

A TWELVE MONTH CLINICAL 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 prospective clinical trial of twelve months duration. The trial consisted of 3 stages: two month pre-treatment, two month treatment, and two months post treatment. Comparison of outcomes to the initial baseline factors was made and also 6 months after the cessation of the study.

Setting: Chiropractic Research Centre of Macquarie University

Participants: Thirty two volunteers, between the ages of 20 to 65 were recruited through media advertising. The diagnosis of migraine was based on a self reported detailed questionnaire, with minimum of one migraine per month.

Interventions: Two months of chiropractic SMT at vertebral fixations determined by the practitioner, through orthopedic and chiropractic testing.

Main Outcome Measures: Participants completed 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 initial 32 participants showed statistically significant ($p < 0.05$) improvement in migraine frequency, VAS, disability, and medication use, when compared to initial baseline levels. A further assessment of outcomes after a six month follow up (based on 24 participants), continued to show statistically significant improvement in migraine frequency ($p < 0.005$), VAS ($p < 0.01$), disability ($p < 0.05$), and medication use ($p < 0.01$), when compared to initial baseline levels.

In addition, information was collected regarding any changes in neck pain following chiropractic SMT. The results indicated that 14 participants (58%) reported no increase in neck pain as a consequence of the two months of SMT. Five participants (21%) reported a slight increase, three participants (13%) reported mild pain, and two participants (8%) reported moderate pain.

Conclusion: The results of this study support the hypothesis that Chiropractic SMT is an effective treatment for migraine, in some people. However, a larger controlled study is required.

Key Indexing Terms (MeSH): Migraine; chiropractic; spinal manipulation; prospective trial; neck.

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INTRODUCTION

The cervical spine as a cause of headache has been well described in the literature (1,2). The Headache Classification Committee of the International Headaches Society, has defined cervicogenic headache, in addition to the other types of headaches, including migraine and tension type headache (3).

However, the role of spinal conditions (especially the cervical spine) and their associated treatment for migraine does not have a well established causal relationship or clear aetiological pathway (4-7). In addition, migraine often has uncertain or overlapping diagnostic criteria thus making the role of the cervical spine as an aetiological factor even more uncertain (8,9).

Migraines are a common and debilitating conditions yet because of this uncertain aetiology, the most appropriate long term treatment has not been established (9,10). Most aetiological models relate to vascular causes of migraine, where episodes seem to be initiated by a decreased blood flow to the cerebrum followed by extracranial vasodilatation during the headache phase (11,12). However, other aetiological models seem connected with vascular changes related to neurological causes and associated serotonergic disturbances (10). Therefore, previous treatments have focused on pharmacological modification of blood flow or serotonin antagonist block (11).

This paper will evaluate the efficacy of chiropractic spinal manipulative treatment during a prospective clinical trial of twelve months duration.

CHIROPRACTIC TREATMENT

Chiropractic SMT is defined as a passive manual manoeuvre during which the three joint complex is carried beyond the normal physiological range of movement without exceeding the boundaries of anatomical integrity (4). SMT requires a dynamic force in a specific direction, usually with a short amplitude to correct a problem of reduced vertebral motion or positional fault. Treatment usually consists of short amplitude, high velocity spinal manipulative thrusts (diversified technique), on areas of vertebral fixation determined by a clinical history and physical examinations

The most commonly used factors to locate vertebral fixation (denoted vertebral subluxation complex by

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chiropractors) are a clinical history relating to mechanical pain patterns and medical details to excluded possible non-mechanical causes (4). These findings would then be confirmed by a thorough physical examination, by assessing which tests/signs (orthopaedic and chiropractic) were able to reproduce the presenting symptom (7).

Studies in effectiveness and cost-effectiveness of treatment for back pain have found significant benefit for chiropractic spinal manipulative therapy (SMT). These studies have been detailed in a previous publication by this author on chiropractic in the workers compensation system (13). In addition, numerous studies have identified improvement in neck pain and headache following chiropractic SMT (4,7,14-17).

This paper will test an hypothesis that spinal conditions appear to contribute to the aetiology and morbidity of migraine.

METHODOLOGY

The study was twelve month prospective clinical trial which involved 32 subjects who received a two month course of chiropractic SMT. Treatment consisted of short amplitude, high velocity spinal manipulative thrusts (chiropractic adjustive technique), on areas of vertebral subluxation determined by the physical examination.

Participants were recruited via the radio and newspapers in the Sydney region. Applicants completed a previously reported questionnaires, and were selected according to responses in the following symptoms. The participants needed to a minimum of 5 of the following IHS indicators: reaction to pain requiring cessation of activities, the need to seek a quiet dark area, unilateral pain located parieto-temporal, pain described as pulsating/throbbing, associated symptoms of nausea &/or vomiting, photophobia &/or phonophobia, migraine aggravated by head or neck movements, and a family history of migraine (3).

Inclusion was also based on participants experiencing at least one migraine a month. Exclusion was based on non-migraine indicators of a daily migraine or the initiating factor being trauma. Participants were also excluded from the study if there were contra-indications to SMT, such as meningitis or cerebral aneurysm. In addition, participants with temporal arteritis, benign intracranial hypertension or space occupying lesions were also excluded due to safety aspects.

Participants completed diaries during the initial six month trial noting the frequency, VAS, duration, disability, associated symptoms and use of medication for each migraine episode. Participants were instructed 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 hours the migraine lasted and the time before they could return to normal activities. In addition, participants noted associated symptoms using a letter abbreviation and they noted the type and strength of medication for each migraine episode.

Patient's blinding was achieved by participants being informed that they may be randomly assigned to a control group which would receive a placebo (non effective) treatment. Concurrently, the practitioners were "blinded" to previous treatment results, assignment of control procedures and other outcome measures.

The first aspect of the trial was conducted over six months, and consisted of 3 stages: two months pre-treatment, two months treatment, and two months post treatment. Participants were contacted by the author a further six months after the initial trial and asked to complete another questionnaire regarding their current migraine episodes for comparison to baseline data. The follow up questionnaire sought information on the same outcome measures, as detailed in the diaries described above.

Comparison was made to initial baseline outcome measurements of migraine preceding commencement of SMT, data at the end of the two months post SMT, and to the six month follow up data. Statistical analysis involved comparing the changes of the different outcome measurements of frequency, VAS, duration, disability, and medication use throughout the trial. Statistical tests employed were a paired t test to test for significant difference between each group and a one way analysis of variance (ANOVA) to test for changes for all groups.

RESULTS

Thirty two participants, between the ages of 23 to 60, joined the study with there being 14 males and 18 females. Table 1 gives the comparative descriptive statistics for the group. The length of time the person had migraines ranged between 5 to 36 years for the group, with the average being 18.1 years. The duration of a typical migraine episode ranged between 0.75 to 108 hours for the group, with the average being 23.3 hours. The disability (length of time before the person could return to normal activities) of a typical migraine ranged between 0 to 108 hours for the group, with the average being 25.0 hours.

Table 1. Comparative Statistics for group prior to commencement of study

FACTOR	DATA
Total Subject	n=32
Sex ratio	14M: 18F
Age range	23 to 60 (mean 39.5)
Onset (years)	5 to 36 (mean 23.4)
Frequency (No/ month)	1 to 18 (mean 18.1)
Disability (hours)	0 to 108 (mean 16.3)

The percentage response for each of the diagnostic criteria of the IHS guidelines is detailed in table 2 (Table 2). The highest responses were for photophobia (91%), nausea (88%), reaction to pain requiring the person to seek a quiet dark area (84%), phonophobia (72%), throbbing pain characteristic (69%), parieto-temporal pain location (69%), inability to continue normal activities (66%), and family history (63%).

Table 2. IHS criteria questionnaire responses for group prior to commencement of study

Question	Number of responses (%)
Reaction to pain	27 (84)
Location of pain	22 (69)
Pain character	22 (69)
Inability to continue	21 (66)
Nausea	28 (88)
Vomiting	18 (56)
Aura	10 (31)
Photophobia	29 (91)
Phonophobia	23 (72)
Aggravated by head/neck movement	17 (53)
Previous diagnosis by specialist	17 (53)
Family history	20 (63)
Visual change/parathesias	14 (44)

The IHS diagnostic criteria with the lowest responses were aura (31%), migraines aggravated by head or neck movement (53%), and vomiting (56%). A moderate number (44%) of people did not indicate aura as a feature, however, they described either homonymous visual changes or parathesias. Therefore, the number of people experiencing migraine with aura (MA) for this group was twenty four (75%) of a total group of thirty two.

The group showed statistically significant improvement ($p < 0.05$) in migraine frequency, VAS, duration and disability, when compared to initial baseline levels. The frequency rates reduced by 46% for the group, severity reduced by 12%, duration reduced by 20%, disability reduced by 14% only one participant (3.1 %) reported that their migraine episodes were worse after the two months of SMT, but this was not sustained at the two month post treatment follow up period. Table 3 demonstrates variate scores in each of the six diary categories for the three phases of the trial.

Table 3. Comparative results for group (n=24) prior to commencement of study (baseline) and at a 12 month follow up period.

Value	Baseline					12M follow up				
	Freq	VAS	Dur	Dis	Med	Freq	VASI	Dur	Dis	Med
Mean	6.53	7.88	24.5	24.5	11.8	2.64	6.84	19.7	21.3	7.0
SE	1.46	0.3	7.6	6.7	2.6	0.71	0.3	5.9	6.5	2.6
Median	4	8	9	12	12	1	7	6.5	7	2
Min	0.5	4.5	1.5	1.5	0.5	0.25	4.0	1.5	1.5	0
Max	20	10	120.0	96.0	40	10.0	10.0	72	96	40

From the initial thirty two participants who entered the study, four participants failed to complete the entire trial, one due to alteration in work situation, one due to a fractured ankle, one due to soreness after SMT, and one ACO

following a perceived worsening of their migraine due to chiropractic SMT. In addition, four people failed to return their six month follow up data, and were excluded from the assessment. Therefore the assessment of changes in migraine at the twelve month period was based on 24 participants. Table 4 gives the comparative statistics for this group at the end of the 12 month period.

Table 4. Changes in outcome measures for group baseline levels compared to the 12 month follow up.

Outcome	% change	p value
Frequency	60% reduction	>0.005
VAS	14% reduction	>0.01
Duration	20% reduction	>0.05
Disability	13% reduction	NS
Medication	36% reduction	>0.01

The average response at twelve months (n=24) showed statistically significant improvement in migraine frequency ($p < 0.005$), VAS ($p < 0.01$), duration ($p < 0.05$), and medication use ($p < 0.01$), when compared to initial baseline levels (Figure ???). The greatest area for improvement was with the frequency of episodes (60% reduction), and the associated severity of each migraine (14% reduction). In addition, the duration of the migraine (20% reduction) and the use of medication, reduced significantly following the SMT intervention (36% reduction). Table 3 shows mean variate scores for the three phases of the trial and statistical significance by analysis of variance (ANOVA).

Another additional result related to associated neck pain. Fourteen participants (58%) reported no increase in neck pain as a consequence of the two months of SMT. Five participants (21%) reported slight pain, three participants (13%) reported mild pain, and two participants (8%) reported moderate pain.

DISCUSSION

The majority of participants were chronic migraine sufferers, on average they had experienced migraines for 18.1 years. However, the results have demonstrated a significant ($p < 0.005$) reduction in their migraine episodes and their associated disability. The mean number of migraines per month reduced from 7.6 to 2.6 episodes.

A twelve month study gives the results substantial significance because a criticism of early studies were that the length of the trial was too short to allow for the cyclical nature of migraines (18). However, the study was limited in the sample size and the fact that the trial was a pragmatic study which did not consider what aspects of chiropractic SNIT had contributed to the improvement in the migraines.

In addition, the study was limited due to the lack of a control group. However, it could be argued that participants acted as their own form of control, due to the

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baseline two months data collection, especially given the fact that this group were chronic migraine sufferers.

A further limitation of this study, as with other studies of migraine or headaches was that there is substantial overlap in diagnosis and classification of migraines. The questionnaire used in this study proved to have good reliability, however, there is strong suggestion that many headache sufferers may have more than one type of headache (6-9). An advantage with the design of this study is that regardless of the exact "diagnosis" of the migraine, self reported improvement of outcome measures allow assessment of the validity of the therapy in question (4).

This study appears to confirm that there are a number of precipitating or aggravating factors involved in migraine episodes and therefore a single treatment regime may prove ineffective in the long term (4,5,9,15).

Practitioners need to be aware of the various treatment strategies and their relative advantages or limitations.

Importantly, many of the associated symptoms suffered by participants on the trial were reported to be decreased following the SMT. The associated symptoms which decreased following the trial included nausea (41% of participants felt reduction), photophobia (31 % felt reduction), vomiting (25% felt reduction), and phonophobia (25% felt reduction). Commonly reported side effects which often increase following pharmaceutical trials include nausea, vomiting, fatigue, chest pain, paraesthesia, somnolence, syncope, vertigo and less commonly atrial fibrillation. In addition, recent evidence has identified sumatriptan to be a potential cause of birth defects and myocardial infarction (19,20).

Whilst not a factor noted by the IHS, stress as either an aggravating or precipitating factor was cited by 73% of participants. In addition, 66% of people reported neck pain at the time of the migraine, with a further 31 % of people reporting upper back pain (some people noted both simultaneously).

Interestingly, five people at the end of the 12 months followup had no migraines and had decreased need for medication by 100% following chiropractic SMT. No patients reported that their migraines had increased as a result of the SMT trial.

CONCLUSION

The results of this study support the hypothesis that Chiropractic SMT is an effective treatment for migraine, in some people. However, due to the multifactorial nature of migraine, and the finding that episodes usually reduce following any intervention, further larger controlled study is required.

A prospective randomised controlled trial utilising detuned EPT (interferential), a sham manipulation group and an SMT group is nearing conclusion. It is anticipated this trial will provide further information of the efficacy of Chiropractic SMT in the treatment of migraine with aura.

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