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The Effect of Spinal Manipulation in the Treatment of Cervicogenic Headache

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ABSTRACT

Purpose: To study whether the isolated intervention of high-speed, low-amplitude spinal manipulation in the cervical spine has any effect on cervicogenic headache.

Design: Prospective randomized controlled trial with a blinded observer.

Setting: Ambulatory outpatient facility in an independent research institution.

Participants: Fifty-three subjects suffering from frequent headaches who fulfilled the International Headache Society criteria for cervicogenic headache (excluding radiological criteria). These subjects were recruited from 450 headache sufferers who responded to newspaper advertisements.

Intervention: After randomization, 28 of the group received high-velocity, low-amplitude cervical manipulation twice a week for 3 wk. The remaining 25 received low-level laser in the upper cervical region and deep friction massage (including trigger points) in the lower cervical/upper thoracic region, also twice a week for 3 wk.

Main Outcome Measures: The change from week 1 to week 5 in analgesic use per day, in headache intensity per episode and in number of headache hours per day, as registered in a headache diary.

Results: The use of analgesics decreased by 36% in the manipulation group, but was unchanged in the soft-tissue group; this difference was statistically significant ($p = .04$, χ^2 for trend). The number of headache hours per day decreased by 69% in the manipulation group, compared with 37% in the soft-tissue group; this was significant at $p = .03$ (Mann-Whitney). Finally, headache intensity per episode decreased by 36% in the manipulation group, compared with 17% in the soft-tissue group; this was significant at $p = .04$ (Mann-Whitney).

Conclusion: Spinal manipulation has a significant positive effect in cases of cervicogenic headache. (J Manipulative Physiol Ther 1997; 20:326–30).

Key Indexing Terms: Headache; Chiropractic Manipulation; Randomized Controlled Trial.

INTRODUCTION

Recent studies suggest that cervicogenic headache, as defined by the International Headache Society (IHS) (1), accounts for some 15–20% of all recurrent headaches (2–4). This is a very large number of individuals indeed, when one considers that the point prevalence of headache in the general population is approximately 16% (5).

Spinal manipulation/mobilization has been shown to have a positive therapeutic effect in post-traumatic headache (6), and is very likely to have an effect in chronic tension-type headache (7), but apart from these, no clinical effect of spinal manipulation has been demonstrated convincingly under controlled, randomized conditions for other forms of headache.

Previously, we published a randomized controlled clinical trial on the effect of spinal manipulation in the treatment of cervicogenic headache (8). Although the manipulation group in that trial fared consistently better that the control group, the difference between the two groups failed to reach the usual level of statistical significance ($p \leq .05$).

A graphical analysis of the data from our 1995 trial suggested that the two treatment groups seemed to be distinct from one another and that the lack of statistically significant differences could have been caused by too few participants (i.e., a type-2 error).

Therefore, we decided to resume the recruitment of headache sufferers into the trial in early 1996, and we report here the results from a total of 54 participants. The results thus include some data from the 39 headache patients already published (8).

METHODS

After advertisements for headache sufferers in the local press over two periods during 1994–96, some 450 persons responded. Through a series of telephone interviews, personal interviews and physical examinations, a group of 55 headache sufferers were invited to take part in the study.

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These were the first 55 headache sufferers examined, who fulfilled all of the following inclusion criteria:

1. Aged 20–60 yr.
2. Headache ≥ 5 days per month for at least 3 months.
3. No prior spinal manipulation in the cervical spine.
4. No effect of migraine medication (if these had been tried).
5. Headache located in the occipital region, with or without forward radiation.
6. Subjects could spontaneously identify special neck movements or sustained neck postures that precipitate or aggravate their headaches.
7. On examination, there was objectively decreased passive range of motion in the cervical spine, as measured with a strap-on head goniometer (9–11).
8. On a visual analogue scale from 0–100 mm, the subjects scored the typical intensity of their headache between 25 and 85.
9. No relative or absolute contraindications to cervical spinal manipulation, based on case history, physical examination and X-ray examination (12).

This means that the subjects included in the present study fulfilled the cervicogenic headache criteria of the IHS (Table 1), apart from its radiological criteria.

After receiving verbal and written information (as approved by the Regional Ethics Committee), one person declined to take part in the study because of the small risk of cerebrovascular accidents, which had been described as a possible side-effect (13). The remaining 54 subjects, who gave their written informed consent, entered the study; their data are given in Table 2.

In the written and verbal information, the subjects were informed that the trial was conducted to compare two different commonly used treatments for cervicogenic headache, to help establish whether one was better than the other, because this was not known. The subjects were thus blind to the underlying purpose of the trial (evaluating spinal manipulation for treating cervicogenic headache).

The study was designed as a prospective randomized controlled trial. A project secretary and two registered chiropractors were responsible for running the treatment block (weeks 1–4), and a blinded observer interpreted headache diaries and questionnaires. The flowchart in Figure 1 illustrates graphically the 5-wk trial period.

The first 39 volunteers had 2 wk of pretreatment monitoring to ensure that they were able to fill in the headache diaries correctly; because this was not a problem, the final 15 volunteers were given only 1 wk of pretreatment monitoring.

The subject's headache activity was monitored using a headache diary in which the subject would, at the end of each day, register the exact periods of headache that day, the number and type of pain killers used that day, and estimate the intensity of that day's headache on a visual analogue scale (VAS) from 0–100 mm (14).

Fifty-six tickets had been prepared in advance (28 labeled "soft tissue" and 28 labeled "manipulation") and randomization was carried out by the project secretary, who drew a ticket randomly for each subject immediately after the initial clinical examination in week 2. Subjects whose tickets read "manipulation" received spinal manipulation totaling six sessions over 3 wk. Manipulative methods used were toggle recoil for the upper cervical region and diversified technique for the mid- and lower cervicals, as determined by the chiropractor on the basis of palpatory examination findings (15). In these techniques, a high-velocity, low-amplitude thrust in a specific line of drive is given at the end point of the normal passive range of motion; this is often accompanied by an audible crack.

Subjects whose tickets read "soft tissue" received deep friction massage (including trigger points) of the posterior muscles of the shoulder girdle, the upper thoracic and lower cervical regions, plus treatment with laser light in the upper cervical region, again totalling six sessions over 3 wk.

The use of laser light was added to include some kind of upper cervical intervention in the control group, so that the two groups were as similar as possible. No effect, apart from placebo, can be expected from such low power laser therapy (16), whereas the massage and trigger points are normally assumed to have some effect (i.e., the control group was not a pure placebo group in this study).

At the end of week 4, the headache diary for week 5 was handed out, and returned 1 wk later. All subjects in both groups were treated by the same two registered chiropractors, who, like everyone else involved in the project, attempted to be as impartial/neutral as possible. Both chiropractors had a similar number of subjects (±1) from either of the trial groups. Contact between the treatment team and the blinded observer was kept at a minimum, and no information on individual subjects was shared before the code was broken.

On the basis of the headache diaries from week 1 and week

Table 1. *The 1990 criteria of the International Headache Society for the diagnosis of cervicogenic headache (1)*

Diagnostic criteria for cervicogenic headache
A. Pain localized to neck and occipital region. May project to forehead, orbital region, temples, vertex or ears.
B. Pain is precipitated or aggravated by special neck movements or sustained neck posture.
C. At least one of the following:
1. Resistance to or limitation of passive neck movements.
2. Changes in neck muscle contour, texture, tone or response to active and passive stretching and contraction.
3. Abnormal tenderness of neck muscles.
D. Radiological examination reveals at least one of the following:
1. Movement abnormalities in flexion/extension.
2. Abnormal posture.
3. Fractures, congenital abnormalities, bone tumors, rheumatoid arthritis or other distinct pathology (not spondylosis or osteochondrosis).
Comment: Cervical headaches are associated with movement abnormalities in cervical intervertebral segments. The disorder may be located in the joints or ligaments. The abnormal movement may occur in any component of intervertebral movement, and is manifest during either active or passive examination of the movement.

Table 2. *Characteristics of the study population in week 1, before the start of treatment*

Variable name	Whole group	Soft-tissue group	Manipulation group	*p*-value for difference
Number of subjects	53	25	28	
Gender				
Male	23	10	13	
Female	30	15	15	.85 (Fischer exact)
Median age (range)	37 yr (20–60)	35 yr (24–60)	42 yr (20–57)	.22 (Mann-Whitney)
Median number of headache hr/day (range)	3.6 (0.3–15.8)	2.9 (1–8.6)	4.1 (0.3–15.8)	.53 (Mann-Whitney)
Median headache intensity–VAS/episode	45/100 (6–76/100)	37/100 (22–65/100)	48/100 (6–76/100)	.15 (Mann-Whitney)
Median number of analgesics/day (range)	0.6 (0–7.9)	0.6 (0–4.4)	0.7 (0–7.9)	.48 (Mann-Whitney)

5, the following primary outcome variables were calculated:

1. percent change in mean number of headache hours per day from week 1 to week 5.
2. percent change in mean number of pain killers per day from week 1 to week 5.
3. percent change in mean visual analogue score per headache episode from week 1 to week 5.

RESULTS

Of the 54 volunteers, 53 completed the full 5-wk trial as planned. One female volunteer from the soft-tissue group was excluded by the blinded observer in week 4 because of a severe head trauma that would have affected her headaches in week 5.

After completion of the trial and analysis of diaries and other data by the blinded observer, the code was broken. Data for the two treatment groups are given in Tables 2–5. Unpaired two-sided statistical analysis was used throughout. Because much of the data were not normally distributed, nonparametric methods were used for the statistical analysis. Most parametric statistical methods are quite robust toward non-normal distribution, but in this case, the non-normality was so severe (kurtosis and skewness up to ± 17) that it would have been meaningless to use parametric methods or parametric concep such as variance and standard deviation.

Table 2 lists the particulars for all 53 volunteers in week of the trial and for each variable compares the soft-tissue gro with the manipulation group for statistical differences. The were no statistically significant differences on any of the va ables between the two groups. We therefore assumed that th were comparable in all respects at the start of the trial.

Table 3 lists the changes in the primary outcome variabl within the two treatment groups from week 1 to week 5. In t soft-tissue group, there was a statistically significant reducti in number of headache hours per day, but neither headac intensity nor analgesic consumption changed significantly. the manipulation group, all three primary outcome variabl showed significant improvement from week 1 to week 5.

Table 4 contrasts the two treatment groups with respect the development in individual variables from week 1 to we 5, and lists the statistical significance of any differences. F each variable, the median change is given plus the interquart range and the median change in percent of the original score week 1.

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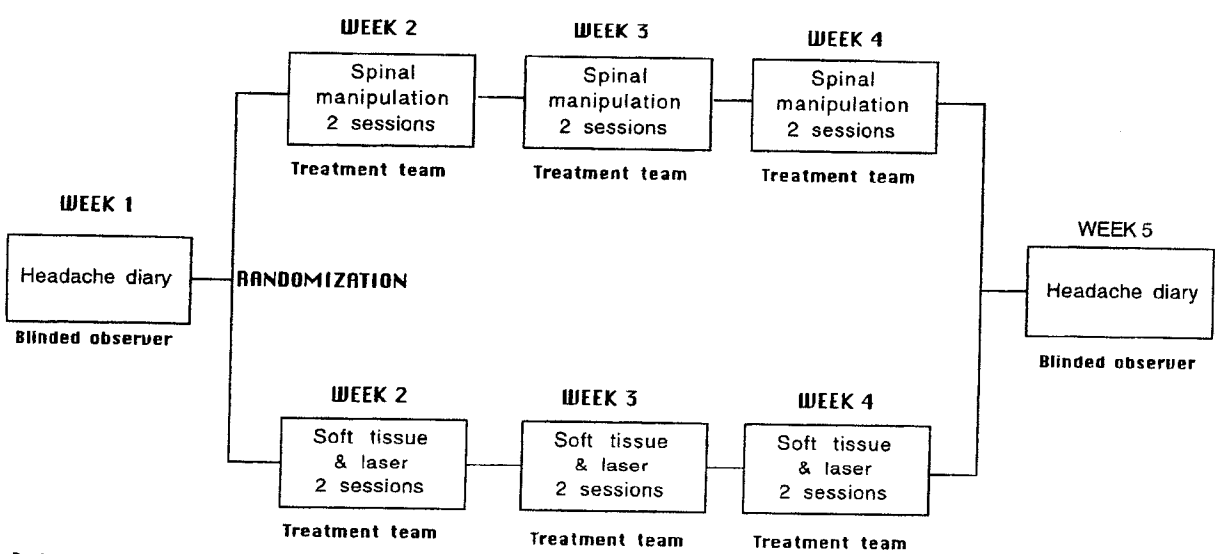

Fig. 1 *Patient flow in the 5-wk trial period.*

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Table 3. *Median/mean pretreatment score compared with the median/mean post-treatment score for the three primary outcome variables in the two groups. Statistical significance of the within-group changes in primary outcome variables from week 1 to week 5*

Variable name	Pretreatment score	Posttreatment score	Statistical significance of percent change
Soft-tissue group			
Median number analgesics/day	0.6	0.4	.50 (Sign test)
Mean number analgesics/day	1.0	0.7	
Median headache hr/day	2.9	1.9	.04 (Sign test)
Mean headache hr/day	4.0	2.4	
Median headache intensity per episode (VAS)	37/100	31/100	.15 (Sign test)
Mean headache intensity peer episode (VAS)	41/100	36/100	
Manipulation group			
Median number analgesics/day	0.7	0.4	.0001 (Sign test)
Mean number analgesics/day	1.5	0.8	
Median headache hr/day	4.1	0.9	.0001 (Sign test)
Mean headache hr/day	5.2	2.0	
Median headache intensity per episode (VAS)	48/100	29/100	.0015 (Sign test)
Mean headache intensity per episode (VAS)	44/100	28/100	

everity (VAS)], the spinal manipulation group consistently fared better than the soft-tissue group. The improvement in the manipulation group was significantly better for headache hours per day ($p = .03$, Mann-Whitney) and for headache intensity ($p = .04$, Mann-Whitney), whereas no significant reduction in analgesic use could be identified with the Mann-Whitney test ($p = .14$).

To check whether the lack of significant reduction in analgesic use might be attributable to a type-2 error, caused by the relatively low number of participants, a χ^2 test for trend was performed on this variable (Table 5). This test identified a significant difference in favor of the manipulation group ($p = .04$) with regard to reduction in analgesic use.

Using the difference in number of pain killers used in week 1 and in week 5 as a variable carries with it the assumption that the subjects would not change their choice of prescription (i.e., that they would not switch between using 10 mild analgesics one week and four strong analgesics the next week).

It seemed from the diaries that 44 of the 53 subjects stayed with the same formulation in weeks 1 and 5. The remaining 9 subjects (4 from the soft-tissue group and 5 from the manipulation group) used combinations of preparations at random with the following contents:

1. 500 mg of paracetamol
2. 500 mg of acetylsalicylic acid
3. 500 mg of acetylsalicylic acid and 10 mg of codeine
4. 200 mg of ibuprofen
5. 500 mg of fenazone

Because these preparations are all classed as "mild analgesics" and because no significant differences in their effectiveness as painkillers has been demonstrated (17), the use of this variable is considered justified.

DISCUSSION

The fact that the manipulation group fared significantly better than the soft-tissue group on all three of the outcome variables strengthens the conclusions of this study. The first 39 volunteers to enter the trial had a protocol slightly different

Table 4. *Changes in the soft tissue group compared with the manipulation group on the individual variables monitored, from week 1 to week 5, and statistical significance of between-group changes*

Variable name	Whole group	Soft-tissue group	Manipulation group	*p*-value for difference
Number of subjects	53	25	28	
Primary outcome variables				
Change in analgesics/day				
Mean	−0.5	−0.3	−0.7	
Median	−0.3	0	−0.4	.14 (Mann-Whitney)
Interquartile range	±0.9	±1.0	±1.0	
Median change in %	−30%	0%	−36%	
Change in headache hours/day				
Mean	−2.4	−1.6	−3.2	
Median	−1.9	−1.0	−2.7	.03 (Mann-Whitney)
Interquartile range	±3.2	±2.5	±3.5	
Median change in %	−56%	−37%	−69%	
Change in headache intensity (VAS)				
Mean	−11	−4.2	−17	
Median	−11	−6	−15	.04 (Mann-Whitney)
Interquartile range	±23	±26	±27	
Median change in %	−23%	−17%	−36%	

Table 5. *Change in use of analgesics from week 1 to week 5 and the statistical significance of between-group changes. Analysed with a χ^2 for trend test ($p = .04$)*

Use of analgesics	Decreased	Unchanged	Increased
Soft-tissue group	12	5	8
Manipulation group	20	6	2

from that of the final 15 volunteers, but we did not consider this to be a problem. It is not likely that the extra pretreatment monitoring week made any difference in the outcome, in that the conditions were the same for members of both the soft-tissue and the manipulation groups and because data from the second week were not used in the analysis.

The volunteers were recruited during two periods approximately 1 yr apart, and this may cause some concern about keeping the unity of time. However, the total period of recruitment was about 1.5 yr, which is no longer than what is generally accepted elsewhere, and recruitment over more than one period of time is also commonly accepted. Whether part of the data have been published or not is not considered relevant, because the data remain the same. However, if any of the readers are troubled by these two periods, they may choose to see the study as an ideal meta-analysis, a methodology that is now generally accepted.

In fact, the significant differences shown in the present study were already embedded in the data in the previously published article (8). In that study, it was possible to construct a post hoc abstract variable that would identify a statistically significant difference between the two treatment groups.

The post hoc abstract variable was as follows:

IF "Use of analgesics reduced by 33%, or mean number of headache hours per day reduced by at least 50%, or mean headache intensity (visual analogue score per episode) reduced by 50%," THEN "Improved" ELSE "Uncertain improvement."

This variable would, with a χ^2 test, result in $p < .05$ (i.e., a significant difference in favor of manipulation). But, because abstract variables generated post hoc always result in much debate about their appropriateness, we decided to err on the side of caution and to increase the number of participants, rather than run the risk of a heated methodological debate that could divert attention away from the clinically relevant results.

Despite all attempts to be impartial and neutral, it is still possible that clinician bias in favor of manipulation or a difference in placebo effect of the two treatment protocols may have influenced the results. This is a potential methodological problem inherent in all trials that involve a physical intervention on conscious patients. However, in our previous publication (8), we tried to control for this by monitoring the change in volunteers' expected treatment outcome on visual analogue scales before randomization and again immediately after the first treatment session, before any somatic treatment effect would have occurred. The expected treatment outcome increased slightly in both groups after the first treatment session, but there was no significant difference between the groups ($p = .71$, Mann-Whitney). We therefore find it unlikely that differences in placebo effect or clinician bias played a major role.

The soft-tissue group in this study served only as a control group, and the results from this group should not be taken to represent the maximum effect possible with treatment of soft tissues. It possible that an effective combination of the therapies could be devised.

CONCLUSION

Spinal manipulation seems to have a significant positive effect in reducing hours with headache and intensity of headache and analgesic consumption in cases of cervicogenic headache.

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ABSTRACT

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