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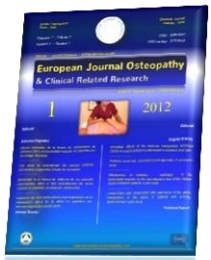

ORIGINAL ARTICLE

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

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ABSTRACT

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 ± 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)[1] carried out a classification of primary and secondary headaches, as well as their characteristics. According to Felício et al.[2] 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[3,4]. Stovner et al[5] 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[6,7] showed similar clinico-epidemiological characteristics.

Couppe et al.[8] 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.[9] 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.[10] maintain that central sensitisation caused by experiencing prolonged periods of pain can cause this to become chronic.

Fernández et al.[11] 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.[12] 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,[13-16] 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: (1º) Selection of the sample; (2º) Signature of informed consent;(3º) Randomization of patients to study groups;(4º) Preintervention assessments in the study groups;(5º) Interventions in the study groups (SIT, OAA, SIT+OAA, CONTROL - without intervention); (6º) Postintervention assessments in the study groups;(7º) 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[16].

INCLUSION CRITERIA	EXCLUSION 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	• 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[18-20].

- Occiput-Atlas-Axis global manipulation (OAA). This technique, first described by Fryette[21], has been used in other trials[22]. 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[19]

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 2ª and 3ª 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.[23] 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[24] 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[25-28] 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 χ^2 test was applied, and for global associations in the ordinal variables the gamma coefficient (γ) 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[1] classification as well as in aspects that influence TTH such as trigger and aggravating factors and having a family history of tension-type headaches[29]. The majority of sufferers are women, which coincides with all of the studies that were revised.[30,31] As with other studies, we

VARIABLE	STUDY GROUP			
HIT-6	**SIT**	**OAA**	**SIT + OAA**	**CONTROL**
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 ≤ 0.05

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

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.[38] 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[1], 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,[29,38] 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[38].

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[38,39] 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[29], the family history of headache was 24% in a sample of 50 subjects, whilst in Holroyd et al. [33] 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
Suboccipital Flexion				
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
Suboccipital Extension				
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
Cervical Flexion				
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
Cervical Extension				
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
Right Rotation				
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
Left Rotation				
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 ≤ 0.05

VARIABLE	STUDY GROUP			
Weekly Register	SIT	OAA	SIT + OAA	CONTROL
Frecuency				
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
Intensity				
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 ≤ 0.05

The pain intensity measured using VAS gave a result of 6.58. Other studies[32,40] coincided in the average severity of pain suffered by the majority of TTH patients, according to the IHS[1]. 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[33]. 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.[39], and Melchart et al.[34], 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[41] 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. [42,43] 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[44] 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[45,46] 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[42] and in the frequency[16] 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[16] 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[47], 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[15,48] 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[49] declaration.

CONFLICT OF INTEREST

The authors of the manuscript declare no conflict of interest.

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