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A Comparison of Selected Osteopathic Treatment and Relaxation for Tension–Type Headaches

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Objective: The objective of this study was to compare the effects of osteopathic treatment and progressive muscular relaxation (PMR) exercises on patients suffering from tension-type headache (TTH).
Background: Relaxation is generally accepted as a treatment for TTH. Osteopathy is considered by some practitioners to be useful for headache management but there is limited scientific evidence regarding the effectiveness. This study compares relaxation and relaxation plus selected osteopathic techniques in the treatment of people with TTH.
Design: This was a single-blind, randomized, clinical study using an experimental design. Twenty-nine patients with TTH according to the International Headache Classification Subcommittee, 2004, were recruited for this study and randomly placed in either a control or experimental group. Both groups practiced PMR exercises at home while the experimental group also received three osteopathic treatments.
Method: All participants recorded headache frequency and intensity in a headache diary (HD) for 2 weeks pretreatment, and continued recording during the treatment period until reassessment for a total of 6 to 7 weeks. All tests of significance were set at $P <$ or $= .05$.
Results: Twenty-six people completed the study. Results indicated that the number of Headache Free Days Per Week was significantly improved ($P = .016$) in the experimental group. Two other measures, the Headache Degree of Improvement ($P = .075$) and the HD Rating ($P = .059$), which combine headache frequency and intensity, did not meet our criteria for statistical significance but both scores are $<.10$ indicating a trend towards improvement in the experimental group that is clinically significant. The HD Rating also showed that the experimental group improved 57.5%, while the control group improved 15.6%. The intensity of headache did not show a significant improvement ($P = .264$).
Conclusion: The people in this study who did relaxation exercises and received 3 osteopathy treatments had significantly more days per week without headache than those who did only relaxation exercises.
Key Words: Tension-type headache, Osteopathy, Relaxation
Abbreviations: TTH Tension-type headache, IHS International Headache Society, CNS Central Nervous System, PMR Progressive Muscular Relaxation, HD Headache Diary, C Control, E Experiment, HI Headache Index, ANOVA Analysis of Variance, VAS visual or verbal analogue scale

INTRODUCTION

Tension-type headache (TTH) is the most frequently experienced type of headache and is more prevalent in women than men.[1] According to the International Headache Classification Subcommittee of the International Headache Society (IHS), 2004, TTHs occur in 30% to 78% of the population.[2] TTH is associated with a limited ability to function in 44% of patients, causing disability and a decreased quality of life.[1-3]

Contraction of head and neck muscles has been thought to play a pathogenetic role in some patients with TTH but it has not been universally demonstrated.[4,5] Electromyography **(**EMG) levels in pericranial muscles may be increased in approximately 60% of patients with TTH, but there is no correlation between EMG activity and headache severity. [6-8] Increased tenderness of pericranial myofascial tissues to manual palpation is the most prominent abnormal finding in patients with chronic TTH.[9] It is thought that a "central sensitization" or facilitation occurs within the central nervous system (CNS), involving increased excitability of neurons which then causes the individual to become more susceptible to headaches and to them becoming chronic.[10,11] Psychological stress and fatigue can be precipitating factors causing a TTH.[12,15]

Very little research has been published on the osteopathic treatment of TTH.

Osteopathy is a natural medicine and science that treats the whole person. Osteopathic diagnosis and treatment utilizes precise palpation, and manual tests and techniques to find and treat the causes of dysfunction and restore mobility to each system of the body. Osteopathic treatment is based on the inter-relationship of anatomy and physiology and sees each person as a functional unit, capable of repairing and healing itself if the structure and physiological functioning of the body is in proper order.[16]

Relaxation therapies used to treat TTH have been shown to be superior to no treatment and to pseudo/placebo treatment.[17] Progressive muscular relaxation exercises (PMR) have been shown to reduce TTH and home based relaxation programs can result in significant improvement in headaches.[18-20] Diaphragmatic breathing and relaxing imagery are often used in conjunction.[21-24]

PATIENTS AND METHODS

Forty-six people received telephone interviews to see whether they fit the criteria for the study. Twenty-nine patients signed consent forms and started the study. Patients were recruited through newspaper and magazine ads and flyers placed in health practitioner's clinics. All patients were initially interviewed on the phone and later filled out health history questionnaires to be certain that they fit the inclusion criteria.

The study was approved by the Research Committee of The Canadian College of Osteopathy. Written, informed consent was obtained from all participants.

Patients were accepted into the study if they were 16 years of age or older and experienced TTH according to the classification of either Frequent Episodic TTH, Chronic TTH or Probable TTH (fulfills all but one criteria for TTH) as defined by the IHS, 2004.[2]

Patients were not excluded if they were taking pain medication. All participants except one were taking medication and many had tried several types of medication. Seven of the 26 participants had not tried treatment other than medication for TTH. For the others: one each had tried EMG biofeedback, yoga, craniosacral therapy, therapeutic touch and nerve blocks, 2 had tried osteopathy, 3 had tried physiotherapy, 5 had tried homeopathy, 6 had tried relaxation, 9 had tried chiropractic, and 11 had tried massage therapy. Eight people had tried three or more of these treatments and all were still seeking relief.

Patients were questioned during a telephone interview and were excluded from the study for the following reasons: (1) They had traumatically induced headaches, cluster or migraine headaches; (2) They had diagnosed TMJ disorders; (3) They had been diagnosed with severe depression, severe anxiety attacks, seizures, uncontrolled diabetes, uncontrolled hypertension, nasal disease or a severe sinus condition (4) They were taking antidepressants.

This was a single blind, randomized, clinical study using an experimental design. The treating practitioner randomly assigned patients to the control group (C) (n=12) or the experimental group (E) (n=14) at the sample selection phase using randomization tables. The assessing practitioner was blinded.

All participants were given a Headache Diary (HD) 2 weeks prior to the start of the study, as recommended by Blanchard, 1987, in order to get a baseline measurement of the frequency and intensity of their headaches.[25] Patients were instructed to fill out the diary four times a day (mealtimes and bedtime) and rate the headache on a 6 point scale ranging from *no headache* (0) *to intense, incapacitating headache* (5). After 2 weeks, all participants were met by the assessing practitioner who checked the HDs to make sure they were being filled out correctly and informed patients to continue recording in the diaries. At this time, all patients were asked to fill out health history questionnaires and underwent a physical assessment of the areas to be treated. All patients were given an audio tape and typed instructions on PMR exercises that they were to practice at home once a day for 20 minutes, until reassessed and a Relaxation Diary in which to record their daily exercises. Patients used an audiotape with instructions to maximally contract major muscle groups, moving from the feet up to the head, to experience the sensation of the contraction and then the subsequent relaxation or decreased intensity of muscle tension. The relaxation tape used in this study was obtained from the Centre for Addiction and Mental Health in Toronto.

Patients in E received osteopathic treatments once a week for three consecutive weeks from the treating practitioner who focused on the pelvis, cranium, cervical and upper thoracic spine, clavicles and upper ribs. These areas were targeted because they were recommended by osteopaths in the literature review to be primary areas to treat to relieve TTH.[13,16, 26-41]

Upledger and Vredevoogd (1983) defined a restriction as "an impairment to normal physiological motion within the body" (p.19).[40] Each patient in E received the same treatment protocol if restrictions were found and treatment was required in the

areas mentioned above. Treatment included unwinding, inhibition and stretching techniques to the cervical muscles and fascia and pleural dome ligaments. Joint mobilizations, including functional, muscle energy, strain/counterstrain and osteoarticular techniques were used on the cervical spine, T1-4 of the upper thoracic spine, sacrum and ilia. Cranial osteopathic treatment was used to facilitate movement in the cranial bones and also the sacrum.

Cranial osteopathic treatment is based on the cranial concept that was discovered by William G. Sutherland in1899 and further described by Harold Magoun.[16,38] Cranial osteopathic treatment is believed to release strains in the dura mater which may result in a normalization of neural function and a calming of the CNS.[16-26,27] Other cranial techniques such as venous sinus, CV4 and core link were used to achieve the same result and facilitate fluid flow such as blood, lymph, and cerebrospinal fluid to aid in the patient's ability to heal.[16]

Functional techniques for the sternum, clavicles and ribs one and two were included to complete treatment of the thoracic inlet. The ribs were also treated with myofascial holding and stretching techniques and rib springing techniques using the breath to release any inhalation or exhalation restrictions.

All participants were reassessed within two weeks posttreatment. The HDs were collected, having been filled out for the duration of the study which lasted 6 to 7 weeks. The Relaxation Diaries were also collected and patients underwent a physical assessment identical to the initial assessment.

Dependent and Independent Variables

The independent variable was the osteopathic treatment. The dependent variables were four headache outcome measures using data from the HD.

The 4 headache outcome measures:

1. The HD Rating is considered to be the most accurate measure of change.[17,24, 42] This equation was adapted from Blanchard and approved by the statistician. It combines headache frequency and intensity to yield a total weekly score and the percentage of improvement.

$$\frac{\text{Pretreatment score - Posttreatment score}}{\text{Pretreatment score}} \times 100$$

2. The Headache Index (HI) is calculated by adding the 28 ratings of headache activity from one week and dividing by 7 to yield an indication of the average daily headache severity.[23-25] The average HI pretreatment minus the HI posttreatment will equal the Headache Degree of Improvement.
3. Improvement in Headache Free Days Per Week (frequency) is calculated by comparing the average number of Headache Free Days Per Week pretreatment to the number of Headache Free Days Per Week posttreatment.[43,44]
4. Improvement in Worst Headache of the Week (intensity) is calculated by comparing the average worst headache score of pretreatment to the worst headache score posttreatment.[43,44]

RESULTS

All tests of significance were set at $P <$ or = .05. The groups were a similar size. There were no significant differences between E and C with respect to Age (P = .265), Gender (P = .759), Number of years with headache (P = .640), Frequent versus Chronic TTH (P = .756), Tension versus Probable Tension Headache (P = .116), and Number of Headache Free Days Per Week pretreatment (P =. 427).

Participation rate for the relaxation exercises was 78% for E and 76% for C.

Twenty-six people completed this study. One person dropped out because she did not have time to do relaxation exercises daily. One person was dropped because she did not complete the headache diary after the initial assessment. The third patient did not attend the final assessment and was dropped from the study.

Results of the statistical analysis are shown in Tables 1 and 2. Data obtained from the HD using the t-test and analysis of variance (ANOVA) demonstrated a significant improvement in the number of Headache Free Days Per Week in E as compared to C (P = .016). As shown in Table 1, E experienced on average 1.79 Headache Free Days Per Week and C experienced .21.

The HD Rating showed that E had a 57.5% improvement in the reduction of headache frequency and intensity as compared to C, which showed a 15.6% improvement. The Headache Degree of Improvement (P = .075) and the Headache Diary Rating (P = .059) do not meet the criteria of $p <$ or = .05. There was no significant difference in the intensity of the worst headache of the week as seen in the Table 2.

F = 1.306, df = 1.24, P = .264

Table 1. Headache Measures-Comparison of Means & t-Tests

HA Free Days Per Week	Group	N	Mean	Std. Deviation	Range Minimum	Range Maximum	T-Value	df	Sig. 2-tailed
	C	12	.21days	1.685 days	-3	4	-2.589	24	.016
	E	14	1.79 days	1.424 days	-1	4			
	Total	26	1.06 days	1.717 days	-3	4			
HA degree of Improvement									
	C	12	.656	1.953	-2.58	2.36	-1.860	24	.075
	E	14	1.881	1.394	0.00	4.46			
	Total	26			-2.58	4.46			
HA Diary Rating									
	C	12	15.637	73.469	-138.5	100.0	-1.987	24	.059
	E	14	57.565	27.321	.0	100.0			
	Total	26			-138.5	100.0			
Worst HA of Week									
	C	12	.92	1.505	-1	4	-1.143	24	.264
	E	14	1.50	1.092	0	4			
	Total				-1	4			

C = Control; E = Experimental

Improvement in Headache Free Days Per Week (frequency): comparison of the average number of Headache Free Days Per Week pretreatment to the number of Headache Free Days Per Week posttreatment.

Headache Degree of Improvement: average HI pretreatment minus the HI posttreatment

Headache Diary Rating: $\frac{\text{Pretreatment weekly score} - \text{Posttreatment weekly score}}{\text{Pretreatment weekly score}} \times 100$

Improvement in Worst Headache of the Week (intensity): comparison of the average worst headache score of pretreatment to the worst headache score posttreatment.

Table 2. ANOVA for Headache Outcome Measures

	Sum of Squares	df	Mean Square	*F* Statistic	*P* Value
HA Free Days Per Week					
Between Groups	16.077	1	16.077	6.700	.016
Within Groups	57.586	24	2.399		
Total	73.663	25			
HA Degree of Improvement					
Between Groups	9.694	1	9.694	3.460	.075
Within Groups	67.230	24	2.801		
Total	76.924	25			
HA Diary Rating					
Between Groups	11358.691	1	11358.691	3.946	.059
Within Groups	69079.614	24	2878.317		
Total	80438.305	25			
Worst HA of Week					
Between Groups	2.199	1	2.199	1.306	.264
Within Groups	40.417	24	1.684		
Total	42.615	25			

COMMENTS

The results of this study demonstrated that people in E who did home relaxation exercises and received three osteopathic treatments had significantly less frequent headaches than those in C who did only home relaxation exercises. Because E and C were equivalent prior to the intervention it can be concluded that the decreased frequency of headaches was directly

attributed to the selected osteopathic treatment. The Null Hypothesis was not proven with respect to this variable. Several studies using other types of treatment have found that the frequency of headache is the most sensitive to change and responsive to treatment.[44-50] Other osteopathic studies for TTH did not measure the frequency of the headaches, so this study cannot be compared with them.[31,51]

The HD Rating for E demonstrated a 57.5 % improvement compared to a 15.6 % improvement with C. Blanchard et al (1990) defined a successful reduction of headache as an improvement of at least 50%.[24] The placebo effect is accepted to be between 30% and 33%. E improved more than the placebo effect and more than 50%.

The ANOVA in E produced a value of $P = .075$ for the Headache Degree of Improvement and a value of $P = .059$ for the HD Rating. Both of these P values are $<.10$ which is acceptable in exploratory analysis. Both of these measures show a clinically significant change in the frequency and intensity of headaches and are useful measures that warrant further research in future studies with larger sample sizes.

There was no significant difference in the intensity of the Worst Headache of the Week ($P = .264$). One study that used the HD also showed no significant improvement in the intensity of the headache.[48] Other osteopathic studies did find decreased intensity of headaches.[31,51] These studies used the visual or verbal analogue scale (VAS) as the subjective headache measure, while this study used the HD.[24, 42] HD scores are a more reliable and conservative estimate of pain reduction than global improvement ratings such as the VAS.[17] The HD gives a more accurate description than the VAS and is not subject to distortions of memory.[52] The VAS only reflects the intensity of the headache at one point in time and does not rate frequency. It is more difficult to show a decreased intensity of headaches using the HD. It is possible that studies using the VAS may have had a false positive effect while this study had a significant positive outcome.

Clinical Significance

Although this study had a small sample size, it did show a significant result. TTH is a common problem that is caused by physical factors and likely also by a complex interaction of psychological stress and emotional factors.[12-15,17] It is our opinion that the cause of recurring TTH is a combination of osteoarticular and myofascial dysfunction and an emotional element that makes these people more sensitive and less resistant to stressful events. Stiles (1976) wrote, "in a patient having some somatic dysfunction, the increased muscular contractions in the suboccipital area may not cause any symptomatology until the patient is faced with a stressful situation. He may then develop the typical TTH" (p. 49-50).[53] This combination of factors could lead to a state of central sensitization of the CNS causing the patient to be more susceptible to TTH.

The following comments are proposed hypotheses of the osteopathic treatment that was given in this study and its effects on the patient's physiological functioning and in reducing the frequency of TTH.

Pain elicits a heightened response of the sympathetic nervous system that can cause vasoconstriction, ischemia, chemical changes, more muscle contraction and pain, creating a vicious cycle.[54] Osteopathic treatment to the cervical and upper thoracic spine relieves joint restrictions and myofascial tension, preventing segmental facilitation and thereby reducing nociceptive input to the CNS.

Pain sensitive structures in the cranium such as major arteries, venous sinuses and the dura mater, are mostly innervated by the trigeminal nerve. The dura also receives innervation from upper cervical dorsal nerve roots C1-3, and the glossopharyngeal and vagus nerves in the posterior cranial fossa. All of these nerves communicate with each other via pars caudalis, the spinal nucleus of the trigeminal nerve in the upper cervical region.[55,56] This convergence of nerves on pars caudalis is considered to be the basis of referred pain in the head and upper neck.[55]

Treatment of the cranial bones and the sacrum where there are strong dural attachments, relieves tension on the dura and any nerves and blood vessels passing through it that may be compressed or entrapped, again reducing nociceptive input. Treatment of the cranial sutures would have the same effect because of the extensive vasculature and nerve endings found in the sutures.[36,57]

Treatment of the sternum, clavicles and upper ribs further removes restrictions in the thoracic inlet allowing for unimpeded arterial blood flow and venous and lymphatic drainage to and from the cranium.

All of these osteopathic manual treatments are believed to improve circulation, release restrictions in the joints, reduce tension in the muscles, fascia and the dura mater, decrease nociceptive input and promote a normalization or calming effect of the CNS, thus reducing the frequency of TTH.

The World Health Organization considers that headaches are a major public health disorder requiring better management.[58] Kuchera (1998) stated that osteopathic management of patients with TTH consists of 2 parts; treatment to eliminate segmental facilitation and stress education.[34] This study demonstrated that selected osteopathic manual techniques combined with home-based relaxation exercises significantly decreased the frequency of TTH more than relaxation alone.

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