

DOSE RESPONSE FOR CHIROPRACTIC CARE OF CHRONIC CERVICOGENIC HEADACHE AND ASSOCIATED NECK PAIN: A RANDOMIZED PILOT STUDY

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ABSTRACT

Objective: To acquire information for designing a large clinical trial and determining its feasibility and to make preliminary estimates of the relationship between headache outcomes and the number of visits to a chiropractor.

Design: Randomized, controlled trial.

Setting: Private practice in a college outpatient clinic and in the community.

Subjects: Twenty-four adults with chronic cervicogenic headache.

Methods: Patients were randomly allocated to 1, 3, or 4 visits per week for 3 weeks. All patients received high-velocity low-amplitude spinal manipulation. Doctor of Chiropractics could apply up to 2 physical modalities at each visit from among heat and soft tissue therapy. They could also recommend modification of daily activities and rehabilitative exercises. Outcomes included 100-point Modified Von Korff pain and disability scales, and headaches in last 4 weeks.

Results: Only 1 participant was insufficiently compliant with treatment (3 of 12 visits), and 1 patient was lost to follow-up. There was substantial benefit in pain relief for 9 and 12 treatments compared with 3 visits. At 4 weeks, the advantage was 13.8 ($P = .135$) for 3 visits per week and 18.7 ($P = .041$) for 4 visits per week. At the 12-week follow-up, the advantage was 19.4 ($P = .035$) for 3 visits per week and 18.1 ($P = .048$) for 4 visits per week.

Conclusion: A large clinical trial on the relationship between pain relief and the number of chiropractic treatments is feasible. Findings give preliminary support for the benefit of larger doses, 9 to 12 treatments, of chiropractic care for the treatment of cervicogenic headache. (*J Manipulative Physiol Ther* 2004;27:547–553)

Key Indexing Terms: *Headache; Cervicogenic Headache; Neck Pain; Manipulation; Chiropractic*

Headache (HA) is one of the most common ailments. With prevalence in the general population of about 16%,¹ epidemiologic studies report that 4% of those adults have HAs on a daily basis.²

Approximately 7 million people suffer from HAs at least every other day, which translates into millions of lost workdays and severely impacts work efficiency.³

Cervicogenic HA, defined as pain originating in the cervical spine and referred to the head,⁴ became ensconced in the International Headache Society diagnostic classification in 1988.⁵ Although not as prevalent as tension-type headache or migraine, cervicogenic HA nevertheless is diagnosed in 0.4% to 2.5% of the general population.^{6,7} However, in pain clinics, cervicogenic HA occurs in 33.8% of HA patients.⁸ According to a recent survey of complementary and alternative therapy use, chiropractic was frequently selected for the relief of head and neck pain,⁹ accounting for 18 to 38 million manipulations performed annually.^{10,11}

The scientific evidence to support the efficacy/effectiveness of cervical manipulation for the relief of chronic HA has been assessed in systematic reviews of random, controlled trials.¹¹⁻¹⁴ The reviews conclude that more rigorous studies need to be performed to make definitive recommendations about treatment efficacy. However, the

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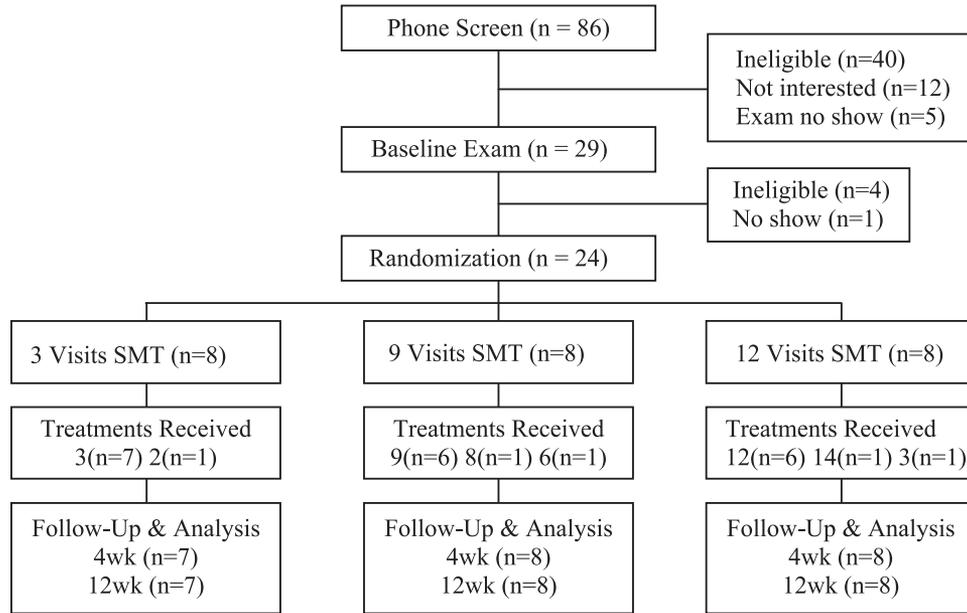


Fig 1. Study flow diagram. Exam, examination; phone, telephone; SMT, spinal manipulative therapy; wk, week.

most recent systematic reviews^{12,13} have found higher quality evidence supporting manipulation as an efficacious therapy for cervicogenic HA. Three studies have found manipulation superior to placebo^{15,16} and to a no-treatment control.¹⁷

An important question that is not addressed in any of the efficacy studies is the possible effect that treatment dosage may have on HA outcomes. Recommendations for the duration and frequency of chiropractic care vary,¹⁸⁻²⁰ because there is no evidence-based guideline for optimal treatment. The purpose of this pilot study was to determine the feasibility of a large clinical trial and to gather preliminary data on the dose-response relationship between the number of chiropractic treatments and relief of pain in cervicogenic HA sufferers.

METHODS

Design

This study was a prospective, randomized, controlled trial (Fig 1). Twenty-four participants were randomized to 1 of 3 treatment groups by using an equal allocation algorithm (n = 8 per group). Design adaptive randomization was used to balance potential predictors of outcomes across groups (baseline HA pain and disability, neck pain and disability, and treating chiropractor).^{21,22} Group allocation was concealed before randomization; data required by the allocation program were entered at the time of randomization. Each participant was treated for 3 weeks. One group received a total of 3 office visits for manipulation (1 per week), the second group received 9 visits (3 per week), and the third group received 12 visits

(4 per week). Follow-up time points were 4 and 12 weeks after randomization.

Setting

Between February and October 2002, half of the participants were treated in the faculty practice at the Western States Chiropractic College Outpatient Clinic and half at a private area clinic. Study guarantees of participant rights and safety were approved by the Western States Chiropractic College Institutional Review Board.

Study Protocol

Participants were recruited through advertisements in local newspapers. Project managers conducted an initial eligibility screening by telephone. At the first baseline visit, all participants provided informed consent and completed the first baseline questionnaire. Participants treated at the college clinic received the screening physical examination at the first baseline visit and those treated at the private clinic received the physical examination at the second baseline visit. At the second baseline visit, participants completed a second baseline questionnaire. They were then randomized and received their first chiropractic treatment. Two follow-ups were conducted by mailed questionnaire. Participants were contacted regularly by phone (weeks 1, 2, 3, 4, 6, 8, 10, and 12) to keep them engaged in the study and to remind them to return the mailed questionnaires. They also received reminder calls for their treatment appointments. For ethical reasons, participants were permitted to seek care for HA outside the study protocol. Study chiropractors were not

permitted to recommend additional care on completion of study treatment. No costs were incurred by participants.

Participants

Persons were eligible if they had uncomplicated, chronic cervicogenic HA as defined for the trial by Nilsson et al.²³ Participants were required to have a history of at least 5 cervicogenic HAs per month for a minimum of 3 months. They had to fulfill the IHS criteria for cervicogenic HA,⁵ excluding the radiographic criterion²⁴: 1) pain localized in the neck and occipital region that may also project to forehead, orbital region, temples, vertex, or ears; 2) pain precipitated or aggravated by particular neck movements or posture; and 3) either resistance/limitation of passive neck motion, palpatory changes in neck musculature or altered response to stretching/contraction, or abnormal neck muscle tenderness. Additional criteria were age 18 and older and English literacy.

Persons were ineligible if they had contraindications to spinal manipulation^{25,26} or complicating conditions that might have been related to clinical outcomes: malignancy or history of cancer, spinal infection, vertebral tumors or fracture, lumbar instability, blood dyscrasia, severe trauma within the last 3 months, neck surgery within the previous 12 months, radiating pain to the upper extremities or cervical disk condition, arthritis of the cervical spine, referred neck pain of organic origin, or other types of HA with causes that may confound the effects of manipulation on the cervicogenic component. These HA types included migraine, cluster, metabolic/toxic, sinus, and headache associated with temporomandibular disease, tumors, and glaucoma.⁵ Participants were also excluded if they were in litigation for a health problem or if they missed either baseline visit (before randomization) and, hence, deemed unlikely to comply with the study protocol.

Therapy

Three chiropractors with 3 to 9 years of practice experience were the treating physicians. Multiple therapists permitted scheduling convenience for the patients. Potential participants were screened for study eligibility through case history, standard orthopedic examination, and radiographs (if indicated) by using the protocols of Vernon¹⁸ and Souza²⁷ for HA and those of Gatterman and Panzer^{25,26} for the cervical region. The therapist made the final determination of eligibility for the study.

The principal therapy was high-velocity, low-amplitude spinal manipulation as described by Bergmann et al.²⁸ Discretionary therapy included the administration of up to 2 physical modalities selected from the following: heat and soft tissue therapy including massage²⁹ and trigger point therapy.³⁰ These modalities are commonly used by chiropractors.³¹ Treating chiropractors were also at liberty to recommend modification of daily activities and rehabilita-

tive exercises.³² Therapists were instructed not to alter therapy based on the number of assigned visits. Specific manipulation and other modalities were determined at each visit by the therapist through ongoing evaluation of the participants.^{25,26,28}

Study Outcomes and Baseline Variables

HA and functional disability were evaluated by using the Modified Von Korff (MVK) Scales of Underwood et al.³³ This instrument consists of six 11-point numerical rating scales. The MVK Pain Scale, the primary outcome, is the average of 3 numerical rating scales (scaled to 100 points) rating: HA pain today, worst HA pain in last 4 weeks, and average HA pain in the last 4 weeks. The MVK Disability Scale is the average score of 3 numerical rating scales measuring interference with 1) daily activities, 2) social and recreational activities, and 3) the ability to work outside or around the house. Neck pain and associated disability were also evaluated with these scales. The MVK Scales have been shown to be reliable, valid, and responsive instruments for measuring pain and disability.³³ For the purpose of interpreting the data, a 10-point difference between groups, 20% to 25% of the baseline score, was designated a priori as clinically important.³⁴ The number of HAs in the previous 4 weeks was also recorded. Lower scores for all outcomes indicate better health.

The feasibility of a larger study was determined by the following criteria. Completion rates for the follow-up questionnaires had to be 90% and participants had to attend at least two thirds of scheduled visits, attesting to acceptability of treatment schedule. A large number of visits for care sought outside the study was considered to be indicative of under treatment. Participants reported outside care from chiropractors and other providers (medical doctors, nurse practitioners, physical therapists, acupuncturists, and massage therapists).

Baseline variables included sociodemographics, general health status, and the baseline scores of study outcomes. The general health status measures were the energy/fatigue, emotional well-being, self-rated health, and depression screen indices of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).³⁵ The SF-36 has shown content validity, construct validity, reliability, generalizability, acceptability, and practicality.³⁵⁻³⁷

Analysis

An intention-to-treat analysis was conducted whereby participants were included in their assigned group no matter the number of treatments actually received. The primary analysis consisted of simultaneous regressions of an outcome measure at 4 and 12 weeks (the *sureg* procedure in Stata, Version 8, College Station, TX).³⁸ This is a refinement of repeated-measures analysis of covariance with the advantage of a general increase in power because the

Table 1. Baseline characteristics: mean (SD) or percentage

Characteristic	Group 1/wk (n = 7)	Group 3/wk (n = 8)	Group 4/wk (n = 8)	All (n = 23)
Age (yr)	38.9 (11.9)	46.6 (6.0)	35.4 (9.9)	40.3 (10.2)
Sex: female	71%	75%	100%	83%
Race: white non-Hispanic	71%	88%	88%	83%
Marital status: married	29%	63%	50%	48%
Education: college degree	86%	63%	100%	83%
Income: < \$24,000	43%	75%	13%	43%

Table 2. HA and neck pain outcomes by visit-dose-intensity group*

		Raw Data by Visit-Dose Group						Adjusted Group Mean Effects					
		1 Visit/wk		3 Visits/wk		4 Visits/wk		3 Visits-1 Visit		4 Visits-1 Visit		4 Visits-3 Visits	
		Mean	SD	Mean	SD	Mean	SD	Mean	SE	Mean	SE	Mean	SE
HA	Baseline	51.4	19.5	61.2	10.4	45.0	19.0						
Pain	4-wk	40.5	15.6	31.3	15.6	18.7	14.5	-13.8	9.2	-18.7[†]	9.2	-5.0	9.2
	12-wk	49.0	19.8	34.2	12.3	27.9	30.3	-19.4[†]	9.2	-18.1[†]	9.2	1.3	9.2
HA	Baseline	45.2	27.3	36.3	20.7	32.5	24.1						
disability	4-wk	25.2	19.7	18.3	13.7	7.9	10.1	-2.4	8.2	-10.9	8.2	-8.5	7.8
	12-wk	39.0	25.8	17.5	16.1	14.6	27.3	-17.0[†]	8.2	-18.1[†]	8.2	-1.0	7.8
# HAs	Baseline	17.0	6.9	18.1	9.8	14.9	9.7						
	4-wk	10.0	6.9	10.0	10.8	5.8	6.4	-0.8	3.6	-2.8	3.6	-2.0	3.5
	12-wk	14.7	8.9	11.5	11.9	7.0	9.8	-4.0	3.6	-6.2	3.6	-2.2	3.5
Neck Pain	Baseline	61.0	19.0	58.7	15.4	49.6	20.8						
	4-wk	41.9	11.7	29.6	15.6	22.5	14.9	-11.8	8.8	-16.7	8.9	-4.9	8.6
	12-wk	42.4	19.4	27.1	12.5	30.8	25.6	-14.8	8.8	-8.8	8.9	5.9	8.6
Neck	Baseline	46.7	27.6	36.7	22.3	33.8	24.5						
disability	4-wk	31.4	17.7	22.1	24.4	9.8	12.1	-4.9	7.8	-16.1	7.8	-11.2	7.5
	12-wk	33.3	9.6	14.2	14.1	13.7	20.0	-14.7	7.8	-13.9	7.8	0.9	7.5

Statistically significant results are in boldface.

*For all analysis, n = 7, 8, and 8 for the 3 visit-dose groups respectively. The adjusted group mean effect is a comparison of groups adjusted for baseline differences on the outcome measure. A negative value indicates an advantage for the first group listed (ie, higher dose of care).

[†]P < .05 for a 2-tailed test of significance.

potential correlation among the residuals. Separate analyses were conducted for each study outcome; HA pain was the primary outcome. The explanatory factors were baseline value of the outcome measure and visit-group indicators. The procedure was used to estimate and test differences between visit-group means adjusted for baseline values. In addition, linear dose-response effects were modeled.

RESULTS

The staff conducted 86 phone screens (Fig 1). Of these, 57 were ineligible or not interested. The study chiropractors conducted 29 screening physical examinations. Four were ineligible and 1 was a no show. Twenty-four participants were randomized over 8 months. The typical participant was a white woman, age 40, with a college degree (Table 1). The total sample mean scores were: HA pain, 52.6 (SD = 17.4); HA disability, 37.7 (SD = 23.5); number of HA, 16.6 (SD = 8.7); neck pain, 56.3 (SD = 18.4); and neck disability, 38.7 (SD = 24.2).

Physical modalities were administered at 86% of visits: massage/trigger point therapy at 84% and hot/cold packs at 31% of visits. All participants received physical modalities at least once and two-thirds of patients received physical modalities at every visit.

Compliance and Dropout

Of the patients randomized, 20 of 24 received all assigned treatment. Only 1 participant attended less than the two-thirds of assigned visits required for compliance (attended 3 of 12). This individual stopped because of concerns that treatment was not working, but completed both follow-up questionnaires. A second individual stopped treatment after 6 of 9 visits because of travel time. There was only 1 dropout. This participant, who was disappointed in receiving less than an hour of care per visit, stopped after 2 of 3 visits and refused to return follow-up questionnaires. One individual received 14 of 12 treatments because of an administrative error unrelated to the patient's condition. The response rate to mailed questionnaires was 96%, and

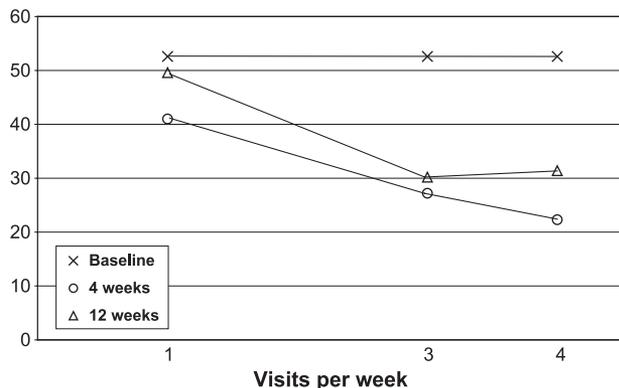


Fig 2. HA pain. The adjusted mean pain scores are shown for the 3 dose groups. The SE = 3.6 for the baseline mean. For both follow-ups: SE = 6.6 for the 1 visit per week group means, and SE = 6.2 for the 3 and 4 visits per week group means.

there was no missing data on these forms. No adverse events were reported.

Outcomes

For HA pain, substantial differences were found between participants receiving 1 treatment per week and those receiving either 3 or 4 treatments per week (Table 2). At 4 weeks after randomization, the advantage was 13.8 (SE = 9.2, $P = .135$) for 3 visits per week and 18.7 (SE = 9.2, $P = .041$) for 4 visits per week. At the 12-week follow-up, the advantage was 19.4 (SE = 9.2, $P = .035$) for 3 visits per week and 18.1 (SE = 9.2, $P = .048$) for 4 visits per week. Fig 2 shows the trends in pain relief across the visit groups. The estimates of the linear effects of care were measured in points improvement per additional 3 treatments: 6.4 points (SE = 3.0, $P = .031$) at 4 weeks and 6.6 points (SE = 3.0, $P = .027$) at 12 weeks. Fig 2 also shows that improvement was substantial in magnitude compared with baseline for the higher dose groups. However, there is still sizeable room for improvement.

Comparable differences between groups were found for HA disability at 12 weeks (Table 2). The linear effect was 6.3 points improvement per 3 visits (SE = 2.7, $P = .018$). The advantage for greater number of visits was not as dramatic at 4 weeks, with a linear effect of 3.3 points per 3 visits (SE = 2.7, $P = .209$). There was also considerable reduction in the number of HA compared with baseline. The advantage of the higher dose groups over the lowest treatment group was 4 to 6 headaches per month.

Neck pain and associated disability magnitude appeared to parallel headache outcomes (Table 2). Estimated linear effects for pain were 5.7 points improvement per 3 visits (SE = 2.9, $P = .051$) at 4 weeks and 3.5 points (SE = 2.6, $P = .223$) at 12 weeks. For disability the linear effects were 5.0 points improvement per 3 visits at both 4 and 12 weeks (SE = 2.9, $P = .050$ and $P = .053$).

Table 3. Number of participants making outside visits to chiropractors and other providers

Outside Visits:	0	1	2	3	4
Chiropractors					
4-wk	21	2			
12-wk	18	2	2		1
Other providers					
4-wk	22			1	
12-wk	20	2			1

Outside Care

A summary of outside care sought by participants at their own discretion is presented in Table 3. At 4 weeks, only 2 participants had seen a chiropractor for unscheduled treatment and 1 person had sought care from another type of provider. By 12 weeks, 5 participants had seen a chiropractor outside the study and 3 people sought other types of care.

DISCUSSION

Our pilot study showed the feasibility of a larger randomized trial. Participants were willing to be randomized, follow the treatment protocol, and complete the baseline and mail follow-up questionnaires. Only 1 person dropped out of the study because of disappointment that treatment visits were not an hour long. Noncompliance with the treatment schedule was minimal (1 person). Perhaps the success with these feasibility criteria can be attributed to 3 design strategies. We included 2 baseline visits as a strategy for reducing the dropout rate.³⁹ Persons who missed either baseline appointment were excluded from the study under the assumption that they were more likely to be non-compliant. The second strategy was regular telephone calls to patients to maintain rapport and keep them engaged in the study. Participants also received a nominal sum of \$5 for each returned questionnaire.

The data suggest preliminary support for a dose-response relationship between cervicogenic HA pain/disability and the number of chiropractic treatments. Larger numbers of visits produced greater benefit. It remains to be determined if the observed benefit is attributable to larger total treatments or greater short-term concentration of care. It also appears that the range of treatments under study fell in the linear range of the dose-response curve with much room for health improvement possible. This implies that more treatments may be required to achieve maximum benefit and saturation of the dose-response curve. However, it must be pointed out that caution is required in interpreting the data. Because of the small sample size, the groups may have been unbalanced in important prognostic variables that could not be controlled in the analysis. Even statistically significant results must therefore be viewed with caution. Confidence intervals were also large, so that effect sizes and the shapes

of the dose-response curves are still far from clear. Long-term benefit of care was not evaluated.

It should be noted that the patient population was limited to chronic cervicogenic HA. Persons were excluded for concomitant HAs such as migraine. This can slow recruitment, because many cervicogenic HA patients also suffer migraines.⁸ A trial on mixed HAs may be valuable, because manipulation appears beneficial for both types of HA.¹² It is interesting to note that medication for migraines has not been successful in treating the cervicogenic component of a cervicogenic/migraine mix.²⁴

Few participants sought additional care outside the study for their HAs. This is encouraging for future studies because there was minimal potential confounding of study results by outside care. Participants were permitted to seek outside care for ethical reasons and because we wanted honest accounting of all treatment. Reporting of outside care could have been compromised by any injunction against it.

Additional lessons were learned about the order of activities at the 2 baseline visits. We started the study with potential participants attending an information session at the first baseline and the physical examination and first treatment at the second visit. For the second half of the study, persons received the screening examination at the first visit. The advantage of the first design is that money is saved on examinations for people who change their minds about joining the study and do not show up for the second visit. One disadvantage is that there may be insufficient time for examination and treatment on the same day. Patients attending satellite clinics run the risk of having to make multiple trips to campus for radiographs. In the second design, individuals are given time to think over participation for several days after they have all clinical information available. We found the second method more logistically viable for a clinical trial.

CONCLUSION

A large clinical trial on the relationship between cervicogenic HA outcomes and treatments from a chiropractor is feasible. Findings suggest the benefit of 9 to 12 visits over 3 weeks for the treatment of HA/neck pain and disability. A larger number of visits than 12 in 3 weeks may be required for maximum relief and durability of outcomes.

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