2009 WFC Award Winning Paper

Physical Examination and Self-Reported Pain Outcomes From a Randomized Trial on Chronic Cervicogenic Headache

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Abstract

Objective: Objective clinical measures for use as surrogate markers of cervicogenic headache (CGH) pain have not been established. In this analysis, we investigate relationships between objective physical examination (PE) measures with self-reported CGH outcomes.

Methods: This is an exploratory analysis of data generated by attention control PE from an open-label randomized clinical trial. Of 80 subjects, 40 were randomized to 8 treatments (spinal manipulative therapy or light massage control) and 8 PE over 8 weeks. The remaining subjects received no PE. Physical examination included motion palpation of the cervical and upper thoracic regions, active cervical range of motion (ROM) and associated pain, and algometric pain threshold evaluated over articular pillars. Self-reported outcomes included CGH and neck pain and disability, number of CGH headaches, and related disability days. Associations between PE and self-reported outcomes were evaluated using generalized linear models, adjusting for sociodemographic differences and study group.

Results: At baseline, number of CGH and disability days were strongly associated with cervical active ROM ($P <$ .001 to .037). Neck pain and disability were strongly associated with ROM-elicited pain ($P <$ .001 to .035) but not later in the study. After the final treatment, pain thresholds were strongly associated with week 12 neck pain and disability and CGH disability and disability days ($P \leq$ .001 to .048).

Conclusions: Cervical ROM was most associated with the baseline headache experience. However, 4 weeks after treatment, algometric pain thresholds were most associated. No one PE measure remained associated with the self-reported headache outcomes over time. (J Manipulative Physiol Ther 2010;33:338-348)

Key Indexing Terms: *Chiropractic; Headache Disorders; Cervicogenic Headache; Examination; Physical; Range of Motion; Articular*

Globally, the estimate of those with an active headache disorder is 46% of the adult population.[1] According to a recent study, headache is the most common pain condition causing loss of productive time in the US workforce, with an average loss of 3.5 h/wk.[2]

Cervicogenic headache (CGH) is a type of headache causally associated with cervical myofascial tender spots or cervical spine dysfunction.[3] The reported prevalence of CGH varies from 13.8% to 17.8% of the headache population in different epidemiological studies.[4-6]

Persons with headaches are frequent users of complementary and alternative medicine. Thirteen percent of those who reported headaches, in a survey published in 1998,[7] visited a complementary and alternative medicine practitioner for their condition within the last 12 months. Complementary and alternative medicine practitioner visitation, within the last 12 months, was 37.5% among those who reported neck problems.

Manual therapy of the spine for the treatment of CGH is practiced by chiropractors, osteopaths, physical therapists, and naturopaths. Spinal manipulative therapy (SMT) is here defined as controlled directional, high-velocity, low-amplitude thrust.[8] The primary objectives of SMT in the treatment of headache and neck pain is the alleviation of pain, muscle spasm, and functional impairment.[8-10]

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The scientific evidence on SMT for the relief of chronic headache has been well discussed in systematic reviews of randomized trials.[11-18] These reviews have primarily evaluated patient self-reported outcomes, such as pain intensity, headache index, frequency, duration, and improvement. Physical and functional measures commonly used by treating physicians have not been as systematically included in clinical trials.

The research presented here uses data gathered during attention control visits to serve 2 goals: first, to find observed differences in physical examination (PE) outcomes between low-dose groups, and second, to assess relationships between subjective patient-reported outcomes and objective PE measures. What can this tell us about CGH pathophysiology or about potential outcomes for use by the practicing physician or in future clinical trials? Observed relationships and the potential utilization of PE procedures as objective surrogate markers of the patient's headache experience in clinical practice and clinical trials will be discussed.

Methods

Design

This secondary analysis utilized data from an open-label prospective randomized controlled trial registered on ClinicalTrials.gov (NLM identifier NCT00246350). The trial is discussed in detail by Haas et al.[19] The study made a preliminary evaluation of the relative efficacy of SMT for the treatment of CGH; it also looked at the effect of SMT dose. The study was conducted in the Portland, Ore, area between September 2004 and July 2007. A total of 40 of 80 participants (n = 20 per group) were randomized to receive 8 treatments and 8 additional attention visits including a PE. The participants had 1 treatment visit and 1 examination visit weekly for 8 weeks. The remaining 40 patients received 16 treatments and no attention PEs after baseline and were thus excluded from this article. The 40 patients receiving 8 treatments and 8 attention control visits were randomized to 2 levels of care: SMT or a minimal light massage (LM) control to isolate the effect of SMT above the effect of touching the patient therapeutically.

Patients were randomized immediately preceding the first treatment using computer-generated, design-adaptive allocation,[20-22] a minimization technique to balance potential confounders across groups. This included the following variables: age, sex, migraine, baseline CGH pain intensity index, baseline number of CGH, relative confidence in SMT and massage, and difference in expected optimal number of visits for treatment with SMT and LM. Hence, study group allocation was concealed from all study personnel before randomization.

Data for the objective measures were collected at baseline and weekly for 8 weeks; subjective measures were collected at baseline and at 4, 8, 12, and 24 weeks after the first treatment by telephone interview and mailed questionnaire. Study guarantees of the participants' rights and safety were approved by Western States Chiropractic College Institutional Review Board (FWA 851), and data were secured in the College's Center for Outcomes Studies. All participants signed a consent form.

Participants

Volunteers were eligible if they had a history of at least 5 CGH per month for a minimum of 3 months, with CGH as defined by the International Headache Society (IHS) in 1998 (excluding the radiographic criterion)[23] and used in the trial by Nilsson.[24] The IHS criteria were (1) pain localized in the neck and occipital region, may 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. The newer IHS criteria[3] differ in that they include post hoc headache resolution unusable for study eligibility. To prevent a floor effect, participants were required to have a minimum score of 25 on the 100-point pain intensity scale described below.

A chiropractor/faculty member with 15 years experience screened potential participants for study eligibility through case history, standard orthopedic/neurological examination, heat sensitivity test, and 3-view cervical x-ray using the protocols of Vernon et al[12] and Souza[25] for CGH, and those of Gatterman and Panzer[10] for the cervical region.

Potential participants were excluded if they were taking prophylactic prescription medication for the treatment of headache or had manipulation/professional massage care for the neck or headache in the 3 months before baseline. Participants were ineligible for contraindications to spinal manipulation[10] or complicating conditions that may be related to clinical outcomes: malignancy or history of active cancer in the last 5 years, spinal infection, vertebral tumors or fracture, cervical instability, blood dyscrasia, anticoagulant therapy (warfarin/Coumadin or heparin), thrombophlebitis, long-term corticosteroid use, current use of prophylactic headache medication, severe head/neck trauma within the last 12 months, neck/intracranial surgery within the previous 5 years, radiating pain to the upper extremities or cervical disc condition, arthritis of the cervical spine, severe osteoporosis (suspected from x-ray), referred neck pain of organic origin, or pregnancy (x-ray prohibited).

Persons were also ineligible for other types of headache with etiologies that may confound the effects of manipulation on the cervicogenic component. These headache types[3] include cluster, metabolic/toxic, sinus, and headache associated with temporomandibular disease, tumors, and glaucoma.