)
Follow-up	56,68 (11,13)	51,37 (10,73)	53,00 (10,54)	52,74 (10,58)
Pre-Post Treatment	$z=-2,96$ ; $p=0,003^*$	$z=-1,69$ ; $p=0,09$	$z=-0,91$ ; $p=0,36$	$z=-2,36$ ; $p=0,02^*$
Effect size	0,82	0,21	0,06	0,36
Pre Follow-up	$z=-2,07$ ; $p=0,04^*$	$z=-0,50$ ; $p=0,62$	$z=-0,60$ ; $p=0,55$	$z=-2,03$ ; $p=0,04^*$
Effect size	0,55	0,09	0,01	0,18
<b>Cervical Extension</b>				
Pre-treatment	51,89 (14,19)	48,16 (10,33)	53,16 (13,37)	51,32 (11,28)
Post-treatment	57,84 (13,20)	56,16 (12,15)	58,21 (14,80)	53,89 (11,26)
Follow-up	55,00 (12,68)	53,68 (7,72)	58,58 (11,32)	54,42 (11,64)
Pre-Post Treatment	$t=-2,15$ ; $p=0,04^*$	$t=-2,41$ ; $p=0,03^*$	$t=-2,209$ ; $p=0,04^*$	$t=-1,47$ ; $p=0,16$
Effect size	0,40	0,74	0,36	0,22
Pre Follow-up	$t=-0,85$ ; $p=0,41$	$t=-2,16$ ; $p=0,04^*$	$t=-1,72$ ; $p=0,10$	$t=-1,79$ ; $p=0,09$
Effect size	0,21	0,51	0,39	0,26
<b>Right Rotation</b>				
Pre-treatment	60,63 (11,74)	60,26 (8,35)	62,47 (9,61)	58,26 (10,08)
Post-treatment	65,00 (12,26)	69,05 (7,91)	67,58 (10,09)	61,53 (7,84)
Follow-up	61,16 (12,22)	66,79 (7,56)	65,58 (10,93)	60,47 (8,08)
Pre-Post Treatment	$z=-2,23$ ; $p=0,03^*$	$z=-3,34$ ; $p=0,001^*$	$z=-2,02$ ; $p=0,04^*$	$z=-1,77$ ; $p=0,07$
Effect size	0,36	1,00	0,51	0,31
Pre Follow-up	$z=-0,33$ ; $p=0,74$	$z=-2,65$ ; $p=0,008^*$	$z=-1,55$ ; $p=0,12$	$z=-0,28$ ; $p=0,78$
Effect size	0,04	0,75	0,31	0,21
<b>Left Rotation</b>				
Pre-treatment	56,95 (14,59)	64,11 (8,53)	62,84 (11,24)	62,21 (9,87)
Post-treatment	64,11 (13,84)	71,84 (7,67)	67,74 (12,34)	63,47 (10,19)
Follow-up	62,58 (10,77)	69,16 (8,30)	66,37 (11,92)	61,47 (10,00)
Pre-Post Treatment	$t=-4,1$ ; $p=0,001^*$	$t=-3,02$ ; $p=0,007^*$	$t=-2,42$ ; $p=0,03^*$	$t=-0,98$ ; $p=0,34$
Effect size	0,47	0,87	0,42	0,12
Pre Follow-up	$t=-2,27$ ; $p=0,04^*$	$t=-3,02$ ; $p=0,007^*$	$t=-1,52$ ; $p=0,14$	$t=0,79$ ; $p=0,44$
Effect size	0,37	0,57	0,30	0,07

**Table 3. Results of the range of cervical mobility.**

The results are presented with the mean and standard deviation (SD); z Wilcoxon; t Student; \*  $p \leq 0.05$

VARIABLE		STUDY GROUP			
Weekly Register		SIT	OAA	SIT + OAA	CONTROL
<b>Frequency</b>					
	Week 1	3,16 (2,32)	2,74 (1,82)	3,74 (1,82)	3,11 (1,52)
	Week 4	2,58 (2,19)	1,53 (1,90)	1,47 (1,50)	2,53 (1,50)
	Week 7	3,32 (2,06)	2,05 (2,27)	1,37 (1,26)	2,89 (1,97)
	Week 1-4 t/z	t=1,45; p=0,16	z=-2,56; p=0,01*	z=-3,53; p=0,000*	t=1,64; p=0,12
	Effect size	0,24	0,64	1,19	0,36
	Week 1-7 t/z	t=1,60; p=0,13	z=-1,34; p=0,18	z=-3,16; p=0,002*	t=0,44; p=0,66
	Effect size	0,07	0,36	1,25	0,14
<b>Intensity</b>					
	Week 1	4,80 (2,32)	5,06 (2,00)	4,72 (1,69)	5,22 (1,86)
	Week 4	3,66 (2,53)	2,90 (2,81)	3,25 (2,80)	4,05 (2,13)
	Week 7	2,70 (2,20)	3,14 (2,37)	2,87 (2,57)	3,88 (2,06)
	Week 1-4 t/z	t=1,62; p=0,12	t=2,60; p=0,02*	z=-1,98; p=0,05*	t=2,14; p=0,05*
	Effect size	0,47	1,03	0,83	0,60
	Week 1-7 t/z	t=2,43; p=0,03*	t=2,79; p=0,01*	z=-2,42; p=0,02*	t=2,17; p=0,04*
	Effect size	0,87	0,92	1,05	0,69

**Table 4. Results of the register of headache with respect to frequency and intensity**

The results are presented with the mean and standard deviation (SD); z Wilcoxon; t Student; \*  $p \leq 0.05$

The pain intensity measured using VAS gave a result of 6.58. Other studies<sup>32,40</sup> coincided in the average severity of pain suffered by the majority of TTH patients, according to the IHS<sup>1</sup>. The pain triggers, either together or in isolation, are found in a majority of patients and are: coughing, nose blowing, physical effort, and the ingestion of alcohol, chocolate, coffee or cheese. Stress is the most important aggravating factor, followed by job related, emotional and family factors - these being similar to other studies<sup>33</sup>. The evolution time of the headaches varied from 1 to 53 years, with a mean of 10.98 years (SD=11.78), signifying that in some cases subjects suffer from TTH almost all their life. In other studies, such as Straube et al.<sup>39</sup>, and Melchart et al.<sup>34</sup>, the average is still higher, being 13 and 14.5 years respectively. The results of our study on the impact of pain showed an average score of 59.21 at the beginning and 55.58 after the treatment; the majority of subjects presenting with a severe condition. By groups, the patients receiving OAA, the combined treatment (SIT+OAA) and the control had all improved, however at 30 days post treatment the three

experimental groups showed significant improvements in the impact of pain, but the control did not. The greatest effect size was for the OAA and the combined (SIT+OAA) group. The range of craniocervical mobility was evaluated using the CROM goniometer. Since this can be regarded as a situational test, subject to different interpretations on the part of the evaluator, a reliability study between the two evaluators was carried out prior to the start of the study and gave a Pearson correlation of 0.98. Other authors<sup>41</sup> obtained reliabilities between 0.61 and 0.97. In this study we have included the evaluation of the two movements of suboccipital flexion and excluded the movement of inclination, since this was not an objective of the treatments used. In suboccipital flexion following treatment and in the follow-up, all the experimental groups improved significantly, but the control group did not. Suboccipital extension improved significantly following treatment and at follow-up in the OAA group and SIT+OAA group. The control showed significant differences following treatment, but these were not found at the follow-up.

With respect to cervical flexion, the SIT group and the control group improved following the treatment and at follow-up, however the effect size in the control group was small. The cervical extension obtained improvements in the three experimental groups following the treatment, but this was only maintained in the OAA group. Mobility in right rotation improved significantly after treatment in all experimental groups but was only maintained in the OAA group and with a large effect size. For the left rotation, the three experimental groups improved significantly following treatment and these improvements were maintained in the SIT group and the OAA group. Our results demonstrate that for the two evaluations performed, the OAA treatment was the most efficient in improving cervical mobility (post-treatment and follow-up). This improvement was observed in 5 of the 6 movements evaluated. The greater efficiency of the OAA manipulation treatment with regard to cervical mobility might be because it involves the application of a technique in bilateral suboccipital rotation, which may have a relaxant effect in this region, thereby facilitating movement at this level. Knutson et al.<sup>42,43</sup> highlight the existence of a component of immediate, post-manipulation relaxation, resulting from the momentary reduction in muscle tone, however in our study this improvement was not only produced following treatment, but was maintained at the 30 day follow-up. In our study we have evaluated each cervical movement separately, whilst other authors<sup>44</sup> have measured ranges: flexion and extension, right/left inclination and both rotations. We consider the separate measurement of each movement to be more informative. The SIT was effective in suboccipital and cervical flexion and in left rotation. This might be because the application of this technique causes the relaxation of the posterior suboccipital muscles that participate in the extension and rotations of the first cervical vertebrae, which may have helped increase the flexion. For the control group, there was an improvement in cervical flexion in both groups, however this was obtained with a small effect size.

The effectiveness of manipulation in the treatment of TTH was shown to be positive in our study, obtaining significant results in the majority of the evaluations performed, both at post-treatment and at follow-up. Other studies<sup>45,46</sup> have not found conclusive results for the effectiveness of vertebral manipulation, probably because they did not include a control, or were performing single blind-control studies. In our study we have manipulated one vertebral segment and obtained better results, not only in frequency and intensity, but also in the impact of the pain and suboccipital mobility. Other authors applied the combination of various techniques, obtaining significant results in the intensity of the pain, the range of cervical mobility<sup>42</sup> and in the frequency<sup>16</sup> however, given that this consisted in the application of various combined techniques, we cannot know which of these was the most effective. The treatments employed in this study require an experienced therapist, due to the precision and complexity of the techniques applied and because of the need to understand headache progression. In our study the techniques used have been performed by therapists with more than 10 years' experience in the application of osteopathic treatments for primary headaches.

The results found in this study indicate that both patients who suffer from TTH, and the professionals who treat this pathology, will be able to benefit from them, since they bring together various aspects implicated in the understanding and treatment of the tension-type headache and provide new perspectives for future research, using other treatments and for other types of primary headaches.

### Study Limitations

Notwithstanding the results for the combined treatment, nor the fact that the combination of the two techniques in our study has proved to be effective in the areas assessed, we nonetheless question whether changing the order<sup>16</sup> of the techniques (OAA followed by inhibition) would have been more effective.

Compared with the other treatments used, we have obtained fewer significant results with the suboccipital soft tissue inhibition technique, this showing itself to be the least effective treatment; probably due to the application procedure that produced no tissue displacement, and was not combined with other techniques<sup>47</sup>, and might therefore resemble a placebo treatment. The application of soft tissue techniques has an relaxant effect on the cervical musculature, reducing both pain frequency and intensity<sup>15,48</sup> but in our study we have not considered specific trigger points. If they had been considered it is possible that changes would have been detected. The positive results found for the control group in some of the parameters or evaluations performed may be due to the fact that the control group design included detailed evaluations and control of the times spent in the rest position. The OAA and combined treatments have proved to be similar in their impact on the pain and in its frequency and intensity. Since the application of OAA requires less time, it might be better suited to the treatment of TTH, however this will require further follow-up to determine the time to effect for both treatments.

## CONCLUSIONS

The inhibition, OAA and combined treatments were effective regard to the impact of pain and in pain intensity. The manipulative treatment of the occiput-atlas-axis is the most effective in increasing cervical mobility, followed by the suboccipital soft tissue inhibition treatment. The combined treatment was the most effective in reducing the frequency and the intensity of the pain. The control group improved in some aspects following treatment, but this improvement usually dissipated over time. The effectiveness of therapies that include OAA in the treatment of tension-type headache is emphasised.

## ETHICS RULES

The study was supervised by the University of Valencia and approved by the local scientific research committee. Prior to the pretest, patients were asked for

their informed consent and all of the procedures were performed in accordance with the Helsinki<sup>49</sup> declaration.

## CONFLICT OF INTEREST

The authors of the manuscript declare no conflict of interest.

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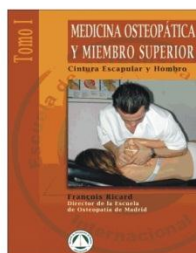
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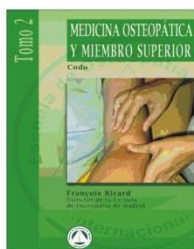
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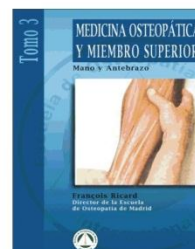
## MEDICINA OSTEOPATICA Y MIEMBRO SUPERIOR



**MEDICINA OSTEOPATICA Y MIEMBRO SUPERIOR**  
Tomo 1 Cintura escapular



**MEDICINA OSTEOPATICA Y MIEMBRO SUPERIOR**  
Tomo 2 Codo

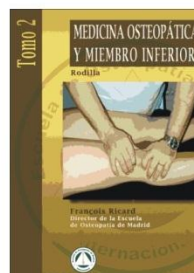


**MEDICINA OSTEOPATICA Y MIEMBRO SUPERIOR**  
Tomo 3 Mano y Antebrazo

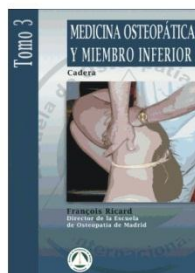
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Tomo 1 Tobillo y pie

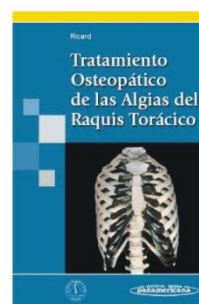
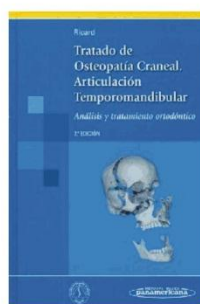
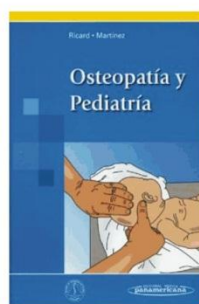
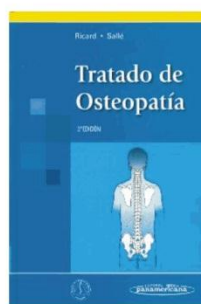
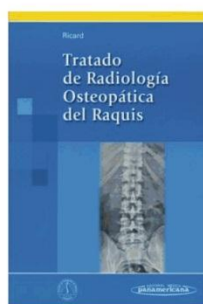
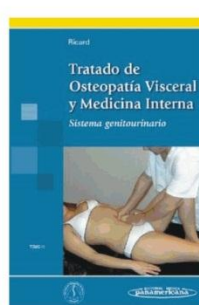
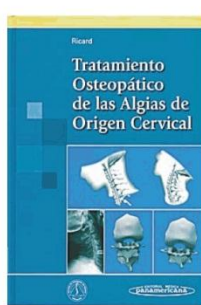
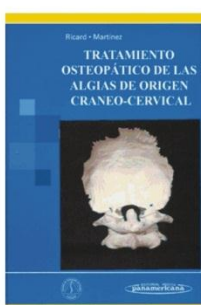
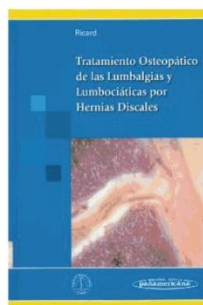


**MEDICINA OSTEOPATICA Y MIEMBRO INFERIOR**  
Tomo 2 Rodilla



**MEDICINA OSTEOPATICA Y MIEMBRO INFERIOR**  
Tomo 3 Cadena

## Otros Títulos





# European Journal Osteopathy & Clinical Related Research



## ORIGINAL ARTICLE

### Effectiveness of the Suboccipital Muscle Inhibition Technique on the Neurodynamic Test of the Median Nerve in Patients with Whiplash: A Pilot Study

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#### ABSTRACT

#### Key Words:

Whiplash Injuries;  
Median Nerve;  
Manipulation, Spinal

**Objectives:** We aim to determine the immediate effectiveness of the Suboccipital muscle Inhibition Technique (SIT) in patients with cervical whiplash regarding self-perceived neck pain, grip strength and response of the elbow joint mobility to the neurodynamic test of the median nerve (Upper Limb Tension Test – ULTT-1).

**Material and Methods:** A randomized, single-blind, clinical trial was carried out in 18 patients (mean age:  $30 \pm 10.35$  years; 19-52 years) randomly distributed into two study groups: control (CG; n=9) and experimental (EG; n=9) group. The CG received a placebo technique consisting in a flexion/extension of hip and knee on the opposite side to which the measurement is taken.

The EG was submitted to the TIS. Neck pain was measured using Visual Analogue Scale (VAS) scores, the grip strength was determined with a hand dynamometer and the elbow mobility with an universal goniometer.

**Results:** The EG showed a statistical increase in the elbow goniometry ( $p = 0.01$ ) compared with the CG. There were no differences between groups in neck pain ( $p = 0.062$ ) and grip strength ( $p = 0.067$ ).

**Conclusions:** The application of the SIT to patients with whiplash improves the response of the elbow joint to the neurodynamic test of the median nerve, although it does not affect neck pain or grip strength.

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## INTRODUCTION

Cervical whiplash injury can cause changes in the median nerve function and affect intervertebral discs, muscles, joints and ligaments <sup>1</sup>. Regarding the nervous tissue, it has been found that whiplash injury can damage the cervical nerve roots, the dorsal sensory root ganglia and the spinal cord <sup>2</sup>. On the other hand, the pain of the nervous tissue comes from the connective tissue surrounding the nerve, which is capable of transmitting pain <sup>3</sup>. It has been shown that both pain and changes in somatosensory thresholds may occur as a result of minor injuries on axons and/or of the inflammation of this connective tissue, without showing axonal damage. Therefore, the neuron ability to transmit nerve impulses through the axon remains intact, converting the electromyography in an inappropriate diagnostic test for this type of minor axonal injury <sup>4</sup>. It is worth noting that neurological symptoms can appear without evident nerve fiber damage <sup>5</sup>.

The neurodynamic test of the median nerve (ULTT-1) is frequently used to assess the mechanics and physiology of the brachial plexus and median nerve. A pathological response to the neurodynamic test of the brachial plexus or neurodynamic test of the median nerve (ULTT-1) is defined as the reproduction of the patient's symptoms and a decreased joint mobility <sup>4,6</sup> by means of the principle of muscle protection <sup>7-9</sup>. In this sense, Jaberzadeh *et al.* <sup>10</sup> found an activation of the mechanoreceptors of the median nerve before pain was felt, suggesting that the nerve tissue may be implicated, as a contributing factor, in the patient symptoms <sup>11,12</sup>. It has also been reported <sup>14,15</sup> an increase in the algescic response in patients with whiplash after applying a tensile force in the brachial plexus (verifiable using the ULTT <sup>13</sup>). In parallel, an entrapment of the median nerve in the carpal tunnel has been suggested as an associated component to the chronic pain of the arm that occurs in cervical whiplash patients <sup>16</sup>.

The irritation of the cervical spine nerve roots can explain many of the symptoms and signs associated with cervical whiplash. Therefore, we aim to perform the technique of inhibition of myofascial tension at this cervical level to try to avoid the spasms of the suboccipital muscles which fix the dysfunction of the

occiput-atlas axis <sup>17</sup>, as well as to achieve the distension of the dura, closely linked to the suboccipital muscles through the myodural bridge <sup>18-20</sup>.

With this pilot study we aim to check if the suboccipital muscle inhibition technique improves the response of the patients with whiplash to the neurodynamic test of the median nerve regarding: (a) the elbow joint mobility, (b) the response to neck pain, and (c) the grip strength of the hand.

## MATERIAL AND METHODS

### Design

A randomized, single-blind, clinical trial was carried out without relationship between the evaluator and the therapist.

### Study Sample

The sample of this pilot study consisted of 18 subjects with a mean age of  $30 \pm 10.35$  (19-52 years), considered adequate for the proposed objectives. The sample was divided into 2 groups: Control Group (CG; n = 9) and Experimental Group (EG; n = 9).

### Randomization

The distribution to each of the study groups, control (CG) and experimental (EG) was carried out using a table of random numbers.

### Study Protocol

The study was conducted in the same room, between 16 and 20 h, and with a temperature about 20-22 °C. The protocol for data collection was the following:

1. The patient, diagnosed by an specialist with cervical whiplash grade I or II according to the Quebec Task Force <sup>21</sup>, was informed of the objectives of the study and signed the informed consent form if meeting the inclusion criteria.

The inclusion criteria were the following: (i) adult (over 18 years old), and (ii) positive response to the ULTT-1. Exclusion criteria were the following: (i) neck pain within 3 months prior to this study, (ii) malformations, previous surgery or injury that



prevent the realization of the neurodynamic test, and (iii) neurological and/or rheumatic disorders.

2. The evaluator determines the side of the upper trapezius muscle that shows more severe symptoms, and the ULTT-1 was carried out in such side following the protocol described in previous works <sup>8,10</sup>.
3. The evaluator performs an initial assessment of each study variable in patients of both groups (CG and EG). The neck pain was measured using the Visual Analog Scale (VAS). The amplitude of the elbow mobility was determined using a universal goniometer during the ULTT-1. The grip strength was assessed with a dynamometer (JAMAR ®, mod 5030J1, Illinois, USA).
4. Patients from the EG were submitted to the intervention technique. The placebo technique was applied to patients of the CG, and subsequently the evaluator measured again each variable in patients of both groups.

### Intervention Technique in the Experimental Group

The suboccipital muscle inhibition technique was performed in patients of the EG during 4 min following the methodology described in previous studies <sup>18,22</sup> (fig.1).

### Placebo Technique in the Control Group

The placebo technique was carried out in patients of the CG. This technique consisted in a movement of flexion/extension of hip and knee on the opposite side to which the measurement was taken (fig. 2).

### Statistical Analysis

The statistical analysis was performed using the SPSS Windows 18.0 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 variables. The Student's t test was used for comparison of variables (goniometry of elbow joint, grip strength and self-perceived neck pain) between control and experimental groups. The level of significance used was 0.05.

**Figure 1**  
**Suboccipital**  
**Muscle Inhibition**  
**Technique.**

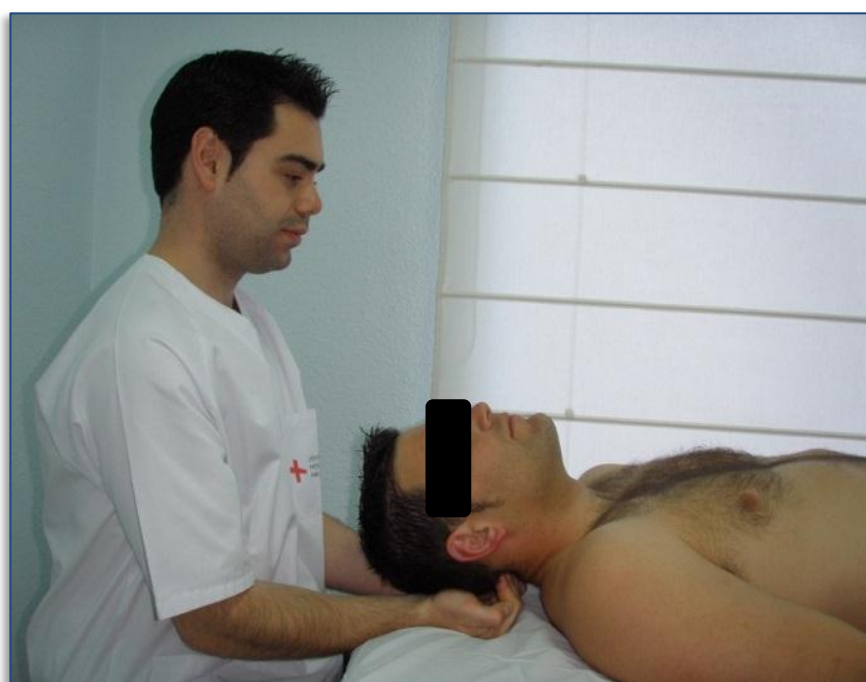




Figure 2

**Placebo technique:  
flexion/extension of hip  
and knee.**

## RESULTS

The sample consisted of 18 subjects, 10 women (55.6%) and 8 men (44.4%); CG (n=9) and EG (n=9). The pre-intervention demographic data and variable values (self-perceived neck pain, grip strength and goniometry of elbow) of each group are shown in table 1.

When comparing both interventions between groups we detected a significant improvement in the EG after the intervention, regards to the goniometry of elbow ( $p=0.010$ ) but not significant increases were detected in neck pain ( $p=0.062$ ) and grip strength ( $p=0.067$ ) (table 2). Although these variables (neck pain and grip strength) did not show any significant difference, the p-value is close to the statistical significance in both cases.

## DISCUSSION

The suboccipital muscle inhibition technique significantly improves the amplitude of elbow joint during the ULTT-1, although there was not any change in grip strength or self-perceived neck pain. The sustained contraction of the trapezius muscle occurs in subjects with cervical whiplash as a protective mechanism of the cervical roots<sup>23-25</sup>.

Thus, muscle activity at this level is justified by the flexor withdrawal reflex, perpetuated by the involvement of the cervical roots. After the whiplash, the constant tension of the trapezius muscle protects the cervical region from suffering from the normal traction of the upper limb weight<sup>10</sup>. The fascial intervention at suboccipital level seems to cause an interruption of the gamma loop that perpetuates the trapezius hyperactivity through the influence that the technique exerts on the posterior elongated hole and, thus, on the spinal nerve (cranial nerve XI). On the other hand, the relaxation of the dural system resulting from the suboccipital inhibition<sup>18</sup> provides a greater path of the elbow during the ULTT-1. It is more complex to explain that neck pain does not decrease after the suboccipital muscle inhibition technique. The presence of a central hyperalgesia in the patients is perpetuated by both physical and psychological aspects that enhance pain at central level<sup>26</sup>. Therefore, it seems to be difficult to significantly decrease such an important parameter using a single intervention. Moreover, the cervical whiplash also involves muscle problems, and malfunctions at many levels including ligaments and joints, so therapeutic treatments should include techniques that also impact directly on such levels.

VARIABLE	GROUP		Z
	EXPERIMENTAL	CONTROL	p
<b>Age</b> (i) (years)	30 ± 11.08	30 ± 10.22	0.879
<b>Gender</b> (ii) (Man, Woman; %)	44.4% (4/9); 55.6 (5/9)	44.4% (4/9); 55.6 (5/9)	1
<b>Assessed shoulder</b> (ii) (Right, Left, %)	55.6 (5/9); 44.4% (4/9)	77.8 % (7/9); 22.2 (2/9)	0.046
<b>Pain</b> (i) (VAS)	5.27 ± 1.43	5.88 ± 2.19	0.494
<b>Grip Strength</b> (i) (Kg/cm <sup>2</sup> )	21.91 ± 10.35	21.08 ± 12.12	0.877
<b>Goniometry</b> (i) (Degrees )	129.78 ± 12.82	111.11 ± 18.30	0.024 *

**Table 1.** Pre-intervention values in each group (control and experimental) for each variable. CONTROL: Control Group; EXPERIMENTAL: Experimental Group; Z: Kolmogorov-Smirnov; VAS: Visual Analogue Scale; p: p-value; (i) Data are expressed as mean ± (SD) standard deviation; (ii) Data are expressed as percentage (partial / total); The statistically significant differences were expressed as \*p<0.05.

VARIABLE	EXPERIMENTAL	CONTROL	p
<b>Pain</b> (VAS)	(- 0.88) ± - 0.85 (-0.22 / -1.54)	(- 0.22) ± - 0.50 (0.16 / -0.61)	0.062
<b>Grip Strength</b> (kg/cm <sup>2</sup> )	0.13 ± 1.87 (1.58 / -1.30)	2.47 ± 3.03 (4.80 / 0.13)	0.067
<b>Goniometry</b> (degrees)	14.33 ± 12.99 (24.31 / 4.34)	(-0.78) ± 8.45 (5.71 / - 7.27)	0.010 *

**Table 2.** Comparison between groups (control and experimental) for each variable (self-perceived pain, grip strength and goniometry of elbow) from post- to pre-intervention. CONTROL: Control Group; EXPERIMENTAL: Experimental Group; VAS: Visual Analogue Scale; p: p-value; Data are expressed as mean ± (SD) standard deviation (95% Confidence Intervals). The statistically significant differences were expressed as \*p<0.05.

Finally, the fascial intervention did not improve the grip strength, although previous works showed that spinal manipulation at different vertebral levels immediately modified this parameter<sup>27,28</sup>. When applying the maximum grip strength is required co-activation of different muscles of the upper limb. The protection mechanism of the trapezius prevents it from further contraction, so that when we apply a slight contraction, it appears that the muscle is unable to do it. However, since our results are close to the statistical significance for both pain and grip strength, we are encouraged to continue the research in this way.

### Study Limitations

One of the possible conflict of interest was the financial compensation that patients might expect, since all of them were injured in traffic accidents. The problem was solved using various filters. Therefore, the specialist who initially evaluated the patients, the evaluator and the therapist took into account this aspect, so we understand that it did not have any impact on the results.

In addition, this study could achieve findings of greater clinical significance using a bigger sample size. Similarly, it is necessary to observe the duration of the exerted effect, so that measurements in a medium-long term would be of great interest.

### CONCLUSIONS

We show that the suboccipital muscle inhibition technique improves the response of patients with cervical whiplash to the neurodynamic test of the median nerve. However, this technique does not modify the neck pain or the grip strength.

### ETHICS RULES

The authors state that this research meets the ethical standards established in the Declaration of Helsinki<sup>29,30</sup>, and subsequent revisions.

### CONFLICT OF INTEREST

The authors of the manuscript declare no conflict of interest.

### ACKNOWLEDGEMENTS

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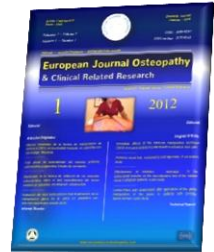
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## European Journal Osteopathy & Clinical Related Research



### ORIGINAL ARTICLE

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

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### ABSTRACT

#### Key Words:

Dysmenorrhea;  
Manipulation, Osteopathic;  
Pelvis; Sacroiliac Joint;  
Pelvic Pain;  
Pain Threshold;  
Serotonin; Catecholamines.

**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 evaluate 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.

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## INTRODUCTION

Primary Dysmenorrhea (PD) is a common gynaecological disorder in women of childbearing age<sup>1,2</sup>, 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<sup>3, 4</sup>. This pain is described as a suprapubic pain, which radiates to both thighs, or to the lumbar-sacral region<sup>1, 3-7</sup>, 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<sup>3</sup>.

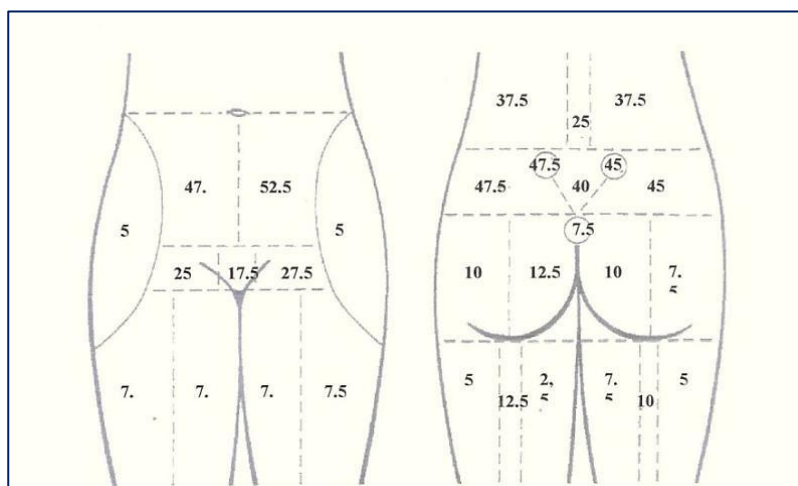
Medical treatment usually involves the administration of non-steroidal anti-inflammatory drugs (NSAIDs) and minor analgesics, since they are peripheral inhibitors of prostaglandin synthesis<sup>8</sup>, which seem to be involved in the pathogenesis of PD<sup>5</sup>. The oral contraceptives are also 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<sup>9</sup>.

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<sup>10</sup>. Also, alternative therapies have been reported to improve PD symptoms, including continuous low-level topical heat at hypogastric level<sup>11</sup>, acupuncture<sup>12</sup>, and transcutaneous electrical nerve stimulation (TENS)<sup>13, 14</sup>. However, these results are not conclusive enough to recommend a routinely use<sup>15</sup>.

On the other hand, several works have analysed the efficacy of spinal manipulative therapy on subjects with PD<sup>6, 16, 17</sup>. 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<sup>17-19</sup>, 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<sup>20-22</sup>, 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<sup>6</sup>: "Estabilidad sacroiliaca 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.

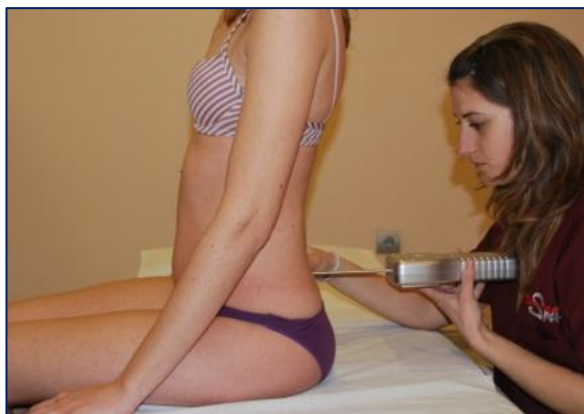
We used a Visual Analogue Scale (VAS) to measure the pain, since it is considered an effective, accurate, sensitive, easy to use, and reproducible method <sup>24</sup> to measure acute and chronic pain and its efficacy has been validated by several works <sup>25-27</sup>. The patient, seated on the treatment 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 <sup>28</sup>. All measurements were expressed in kg/cm<sup>2</sup>. We have previously validated the reproducibility of the pain location in the Posterior Superior Iliac Spine (PSIS) in patients with SIJ dysfunction <sup>29</sup>.

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<sup>10</sup>. The tubes for analysis of catecholamines were frozen at -3 °C until used, while tubes for determination of serotonin were refrigerated at 4 °C. These tubes were insulating from light with aluminium, since light influences serotonin levels.

Catecholamines levels are commonly determined by radioenzymatic methods<sup>30, 31</sup>, or by high-performance liquid chromatography with electrochemical detection<sup>32, 33</sup>.

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

### 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<sup>34,35</sup> (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: (1°) to reduce the slack in the lumbar-sacral facet, the hand increases trunk rotation until perceiving tension in L5, (2°) 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 (3°) 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 ( $\chi^2$ ) 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<sup>36</sup>.

## 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<sup>17,35</sup>.

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

However, Hondras *et al.*<sup>37</sup> 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<sup>38</sup>. This diversity of results can be motivated by the different intervention technique applied in each study and by the different spinal region manipulated<sup>16</sup>. 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<sup>39</sup>.

VARIABLE	CONTROL			EXPERIMENTAL		
	PRE_I	POST_I	p-value	PRE_I	POST_I	p-value
<b>PAIN</b> (VAS)	59.60 ± 27.87	59.40 ± 29.62	0.922	22.60 ± 10.46	16.85 ± 15.57	0.129
<b>PPT_RS</b> (kg/cm <sup>2</sup> )	1.37 ± 0.56	1.35 ± 0.56	0.179	1.64 ± 0.41	1.93 ± 0.46	0.004 *
<b>PPT_LS</b> (kg/cm <sup>2</sup> )	1.39 ± 0.42	1.27 ± 0.39	0.130	1.89 ± 0.44	2.03 ± 0.47	0.011*
<b>ADREN</b> (ng/ml)	43.01 ± 5.82	42.51 ± 7.54	0.698	43.81 ± 9.07	42.99 ± 9.49	0.819
<b>NORADREN</b> (ng/ml)	194.40 ± 38.59	227.50 ± 65.83	0.129	207.25 ± 100.2	181.11 ± 103.7	0.218
<b>DOPA</b> (ng/ml)	76.10 ± 15.24	88.20 ± 21.17	0.193	61.0 ± 9.17	70.1 ± 20.45	0.255
<b>SERO</b> (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: Serotonin 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
<b>PAIN</b> (VAS)	(- 0.2) ± 6.32 (95% CI - 4.32/4.72)	5.75 ± 10.88 (95% CI -2.03/13.53)	0.180
<b>PPT_RS</b> (kg/cm <sup>2</sup> )	0.02 ± 0.04 (95% CI - 0.11/0.05)	(- 0.29) ± 0.24 (95% CI -0.46/0.11)	0.001 *
<b>PPT_LS</b> (kg/cm <sup>2</sup> )	0.11 ± 0.22 (95% CI - 0.04/0.27)	(- 0.13) ± 0.13 (95% CI - 0.23/-0.38)	0.007 *
<b>ADREN</b> (ng/ml)	0.50 ± 3.9 (95% CI - 2.3/3.3)	0.82 ± 11.03 (95% CI -7.07/8.71)	0.932
<b>NORADREN</b> (ng/ml)	(- 33.0) ± 62.67 (95% CI - 77.93 / 11.73)	26.14 ± 62.44 (95% CI -18.52/70.80)	0.058
<b>DOPA</b> (ng/ml)	(- 12.10) ± 27.10 (95% CI - 31.48 / 7.28)	(- 9.1) ± 23.64 (95% CI - 26.01/7.81)	0.795
<b>SERO</b> (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: Serotonin 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<sup>40</sup>. 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<sup>41-45</sup>.

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

Burrell<sup>6</sup> 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.*<sup>18</sup> 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.*<sup>19</sup> 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 mentioned 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<sup>46, 47</sup>. 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<sup>48</sup>, and subsequent revisions.

## CONFLICT OF INTEREST

The authors of the manuscript declare no conflict of interest.

## ACKNOWLEDGMENTS

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# European Journal Osteopathy & Clinical Related Research



## ORIGINAL ARTICLE

# Influence of Lung Compression Technique on Spirometric Values in Smokers : A Pilot Study

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## ABSTRACT

### Key Words:

Lung;  
Osteopathic Medicine;  
Smoking;  
Spirometry.

**Introduction:** The essential function of the respiratory system is to supply oxygen to the blood, which requires an adequate respiratory mechanics. The elastic forces increase lung retraction during inhalation and decrease proportionally to the exhalation. There is evidence that smokers experience a drop in Forced Expiratory Volume in 1 second (FEV1) of about 50 mL/year.

**Objectives:** To evaluate the influence of the Lung Compression Technique (LCT) on Spirometric Values (SV) in smokers.

**Material and Methods:** A randomized pilot study was conducted. We applied a LCT in forty-one (n=41) smokers, which were randomly distributed into two groups (experimental: n=24; control: n=17). All of them underwent spirometry before and after the intervention. They were previously surveyed about their smoking habits and the presence or absence of comorbidities. We analyzed the changes in the following spirometric values: Forced Vital Capacity (FVC), Forced Expiratory Volume (FEV1), Peak Expiratory Flow (PEF), and Forced Expiratory Flow 25–75% (FEF2575). Spirometry was performed according to the rules of the American Thoracic Society (ATS) and Spanish Society of Pneumology and Thoracic Surgery (SEPAR).

**Results:** The results indicate that there are significant variations in PEF (p=0.008) and FEF2575 (p=0.005) in the experimental group versus the control group after application of the LCT. We found an increase statistically significant in PEF and FEF2575 in the experimental group. No changes were found in FVC (p=0.634) and FEV1 (p=0.058) between study groups.

**Conclusions:** The LCT could be helpful for improving respiratory mechanics in smokers, increasing spirometric variables as PEF and FEF25-75%.

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## INTRODUCTION

The essential function of the respiratory system is to supply oxygen (O<sub>2</sub>) to the blood, which will be transported to the tissues, as well as to remove carbon dioxide (CO<sub>2</sub>) from the blood to the atmosphere. This function needs proper respiratory mechanics <sup>1</sup>.

The elasticity of the respiratory system is a decisive force in respiratory mechanics, which depends on the combined elasticity of the lung and the chest <sup>1-5</sup>.

The elastic forces of retraction of the lung increase during inhalation due to increased surface tension and to stretching of the elastic fibers of the lung. These forces decrease proportionally during exhalation <sup>1</sup>.

Smoking is associated with decreased lung function<sup>6-9</sup>, particularly with an important annual decline in FEV1 (40 ml compared to 25 ml in nonsmokers) <sup>10</sup>.

Reduced lung function, measured as Flow Expiratory Volume in one second (FEV1), is associated with increased mortality derived from respiratory problems <sup>11</sup>.

Studies of lung function monitoring have shown that nonsmokers from 30 years old, exempt from any other respiratory disease, experience a significant decline in FEV1 of 30 to 35 mL/year<sup>12</sup>, related to the natural aging process of the lung.

This drop is slightly higher in smokers, about 50 mL/year <sup>13,14</sup>. In fact, smoking is a major risk factor for developing Chronic Obstructive Pulmonary Disease (COPD)<sup>12, 14-27</sup>.

From 40-50 years onwards, the prevalence of developing COPD increases every year and more in smokers <sup>28</sup>. In this sense, a fully effective respiratory cycle can be achieved by increasing the mobility of the ribcage and thoracic spine <sup>29</sup>.

## MATERIAL AND METHODS

### Design

The study was a controlled, randomized, double-blind clinical trial (patients and assessors were blinded).

### Study Population

We included in our research forty-one (n=41) patients, who were divided into two groups: experimental group (EG) and control group (CG). The EG was composed of twenty-four (n=24) patients (11 men and 13 women) with a mean age of  $32.79 \pm 8.4$  years, whereas in the CG were seventeen (n=17) patients (8 men and 9 women) with a mean age of  $32.76 \pm 10.7$  years.

### Randomization

The randomization was performed by random number tables.

### Study Protocol

Patients were surveyed about their smoking habits and recent presence of associated diseases.

They were informed about the study and were given the informed consent form that must be signed prior to treatment.

Afterwards, each patient was randomly distributed in one group (EG or CG). Both groups underwent spirometry before the intervention (pre-intervention).

Then we applied the Lung Compression Technique (LCT) to the EG, but the CG did not receive any intervention. Immediately after applying the LCT, we performed again other spirometry in both groups (post-intervention).

### Selection Criteria

Patients included in the study met the inclusion criteria and did not meet any exclusion criteria (Table 1).

Inclusion criteria were the following:

1. - The patient must sign the informed consent form.

The confidentiality of personal data was respected in accordance with the current spanish legislation (Law 15/1999 Protection of Personal Data <sup>30</sup>). All necessary data, both personal and health data were

essential data for the study. Likewise, we inform participants that their personal information not be disclosed to anyone outside the investigation.

2. - Patients smoking for more than 2 years.
3. - Patients who smoke more than 10 cigarettes/day<sup>31</sup>.
4. - Age between 18 and 50 years <sup>28, 32</sup>.

### Intervention in Experimental Group

Patients of the EG were submitted to the LCT <sup>33, 34</sup>. This technique aims to provoke a therapeutic elastic rebound in the lung, because manual compression which is exerted on the patient in the expiratory phase of respiration, in addition to the sudden decompression is performed in the inspiratory phase of respiration.

The patient remains in the supine position with hip and knee flexion, so that the feet soles are flat on the table. The therapist is placed beside the table, placing a hand behind the patient's thorax and the other hand is resting on the anterior part of the hemithorax (figure 1).

The technique consisted of applying compression to the chest during the expiratory phase, while maintaining this compression at the beginning of the inspiratory phase and dropping abruptly at the end of the inspiratory phase. We performed a rhythmic pumping technique synchronized with the patient breathing in both hemithorax (bilaterally).

### Intervention in Control Group

Patients of the CG were placed in the same position as patients of EG. The therapist performed the same contacts and held such position during 3 breaths, but exerting no compression at all.

### Spirometric Variables

Patients of both groups (EG and CG) underwent three pre-intervention spirometry tests and three post-intervention spirometry tests, and we used the mean of these measurements.

1. - Lung Cancer
2. - Hemothorax
3. - Acute infections
4. - Acute respiratory failure
5. - Myocardial infarction within the last month
6. - Rib fractures
7. - Recent cardiac crisis
8. - Recent surgery (eye, ear, chest and abdomen)
9. - Pregnancy
10. - Poor health status, cardiovascular instability, fever, nausea, vomiting
11. - Pneumothorax
12. - Active tuberculosis
13. - Hemoptysis
14. - Aneurysms
15. - Tracheotomies

**Table 1.** Exclusion Criteria



**Figure 1.** Lung Compression Technique (LCT)

To perform spirometry we used a Datospir 120A spirometer (Sibelmed, Barcelona, Spain), previously calibrated following the manufacturer's recommendations and standards for spirometric testing, according to the American Thoracic Society (ATS) <sup>35</sup> and the Spanish Society of Pneumology and Thoracic Surgery (SEPAR).

Spirometric variables considered were:

- FVC (Forced Vital Capacity): The maximum volume of air exhaled after a maximal inspiration, expressed in liters (L).
- FEV1 (Forced Expiratory Volume in one second): Volume of air exhaled during the first second of FVC in liters (L).
- PEF (Peak Expiratory Flow): Peak flow reached a maximum effort from a position of maximal inspiration, expressed in liters/second (L/s).
- FEF25-75: (Forced Expiratory Flow 25-75 %) Forced Expiratory Flow average measured during the middle half of FVC, expressed in L/s.

### Statistical Analysis

Statistical analysis was performed using the software "SPSS for Windows" version 15.0.

The normality of variables was established using the Kolmogorov-Smirnov test and graphical methods. When we observed a non-normal distribution we applied nonparametric tests (Mann-Whitney).

In the case of normal distribution we used parametric tests (Student t-test). We applied the chi-square tests  $\chi^2$  for analysis of dichotomous variables (table 2).

We established a significance level of  $p < 0.05$ , according to international standards for biomedical research <sup>36, 37</sup>.

### RESULTS

Our results indicated a clear statistical difference in PEF ( $p=0.008$ ) and FEF2575 ( $p=0.005$ ) between the CG and EG.

We found an increase statistically significant in PEF and FEF2575 in the experimental group. No changes were found in FVC ( $p=0.634$ ) and FEV1 ( $p=0.058$ ) between study groups.

Although the FEV1 was statistically not significant ( $p=0.058$ ), we observed a trend to statistical significance. Likewise, no significant variations were observed in FVC (table 3).

### DISCUSSION

Some authors observed that the use of different techniques in smokers produced changes in spirometric parameters.

According to Oscoz<sup>31</sup> (2005) the application of techniques on the diaphragm resulted in the modification of some spirometric values, such as FEV1 or PEF.

Ramos and Cataneo <sup>38</sup> (2007) reported that the application of exercise before surgery in smokers exerted a positive effect on PEF.

On the other hand, treatment with Global Postural Re-education in the anterior muscle chain, applied during 8 weeks to healthy subjects, has modified pulmonary pressures in thoracic expansion and abdominal mobility <sup>39</sup>.

The tension and relaxation of viscoelastic elements of the lung depend on time, so the peak flow immediately after stretching the lungs is higher than after a pause with the lungs at total capacity <sup>40,41</sup>.

Therefore, we may interpret that LCT can temporarily influence on the elastic properties of the lung, thereby improving some spirometric parameters immediately after the LCT.

Such parameters coincide with those most affected in smokers, indicating that the LCT would be considered as a useful procedure in the rehabilitation of lung pathology associated to smoking.



VARIABLES	GROUP		p-value
	EG n= 24	CG n= 17	
<b>SEX</b> (man; woman)	m: 11(45,8%) w: 13(54,2%)	m: 8(47%) w: 9(53%)	0,938
<b>AGE</b> (years)	32,79(8,44)	32,76( 10,72)	0,993
<b>Pre_FVC</b> (liters)	4,30(1,06)	4,05(0,92)	0,560
<b>Pre_FEV1</b> (liters)	3,31(0,75)	3,31(0,85)	0,968
<b>Pre_PEF</b> (liters/second)	6,77(1,74)	6,86(2,34)	0,771
<b>Pre_FEF 2575</b> (liters/second)	3,17(0,88)	3,40(1,32)	0,515

**Table 2. Preintervention Values**

Data are expressed as mean  $\pm$  (SD) standard deviation; n: counting number; age in years; m: man; w:woman; FVC: Forced Vital Capacity (liters); FEV1: Forced Expiratory Volume in 1 second (liters); PEF: Peak Expiratory Flow (liters/second); FEF25-75%: Forced Expiratory Flow 25–75% (liters/second).

VARIABLES	GROUP		p-value
	EG	CG	
<b>Dif_FVC</b> (liters)	0,15(0,56)	0,22(0,45)	0,634
<b>Dif_FEV1</b> (liters)	0,13(0,37)	0,00(0,31)	0,058
<b>Dif_PEF</b> (liters/second)	0,08(0,87)	-0,71(0,95)	0,008 *
<b>Dif_FEF2575</b> (liters/second)	0,03(0,36)	-0,36(0,34)	0,005 *

**Table 3. Intergroup Comparative Pre/Post Intervention Values**

Parametric Data are expressed as mean  $\pm$  (SD) standard deviation; Non-Parametric Data are expressed as median  $\pm$  (IR) interquartil range; Dif\_FVC: Differences in Forced Vital Capacity (liters); Dif\_FEV1: Differences in Forced Expiratory Volume in 1 second (liters); Dif\_PEF: Differences in Peak Expiratory Flow (liters/second); Dif\_FEF25-75%: Differences in Forced Expiratory Flow 25–75% (liters/second).The statistically significant differences were expressed as \*p<0.05.

We believe that the obtained results are interesting, but we must be aware that some variables, such as PEF or FEF25-75%, are dependent on the effort <sup>42, 43</sup>, so that their values (especially the PEF) does not indicate the quality of the spirometry.

On the other hand, we did not control the patient's bronchial hyperreactivity. There is evidence of a direct relationship between PEF and bronchial hyperresponsiveness <sup>44, 45</sup> in patients with asthma and COPD <sup>46-49</sup>.

According to other authors <sup>31,38,39</sup> we can state that the use of Osteopathy Manipulative Treatment (OMT) to treat respiratory problems is beneficial, for both chest mobility problems and chain retraction muscle. Additionally, this technique might also benefit patients with visceral problems.

Finally, it would be of interest in further studies of research to analyzed the results obtained by combining other treatment techniques that have shown effective results (Oscos <sup>31</sup>, Ramos and Cataneo<sup>38</sup>, Moreno <sup>39</sup>).

### Study Limitations

This study is limited by several aspects, including sample size, which should be increased in future studies.

In addition, a study should be conducted to determine the duration of the effect of the LCT, thereby assessing their practical applications.

### CONCLUSIONS

The lung compression technique produces statistically significant increases in spirometric PEF and FEF25-75. By contrast, this technique does not modify FVC or FEV1 in lung.

### ETHIC RULES

This study meets the ethical standards established in the Declaration of Helsinki <sup>50</sup>, and subsequent revisions.

### CONFLICT OF INTEREST

The authors of the manuscript declare no conflict of interest.

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