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A Randomized Controlled Trial of Chiropractic Spinal Manipulative Therapy for Migraine

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ABSTRACT

Objective: To assess the efficacy of chiropractic spinal manipulative therapy (SMT) in the treatment of migraine.

Design: A randomized controlled trial of 6 months' duration. The trial consisted of 3 stages: 2 months of data collection (before treatment), 2 months of treatment, and a further 2 months of data collection (after treatment). Comparison of outcomes to the initial baseline factors was made at the end of the 6 months for both an SMT group and a control group.

Setting: Chiropractic Research Center of Macquarie University.

Participants: One hundred twenty-seven volunteers between the ages of 10 and 70 years were recruited through media advertising. The diagnosis of migraine was made on the basis of the International Headache Society standard, with a minimum of at least one migraine per month.

Interventions: Two months of chiropractic SMT (diversified technique) at vertebral fixations determined by the practitioner (maximum of 16 treatments).

Main Outcome Measures: Participants completed standard headache diaries during the entire trial noting the frequency, intensity (visual analogue score), duration, disability, associated symptoms, and use of medication for each migraine episode.

Results: The average response of the treatment group (n = 83) showed statistically significant improvement in migraine frequency ($P < .005$), duration ($P < .01$), disability ($P < .05$), and medication use ($P < .001$) when compared with the control group (n = 40). Four persons failed to complete the trial because of a variety of causes, including change in residence, a motor vehicle accident, and increased migraine frequency. Expressed in other terms, 22% of participants reported more than a 90% reduction of migraines as a consequenc of the 2 months of SMT. Approximately 50% more participants reported significant improvement in the morbidity of each episode.

Conclusion: The results of this study support previous results showing that some people report significant improvement in migraines after chiropractic SMT. A high percentage (>80%) of participants reported stress as a major factor for their migraines. It appears probable that chiropractic care has an effect on the physical conditions related to stress and that in these people the effects of the migraine are reduced. (J Manipulative Physiol Ther 2000;23:91-5)

Key Indexing Terms: Migraine; Chiropractic; Randomized Controlled Trial

INTRODUCTION

The Migraine Foundation of Australia estimates that some 12% of Australians aged 15 years and over experience migraines.[1] However, the true number of subjects with migraines is unknown because not all such subjects visit a general practitioner.[2] A study performed in Australia estimated the cost of migraines to society as more than $750 million per annum.[3] The estimated cost of migraines in the United States is over $17 billion (in US dollars) per annum.[4]

The Headache Classification Committee of the International Headache Society (IHS) defines migraines as having the following qualities: unilateral location, pulsating quality, moderate or severe intensity, and being aggravated by routine physical activity. During the headache, the person must also experience either nausea, vomiting, or both or photophobia, phonophobia, or both.[5] In addition, there is no suggestion, either by history, physical examination, or neurologic examination, that the person has a headache listed in groups 5 to 11 of their classification system.[5]

The *aura* is the feature that distinguishes migraines with aura from migraines without aura. An aura usually consists of homonymous visual disturbances; unilateral parethesias, numbness, or both; unilateral weakness; aphasia; or unclassifiable speech difficulty.[6] Some subjects with migraines have described the aura as an opaque object or a zigzag line around a cloud, and cases of tactile hallucinations have even been recorded.[7] The new terms *migraine with aura* and *migraine without aura* replace the old terms *classic migraine* and *common migraine*, respectively.[5]

IHS diagnostic criteria for migraine with aura (category 1.2) requires at least 3 of the following: (1) one or more fully reversible aura symptoms indicating focal cerebral cortex dysfunction, brainstem dysfunction, or both; (2) at least one aura symptom developing gradually over more than 4 minutes or 2 or more symptoms occurring in succession; (3) no aura symptom lasting for more than 60 minutes; and (4) headache after aura, with a free interval of less than 60 minutes.

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Recent pharmaceutic treatment for migraine has focused on the serotonergic system or antiemetic symptoms. These include sumatriptan (Imigran), ergotamine (Ergodryl), dihydroergotamine (Dihydergot), or combinations of pharmaceuticals, such as caffeine and ergotamine (Cafergot).[8] Research on these pharmaceuticals suggest significant short-term relief but have not established any long-term benefit.[9-15] For example, Winner[16] assessed results of subcutaneous dihydroergotamine mesylate (DHE-45) versus subcutaneous sumatriptan succinate (Imitrex) on a cohort of 295 patients with migraine. In 2 hours 73% of those receiving DHE-45 versus 85% of those receiving sumatriptan succinate had relief from the migraine. However, 45% of the sumatriptan succinate group and 18% of the dihydroergotamine mesylate group had a recurrence of the migraine within 24 hours after treatment.

Clinical observations suggest that migraines may be aggravated or potentially caused by cervical spine conditions.[17] Even though migraines related to cervicogenic conditions are clinically recognizable, the exact mechanisms are unknown.[18-22] The role of the trigeminocervical nucleus in relation to migraine also remains unclear. The nucleus receives input from the upper 3 cervical spine segments, and therefore spinal problems may contribute to nerve facilitation.[23] One proposed mechanism for how chiopractic treatment could influence migraine is through alteration of the pain sensitivity of the central nervous system.[24] The trigeminal nucleus innervates the cranium, as well as many intracranial and extracranial blood vessels.[25] Afferents from the first 3 cervical vertebrae nerve roots also innervate the dura mater, the scalp, and many suboccipital muscles.[22] This is a similar mechanism to regional pain syndromes, and it is also suggested as one mechanism for serotonin action.[26,27]

The cervical spine has been reported to be involved in headache, dizziness, and other referred pain.[20-24,28-31] Surgical decompression of the C2 nerve root has also resulted in reduction of nausea, photophobia, phonophobia, and vomiting.[29] However, the term *cervicogenic migraine* has been used infrequently and with some controversy because some authors doubt that the cervical spine is a potential etiologic factor for migraine.[23] Most subjects with migraine have numerous symptoms and therefore many potential diagnoses.[2,7,14,17,20,21,24,32] Some authors believe there is a continuum between migraine, tension-type headache, and cervicogenic headache.[18,19] In addition, the precipitating or aggravating factors for headaches and migraines are often the same or similar.[5,17,20,21,33]

This article will assess the results of a randomized controlled trial for chiropractic spinal manipulative therapy (CSMT) in migraine treatment in regard to alteration in symptoms, clinical features, and morbidity.

METHODS

The study design followed that of a previously reported pilot study of chiropractic SMT in migraine treatment.[22] Subjects with migraine were recruited through radio and newspaper advertisements in the Sydney region. Applicants completed a detailed symptom questionnaire and were selected according to a minimum of 5 of the following indicators: inability to continue normal activities or the need to seek a quiet dark area; pain located around the temples; pain described as throbbing; associated symptoms of nausea, vomiting, aura, photophobia, or phonophobia; migraine precipitated by weather changes; migraine aggravated by head or neck movements; previous diagnosis of migraine by a specialist; and a family history of migraine. Inclusion was also based on participants experiencing a minimum of one migraine a month.

Exclusion was based on participants experiencing a daily migraine, with the initiating factor being trauma. Participants were also excluded from the study if there were contraindications to SMT, such as meningitis or cerebral aneurysm. In addition, participants with temporal arteritis, benign intracranial hypertension, or space-occupying lesions were also excluded because of safety concerns.

Participants completed diaries during the entire 6 months of the study, noting the frequency, intensity, duration, disability, associated symptoms, and use of medication for each migraine episode. Participants were instructed on how to complete the diary, which contained a table and an instruction sheet. Participants had to note the date of the migraine, an intensity score based on a visual analogue scale, the number of hours the migraine lasted, and the time before they could return to normal activities. In addition, participants noted associated symptoms by using a letter abbreviation, and they noted the type and strength of medication for each migraine episode. The diaries used are a standard outcome measure for many previous headache-migraine studies.

Participants were randomly allocated to either the experimental group (CSMT) or a control group. Allocation was based on the first letter of the participant's surname and was controlled by an impartial research assistant. Randomization was on a 2:1 basis because participants also acted as their own control subjects on the basis of the establishment of the prestudy baseline. The experimental group received 2 months of CSMT treatment, which consisted of chiropractic diversified technique at vertebral fixations determined by the practitioner (maximum of 16 treatments). Chiropractic SMT is defined as a passive manual maneuver during which the 3-joint complex is carried beyond the normal physiologic range of movement without exceeding the boundaries of anatomic integrity.[22] SMT diversified technique requires a dynamic force in a specific direction, usually with a short-amplitude, high-velocity, spinal-manipulative thrust on areas of vertebral subluxation determined by the physical examination.

Chiropractic vertebral subluxation (CVS) for this study is defined as a limitation of intersegmental motion resulting in loss of joint-ligament springing (denoted as *end feel* or accessory vertebral movement). In addition, the CVS can cause joint tenderness, muscle spasm, and nerve root irritation.

Factors for assessing CVS on each treatment session included a clinical history, physical tests (range of motion, segmental springing, and intersegmental motion assessment), and other specialized chiropractic procedures. In addition, for safety reasons, several vascular investigations were performed where indicated, which included vertebral

Table 1. *Comparative statistics for both groups*

Factor	Control group	Treatment group
Total No. of subjects	40	83
Sex ratio (M/F)	14/27	25/59
Age range (y)	17–66 (mean, 37.8)	10–70 (mean, 39.6)
Frequency (No. per mo)	1–21 (mean, 7.3)	1–24 (mean, 7.1)
Onset (y)	3–56 (mean, 17.4)	2–60 (mean, 18.5)
Duration (h)	1–96 (mean, 22.6)	0.75–108 (mean, 23.3)
Disability (h)	0–96 (mean, 18.9)	0.75–108 (mean, 19.8)

Table 2. *IHS criteria questionnaire responses for group before commencement of study*

Questionnaire responses	No. (%)
Reaction to pain	102 (83)
Location of pain	78 (63)
Pain character	80 (65)
Inability to continue	75 (61)
Nausea	109 (89)
Vomiting	65 (52)
Aura	41 (33)
Photophobia	111 (90)
Phonophobia	90 (73)
Aggravated by head-neck movement	64 (52)
Previous diagnosis by specialist	64 (52)
Family history	78 (63)
Visual change/paresthesias	59 (48)

artery testing, manipulative provocation testing, blood pressure assessment, and abdominal aortic aneurysm screening.

The control group received detuned interferential therapy, which consisted of electrodes being placed on the patient with no current sent through the machine. Patient blinding was achieved by participants being informed that they may be randomly assigned to a control group that would receive a placebo (noneffective) treatment. Concurrently, the practitioners were blinded to previous treatment results, assignment of control procedures, and other outcome measures.

Statistical analysis involved comparing the changes for the different outcome measurements of incidence, intensity, duration, disability, and medication use throughout the trial. Comparison of outcome measurements was made for the control group versus the treatment group by using a paired *t* test for each variable. A one-way analysis of variance was used to test for significant differences between baseline data and final outcome measures for the 2 groups. In addition, analysis of covariance was used to test for significant differences between baseline data for the 2 groups.

RESULTS

One hundred twenty-seven volunteers between the ages of 18 and 70 years were recruited through media advertising. Of the 127 participants who agreed to enter the study, 4 participants failed to complete the entire trial: one because of alteration in work situation, one because of a fractured ankle, one because of soreness after SMT, and one after an increase of migraine caused by chiropractic SMT. Table 1 gives the comparative statistics for both the treatment group (n = 83) and the control group (n = 40).

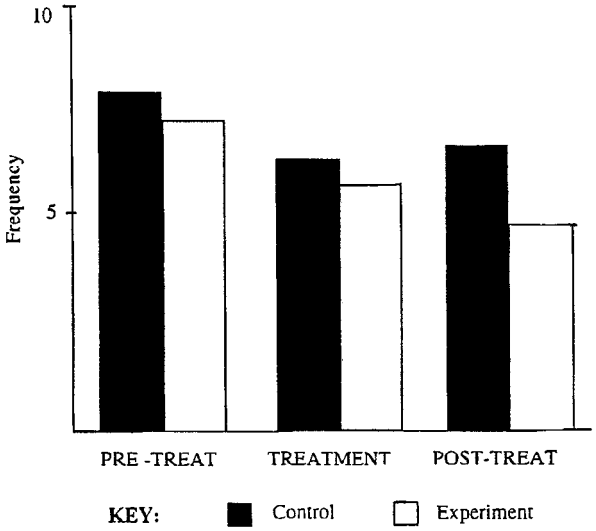

Fig 1. *Comparison of frequency of episodes (per month) for pretreatment, treatment, and posttreatment group means.*

The percentage response for each of the diagnostic criteria of the IHS guidelines is detailed in Table 2. The highest responses were for photophobia (90%), nausea (89%), reaction to pain requiring the person to seek a quiet dark area (83%), phonophobia (73%), throbbing pain characteristic (65%), and parietotemporal pain location (63%). The IHS diagnostic criteria with the lowest responses were aura (33%) and migraine aggravated by head or neck movement (52%). A moderate number (44%) of subjects did not indicate aura as a feature; however, they described either homonymous visual changes or paresthesias.

The average response of the treatment group (n = 83) showed statistically significant improvement in migraine frequency ($P < .005$), duration ($P < .01$), disability ($P < .05$), and medication use ($P < .001$) when compared with the control group. Expressed in other terms, 22% (n = 18) of the treatment group reported a greater than 90% reduction of their migraines as a consequence of the 2 months of SMT. A further 49% (n = 41) reported significant improvement in the morbidity of each episode. A comparison of the CSMT group with the control group shows significant improvement in migraine frequency (Fig 1), duration (Fig 2), disability (Fig 3), and medication use (Fig 4). Only 5 (4.1%) participants reported that their migraine episodes were worse after the 2 months of SMT, but this was not sustained at the 2-month, posttreatment, follow-up period.

An additional finding was that 73 (59%) participants reported no neck pain as a consequence of the 2 months of SMT. Twenty-seven (22%) participants reported slight pain, 16 (13%) participants reported mild pain, and 10 (8%) participants reported moderate pain.

DISCUSSION

The majority of participants had chronic migraines; on average, they had experienced migraines for 18.1 years. However, the results demonstrated a significant ($P < .005$) reduction in migraine episodes and associated disability. The mean

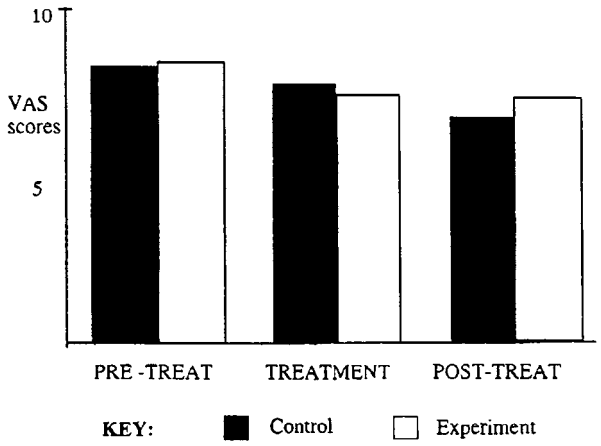

Fig 2. *Comparison of visual analogue scale* (VAS) *scores for pretreatment, treatment, and posttreatment group means.*

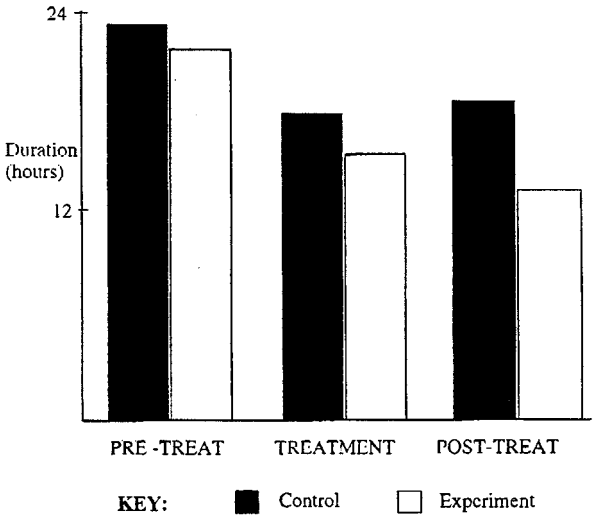

Fig 3. *Comparison of average duration time of migraine (in hours) for pretreatment, treatment, and posttreatment group means.*

number of migraines per month was reduced from 7.6 to 4.1 episodes (Table 3). The greatest area for improvement was medication use ($P < .001$), for which participants were asked to note the use of medication for each episode. A significant number of participants recorded that their medication use had reduced to zero by the end of the 6-month trial.

A 6-month study gives the results more validity than those of previous studies because one criticism of some of those studies was that the length of the trial was too short to allow for the cyclical nature of migraines. However, the study was limited in sample size and the fact that the trial was a pragmatic study that did not consider what aspects of chiropractic SMT had contributed to the improvement in the migraines.

In addition, the study was limited because of the type of control group; interferential does not mimic SMT. However, it could be argued that participants acted as their own form of control subjects because of the baseline (2 months) data collection, especially given the fact that this group consisted of subjects with chronic migraines. Perhaps a better control group would be a group undergoing sham SMT, in which

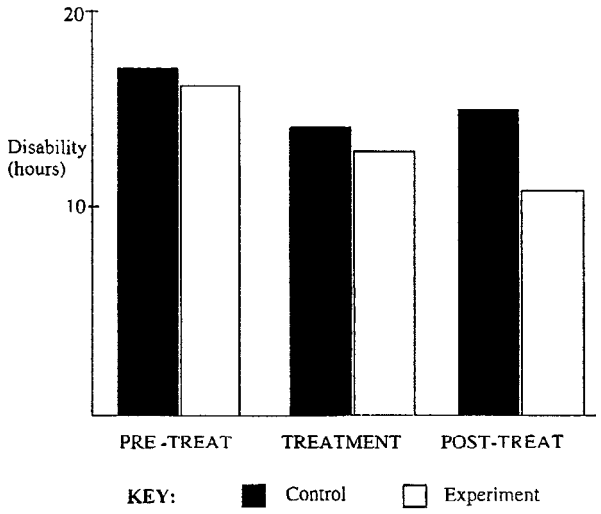

Fig 4. *Comparison of average disability time of migraine (in hours) for pretreatment, treatment, and posttreatment group means.*

participants receive a manipulative thrust into the cervicothoracic junction that was designed to be ineffective.

A further limitation of this study, as with other studies of migraine or headache, was that there was substantial overlap in diagnosis and classification of migraines. The questionnaire used for diagnosis in this study proved to have good reliability when compared with the number of participants that had previously received a diagnosis from a specialist. However, there is a strong suggestion that many subjects with headaches may have more than one type of headache.[17-19,21,24,32] An advantage of the design of this study is that regardless of an exact diagnosis of the migraine, self-reported improvement of outcome measures allows assessment of the validity of the therapy in question.[32]

This study also appears to confirm that there are a number of precipitating or aggravating factors involved in migraine episodes, and therefore a single treatment regimen may prove ineffective in the long term.[17,20-22]

CONCLUSION

There have now been several studies demonstrating significant improvement in headaches or migraines after chiropractic SMT.[17,22,30,36-39] Some of these studies were limited by lack of control subjects, poor control subjects, small sample sizes, and other methodological flaws. However, the level of evidence is steadily increasing to the point where there is now seen to be a moderate level of efficacy for chiropractic SMT in the treatment of headaches or migraines.

A high percentage (83%) of participants in this study reported stress as a major factor for their migraines. It appears probable that chiropractic care has an effect on the physical conditions related to stress and that in these people the effects of the migraine are reduced. However, further studies are required to assess how chiropractic SMT may have an effect on migraine morbidity. Another study currently being completed will assess the effect in other associated symptoms commonly experienced with migraines.

Table 3. *Changes in outcome measures for the control group compared with the treatment group*

	Control group				Treatment group				
Outcome	Baseline	SD	After	SD	Baseline	SD	After	SD	*P* value
Episodes	7.3	6.53	6.9	6.6	7.1	6.98	4.1	6.55	<.005
VAS scores	7.89	1.2	6.2	1.7	7.96	1.4	6.9	1.8	NS
Duration	22.6	27.4	19.8	17.7	23.3	28.3	14.8	19.8	<.01
Disability	18.9	21.2	15.6	18.2	19.8	21.2	13.0	18.2	<.05
Medications	20.1	28.4	16.2	12.4	21.3	28.4	9.8	12.4	<.001

Episodes, Average number of migraines per month; *VAS scores,* 100-mm visual analogue scale for average episode; *duration,* hours for an average episode; *disability,* hours before return to normal activities for an average episode; *medications,* average number of medications taken per month; *NS,* not significant.

A further question that needs to be answered is how to assess the results of other forms of chiropractic SMT in the treatment of headaches or migraines. The results of this study appear to support previous results indicating that some people report significant improvement in migraines after chiropractic SMT. However, future studies may demonstrate that some specific forms of chiropractic SMT do not achieve the same results.

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