

Osteopathic Manipulative Therapy in Patients With Chronic Tension-Type Headache: A Pilot Study

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Context: Nonpharmacologic treatment, such as osteopathic manipulative therapy (OMTh; manipulative care provided by foreign-trained osteopaths) may be a beneficial complementary treatment for tension-type headache. However, to the authors' knowledge, the benefit of OMTh in the management of tension-type headache has not been explored, especially chronic tension-type headache (CTTH).

Objective: To investigate the effectiveness of OMTh compared with traditional treatment in reducing pain intensity, frequency, and duration of CTTH, and to evaluate the objective postural measurement of the forward head posture (FHP) as an integral parameter in the assessment of the effects of OMTh and traditional management of CTTH.

Methods: Patients with CTTH were registered at the Headache Centre of Trieste in Italy. At the time of the study, none of the patients had been taking any headache prophylaxis in the past 3 months. A 3-month baseline period was recorded by all patients with an ad hoc diary. Patients were randomly placed in the test or control group using a simple randomization program in Excel (Microsoft). Patients in the OMTh group underwent a 3-month period of OMTh, and patients in the control group were treated with amitriptyline. Pain intensity, frequency, and duration of headaches, as well as FHP were analyzed.

Results: The study enrolled 10 patients (mean [SD] age, 42.6 [15.2] years) in the OMTh group and 10 patients (51.4 [17.3] years) in the control group. The final assessment of OMTh patients showed statistically significant changes in all headache parameters: pain intensity decreased from a mean (SD) score of 4.9 (1.4) to 3.1 (1.1) ($P=.002$); frequency decreased from 19.8 (6) to 8.3 (6.2) days per month ($P=.002$); and the duration of headaches decreased from 10 (4.2) to 6 (3) hours ($P=.01$). Significant improvement of all parameters was found in the control group as well: pain intensity decreased from a mean (SD) score of 5.9 (0.7) to 4.2 (1.75) ($P=.03$); frequency decreased from 23.4 (7.2) to 7.4 (8.7) days per month ($P=.003$); and duration decreased from 7.8 (2.9) to 3.6 (2.1) hours ($P=.002$). Forward head posture significantly improved in OMTh patients ($P=.003$).

Conclusions: Our data suggested that OMTh may be an effective treatment to improve headaches in patients with CTTH. Our results also suggest that OMTh may reduce FHP.

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According to the 2018 criteria of the International Headache Society,¹ tension-type headaches (TTH) can be classified depending on the temporal frequency of the headaches: infrequent episodic TTH, frequent episodic TTH, and chronic TTH (CTTH). Tension-type headaches are the most common type of headache worldwide across all age groups.²⁻⁴ The 1-year prevalence ranges from 31% to 90%.⁵

Concerning the pathophysiologic process, more evidence for central sensitization (CS) in CTTH highlights the role of pain sensitivity in myofascial pericranial tissues.⁶⁻⁸ Chronic tension-type headache is characterized by CS triggered by nociceptive peripheral inputs, ie, the release of allogenic substances by pericranial tissues. One study found that in patients with CTTH, the pressure pain thresholds were decreased in muscle and skin of the cephalic region more than in healthy controls.⁸ Nociceptive inputs from the peripheral structures may activate painful afferents that produce an increase in peripheral sensitization. Peripheral sensitization is responsible for the plastic changes into the dorsal horn of the trigeminal nerve nucleus caudalis. The increase of the stimulation to the thalamus and cortex could lead to a reduction of the descending inhibitory painful transmission at a supraspinal level. The reduction of the descending inhibitory transmission results in decreased nociceptive thresholds and increased responsiveness to noxious and innocuous peripheral stimuli. The CS may contribute to the amplification of pain and the conversion from episodic to chronic form. Therefore, researchers have concluded that structures innervated by the upper cervical segments (C1-3) and the trigeminal nerve can be responsible for generating and maintaining the nociceptive peripheral input, which contributes to the chronic myofascial head pain, peripheral sensitization, and CS.⁹⁻¹²

However, pharmacologic treatments are still the first choice. The tricyclic antidepressant amitriptyline is recommended for patients who have both CTTH and anxiety.¹³⁻¹⁵ Nonpharmacologic treatments are generally included in clinical guidelines for the prevention

of primary headaches. The European Federation of Neurological Societies guideline,¹⁶ the Italian guideline for primary headaches,¹⁷ and the Italian Consensus Conference on Pain in Neurorehabilitation¹⁸ reported that nonpharmacologic therapies are valid complementary treatments for migraine and TTH

The use of osteopathic manipulative therapy (OMth; manipulative care provided by foreign-trained osteopaths) in patients with CTTH is based on the high prevalence of musculoskeletal dysfunctions¹⁹⁻²² and on the role of affective and social touch in pain modulation.²³ The activation in the insular and orbitofrontal cortex after brain response to soft brush stroking is mediated by unmyelinated low-threshold mechanoreceptors (C tactile) that respond to gentle touch. These observations suggest that manual therapy may be a strategy for desensitisation.^{24,25}

Regarding the correlations with various musculoskeletal disorders, CTTH can cause neck and low back pain, active trigger point and pericranial muscle tenderness, pressure pain threshold, reduction in cervical mobility, and forward head posture (FHP).¹⁰ Forward head posture²⁶⁻²⁹ plays a significant role in the physiopathology of different types of headache (cervicogenic headache, TTH, and migraine) but more so in CTTH. Some authors²⁷⁻²⁹ observed that patients with episodic TTH and CTTH had a greater degree of FHP and thus a reduction of the neck mobility than patients in control groups. Forward head posture is correlated with frequency of headache and with transitioning from episodic TTH to CTTH. The FHP correlation with frequency remains unclear whether the pain causes or is caused by FHP.

This study compared the effectiveness of OMth with pharmacological treatment using amitriptyline in patients with CTTH by measuring the effect each treatment had on headache parameters, such as intensity, pain frequency, and headache duration, and cervical parameters, such as FHP.

Methods

This pilot study took place from November 2015 to September 2016. The study protocol was approved by

the institutional review board of the Collegio Italiano di Osteopatia in Parma. Written informed consent was obtained from all patients. The research was conducted according to the principles of the Declaration of Helsinki.

Study Population

Patients were enrolled by the Headache Centre of the Neurologic Clinic of the University of Trieste.

At the first enrollment visit (T0), patients underwent anamnestic evaluation, neurologic examination, and general objective examination. The inclusion criteria were having a diagnosis of CTTH (diagnostic criteria of International Classification of Headache Disorders) and being 18 years or older. The exclusion criteria were pregnancy, severe psychiatric disorders, severe coexisting conditions (major cranial or cervical trauma, malignant neoplasms, or infectious diseases), major surgical procedures in the 12 months before the study, physiotherapy and/or OMTh in the past 3 months, pharmacologic treatment in the past 3 months, and being younger than 18 years. All patients who met inclusion criteria were asked to participate in this study.

Patients were given a diary to record cephalic outcome, including intensity, frequency (number of days experiencing a headache in a month), and duration of headache. Patients reported the frequency and the doses of NSAIDs in their diaries. The information recorded in each patients' diary was entered into Excel (Microsoft) for subsequent data analysis. The diary of each patient was reevaluated after 1 month. If the diary indicated that a patient had a headache for more than 15 days that month, he or she was considered eligible to participate in the study. Patients were randomized with a simple randomization (1:1) protocol using Excel and assigned to either an intervention (OMTh) or a control (pharmacologic treatment with amitriptyline) group. Both groups were treated over a 3-month period.

Interventions

The OMTh was organized in 10 one-hour sessions. During the first 3 sessions, the patients received an individualized treatment plan that consisted of a variety of

direct and indirect OMTh techniques. The techniques included muscle energy and articular techniques designed to resolve somatic dysfunctions and important clinical signs, such as tenderness, asymmetry, range of motion abnormality, and tissue texture change.³¹

For the last 7 sessions, we used softer and more indirect techniques, such as myofascial release, balanced membranous tension, and cranial, which we believed addressed the chronic nature of the somatic dysfunction in these patients. We focused OMTh on areas that may generate nociceptive impulses of the trigeminal-caudal nucleus level.⁹⁻¹² We started with the fascial treatment of the sacral area and continued with the fascial treatment of the diaphragm, thoracic outlet zone, and throat. We ended with a balanced membranous tension and dural venous sinus release (with particular attention to suboccipital and epicranial areas). The only medications used by patients in the OMTh group were nonsteroidal anti-inflammatory drugs (NSAIDs) or other medications used for headaches and only for a maximum of 2 times per week.

Patients in the control group received 30 to 50 mg of amitriptyline based on body weight (mean [SD], 42 [5] mg). The dose was unchanged during the study period.

Postural Assessment Software

Singla and Veqar³⁰ reviewed the various methods of postural evaluation used on athletes. Among the examined methods, 2 stood out for reliability and reproducibility—radiography and photogrammetry. However, the authors expressed their preference for the Postural Assessment Software/Software for Postural Evaluation (PAS/SAPO) photogrammetric software (BMClab) because of the limitations of radiography, such as excessive cost and risk of radiation exposure for the patients. The PAS/SAPO was developed by a multidisciplinary team of the University of São Paulo in Brazil. The software allows analysts to measure parameters as angles and distances of various body points. Ferreira et al³² provided validation of the software's reliability and reproducibility.

Forward head posture is assessed with the craniovertebral angle (CVA), which is the horizontal line that

passes through C7 with the line that passes through the tragus and C7. Weber et al³³ compared radiography and SAPO measurements and found significant correspondence between the results. Whereas radiography is best for analyzing rachis curves on sagittal planes, photogrammetry is considered to be more reliable in measuring the CVA.

To include CVA degrees in the objective examination, SAPO version 0.68 was used at the beginning and end of the treatment. A camera was placed on a tripod at 1.63 m from the floor and 3.45 m from a standardized still point on the floor. While maintaining internal malleoli at the height of the still point, each patient was photographed in a standing position on the sagittal plane from both the right and left sides. Patients were asked to maintain a natural posture. Three white spherical adhesive markers of 15-mm diameters were applied to the patients' skin: 1 at ear level (on each tragus) and the other at the C7 spinous process level.

Statistical Analysis

Data were analyzed with InStat 3.06 (GraphPad). Parametric and nonparametric tests were used as appropriate. The Wilcoxon nonparametric test of the sample pair was used to compare initial and final evaluations, and the Mann-Whitney test was used to compare the initial and final evaluations. The statistical significance level was $P=.05$.

Results

A total of 24 patients were enrolled in this study; however, 4 patients were excluded because they had not correctly filled out or maintained the headache diary. Therefore, the study sample consisted of 20 patients: 10 patients in the OMTh group and 10 patients in the control group. The OMTh group consisted of 8 women and 2 men, with a mean (SD) age of 42.6 (15.2) years. The control group included 4 women and 6 men, with a mean (SD) age of 51.4 (17.3) years.

No differences were found between the 2 groups at baseline assessment in terms of age ($P=.2$); intensity

($P=.08$), frequency ($P=.3$), and duration ($P=.1$) of headache; or CVA ($P=.9$). Both patient groups showed similar somatic dysfunctions in the cervical (C1-3), thoracic (T1-3), and lumbar (L1-2) spine, compression of the craniosacral movement, and congestion in the small intestine.

No patients reported adverse events during the 3 months of treatment. At the final assessment, mean (SD) headache intensity in the OMTh group decreased from 4.9 (1.4) to 3.1 (1.1) (95% CI, $1.8 < 0.8 < 2.7$; $P=.002$). The mean (SD) headache intensity in the control group decreased from 5.9 (0.7) to 4.2 (1.75) (95% CI, $1.7 < 0.4 < 2.9$; $P=.03$).

Both groups had significant decreases in mean (SD) frequency (OMTh group decreased from 19.8 [6] to 8.3 [6.2] days [$P=.002$]; control group decreased from 23.4 [7.2] days to 7.4 [8.7] days [$P=.003$]). The mean (SD) duration of headaches also decreased for both groups (OMTh group decreased from 10 [4.2] hours to 6.3 [3] hours; control group decreased from 7.8 [2.6] to 3.6 [2.1] hours). The 95% CI was analogous for frequency in both groups (OMTh group, $7.4 < 11.5 < 15.5$; control group, $9.4 < 15.9 < 22.3$). In both groups, the 95% CI for duration was low (OMTh group, $0.6 < 3.7 < 6.7$; control group, $3 < 4.2 < 5.3$). The Mann-Whitney test found no significant difference in the reduction in intensity ($P=.2$), frequency ($P=.3$), or duration ($P=.06$) between the 2 groups.

The mean (SD) CVA of the FHP in the OMTh group significantly decreased from 136.6° (8.1°) to 132.6° (6.1°) ($P=.003$; 95% CI, $1.9 < 4 < 6.1$). We could not analyze the FHP in the control group because 6 patients did not complete the final assessment with SAPO, and the sample size was too small for analysis.

Discussion

Eight patients in the OMTh group reported improvements in their diaries in all of the parameters. Two patients in the OMTh group reported an improvement in intensity and frequency but not in duration. Six patients in the control group had improvements in all

parameters; 3 reported improvement in frequency and duration but not in intensity, and 1 patient reported improvement in intensity and duration but not in frequency.

In both groups, the most improvement was found in frequency. Data suggested that both the OMTh and control treatment had a significant impact on CTTH, bringing about a transition from chronic to episodic headaches.

Osteopathic manipulative therapy proved as effective as prophylactic pharmacologic treatment with amitriptyline in all headache parameters considered in our pilot study population. This finding suggests that OMTh may be an effective treatment option to use along with or instead of medication. Osteopathic manipulative therapy may also have a place in clinical practice for patients who are allergic to medications, are very resistant to taking medication, and are at risk to overuse medication. Based on our findings, we believe that pain reduction was due to the effects of OMTh on the peripheral pain mechanisms related to somatic dysfunction of suboccipital and pericranial muscles.

The correlation between FHP and CTTH indicates that OMTh may decrease FHP,²⁶⁻²⁹ but no relationship was found between improvement in frequency of headache and FHP.^{28,29} According to the data of Fernández-de-las-Peñas et al^{10,28,29} and Raine and Twomey,³⁵ the OMTh patients in these studies presented a CVA before and after treatment in the range observed in asymptomatic patients. In the current study, 9 of 10 OMTh patients reported an FHP reduction at the final assessment. However, we could not correlate the improvement in cervical parameters with pain parameters because the sample size was small.

All OMTh patients showed improvement in and normalization of general tissue texture and suppleness, especially in the suboccipital and upper cervical musculature and fascial elements. The 5 diaphragms of the body—cranial, throat, thoracic inlet, respiratory diaphragm, and pelvic diaphragm—showed greater synchrony. The OMTh group showed improvement in rhythm, amplitude, and vitality of craniosacral motion, as well as vertebral and pelvic alignment. The empirical

manifestation of these palpatory changes was represented by the change in CVA. Furthermore, OMTh reduced the FHP, which can be considered as a result of the rebalancing of the superior pyramidal musculature and concomitant decrease in tissue contraction in this area. Such decreases in tissue contraction allow for normalization of vascular and lymphatic flow to cervical, suboccipital, and pericranial areas, which contribute to pain relief and restoration of normal posture.

One limitation of the study was the uncontrolled variable of being unable to ban pain medications for headaches in patients with primary chronic headache, which may have affected the interpretation of data. For this reason, the study placed a restriction to the consumption of NSAIDs to twice per week.

Another limitation was that the sample size was too small to interpret how gender and age differences may have affected clinical outcomes. The small sample size of 10 cases per group was also low for parametric tests. A future study could highlight the differences in pain modulation between men and women. Future studies could validate PAS/SAPO for other assessment, such as the barycenter point, pelvic angle, femoral-tibial angle, and tibial-tarsal angle, which together could highlight the neuromusculoskeletal changes brought about by OMTh.

Conclusions

Our results suggest that OMTh improved headache parameters (intensity, frequency, and duration) to a similar degree as prophylactic pharmacologic treatment with amitriptyline. Reduced frequency was the parameter with major improvement in both the OMTh and the control groups. Our data also suggest that OMTh may be a reasonable alternative or complement to pharmacologic treatment for CTTH. Osteopathic manipulative therapy did not have any adverse events, such as those found in medication overuse. Furthermore, we believe this pilot study justifies the implementation of a larger randomized controlled trial based on our study design.

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