

Manipulation for Chronic Neck Pain

A Double-Blind Controlled Study

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Twenty-one patients with symptomatic cervical spondylosis or nonspecific neck pain were given an amnesic dose of diazepam before manipulation of the cervical spine. Eighteen patients served as controls and also received diazepam but no manipulation. Results were obtained in a randomized, double-blind fashion. Statements of outcome by patients and mean visual analog scales for pain and activity showed no significant differences between manipulation and control groups, though both tests favored manipulation. Control subjects subsequently treated by manipulation showed no consistent favorable response. Questionnaires dealing with personality, life events, social and medical histories, etc., provided no correlations with outcome, nor did radiographic findings. Diffuse local tenderness correlated with high pain scores after treatment. The authors conclude that the value of a single manipulation of the cervical spine has not been established and that further exploration of indications is needed. The use of intravenous diazepam should be considered because it allows a double-blind experimental design. [Key words: neck pain, cervical spondylosis, spinal manipulation]

MANIPULATION OF THE cervical spine has been recommended for symptomatic treatment of cervical spondylosis and nonspecific neck pain.^{1,6,18} Our experience, and that of others,^{19,26} suggests that this treatment is rather commonly used, though rationales for its use are controversial and indications are based on theoretical neurobiologic mechanisms and clinical experience, rather than proof of efficacy.¹²

Several treatments, not including manipulation, for the common clinical syndrome of chronic neck pain have undergone controlled study, but none was found superior to placebo.² To our knowledge, there has been no previous report of a controlled study of manipulation for chronic neck pain, though manipulation for low-back pain failed to show benefit in controlled, prospective studies.^{7,10}

The need for further study is well recognized,¹¹ especially since serious neurologic complications have occurred following neck manipulations performed by chiropractors and laymen.^{8,19} The present report describes a controlled, double-blind approach to manipulation therapy of the cervical spine. Our purposes were to demonstrate any efficacy of manipulation for relief of pain and other symptoms and to identify any characteristics of our patients which might have prognostic value in this context. The relation of chronic pain states to personality, mood, and life events has been the subject of other reports.^{5,9,21,23}

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METHODS

Thirty-nine subjects were referred for consultation because of complaint of neck pain. Eighteen were randomly assigned to a control group and 21 to a manipulation group by the method described below. Clinical diagnoses were either (1) cervical spondylosis or (2) nonspecific neck pain, as described in standard texts.^{3,13,14,27} There were 13 men and 26 women, with a mean age of 49 years (range 19–68).

Criteria for admission to study included (1) pain of at least one month's duration, (2) no findings suggesting major systemic disease, (3) no progressive neurologic signs, and (4) no extraneous local cause of symptoms, eg, carpal tunnel syndrome or eye-ear-nose-throat lesions.

Mean duration of symptoms was six years (range one month to 30 years). Most patients described continuous or fluctuating pain. Only five acknowledged having had distinct episodes. Ten acknowledged recent trauma. Two patients reported a history suggesting an antecedent viral illness. Nineteen complained of central nervous system symptoms, eg, giddiness, blurred vision, etc. Thirty-seven complained of arm pain. Three reported associated legal or insurance issues. All patients reported that the pain interfered with daily activities: 28 reported sleep disturbances, 24 interference in household chores, and 22 interference with work. Eighteen (similar proportions of men and women) reported that the pain impaired their "ability to cope."

Minimum radiographic examination consisted of a lateral view of the cervical spine in flexion. Findings were graded by one observer, using the Arthritis and Rheumatism Council method,¹⁵ a scale of 0–4. The modal grade was 3 (14 subjects). Four subjects showed degenerative features at four or more levels. In eight patients, radiographic findings were normal. All had limited motion.

Emotional and situational factors were assessed with the Middlesex Hospital Questionnaire⁵ and a Social Readjustment Rating Scale,²¹ modified to 28 items and dealing with life changes of the preceding 12 months. These showed no statistically demonstrable difference between control and manipulation groups. Also comparable were age, sex, range of motion, radiographic grade, examination for tenderness (modified from Ritchie et al²²), tablet count, history of trauma, location of pain, and graphic self-assessments

Table 1. Sample Numerical Value Scale Used to Determine Indication for Second, Crossover Treatment

Pain: change since treatment	
0.	Completely well
1.	Much better
2.	Moderately better
3.	Slightly better
4.	No change
5.	Slightly worse
6.	Moderately worse
7.	Much worse
8.	Worst possible

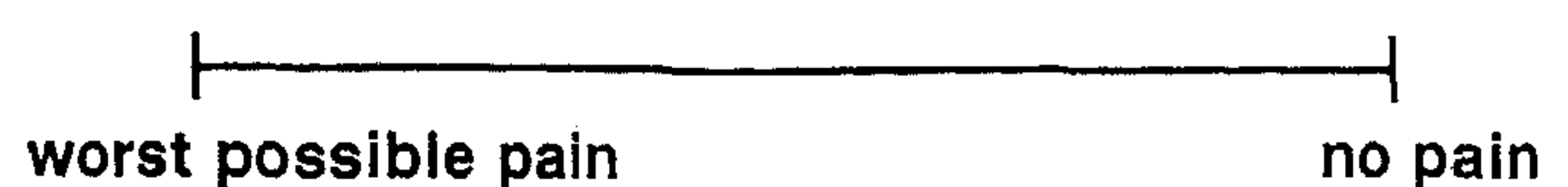


Fig 1. Sample visual analog scale for measuring response to the instructions, "Show the severity of your pain during the last seven days."

of symptoms and disability. Historical data were obtained by written questionnaire.

The baseline examination was performed by the outpatient physician, who described the study and referred patients to a day care center. In the day care center, a second physician, the therapist, confirmed the patients' informed consents, gave diazepam, 20 mg intravenously, and drew a randomized card assigning them to either a control or a manipulation group. Twenty-one subjects received manipulation. Eighteen controls received only diazepam. Both groups were observed in a like manner by the nursing staff until discharge. All manipulations were performed by one therapist, a rheumatologist, experienced in techniques described in major references^{6,16,17,18} and recognized by his colleagues as a consultant proficient in their use.

Follow-up examinations were performed by the outpatient physician three weeks later. The outpatient physician did not know which patients had received manipulation. The therapist-rheumatologist retained this information until the end of the study. In considering a second treatment, a nine-point numerical value scale (NVS) was used (Table 1). A patient was considered to have improved if he responded that the pain was "much better." He was also considered to have improved if he responded both pain and one activity, eg, sleep, were "moderately better." Visual analog scales (VAS) (Figure 1) for pain²⁴ and selected daily activities²⁵ were also obtained.

Patients who had not improved at the three-week examination returned for a second ("crossover") treatment. Neck manipulation was performed on patients who had not received this on the previous visit. Others received only diazepam. Examination was repeated three weeks after the second treatment and at 12 weeks for all patients. Other medical management was not restricted during the study.

RESULTS

None of the methods employed to demonstrate a therapeutic effect of manipulation showed a statistically significant difference between treatment and control groups at three or 12 weeks.

The simplest test of outcome was to ask the patient, "did the treatment help you?" At three weeks, 12 of 21 (57%) patients receiving manipulation responded affirmatively, compared with five of 18 (28%) controls ($\chi^2 = 2.31$, $P = 0.13$). The ten control patients who did not improve on NVS were then treated with manipulation, while maintaining the double-blind design. All of these patients remained unimproved on NVS three weeks later.

The crossover results at three weeks were obtained at the price of considerable difficulty in interpreting later data. At 12 weeks, only 15 patients remained having had only one treatment. While statistically not significant, they suggest a favorable longer-term result among the manipulation group as follows: two of six control-group vs. seven of nine manipulation-group patients affirmed on standard questionnaire that the treatment had helped ($\chi^2 = 1.86, P = 0.17$).

Both control and manipulation groups showed improvement in mean VAS at three weeks: 5 mm (± 32 mm) and 18 mm (± 31 mm), respectively. The results are given as means (with standard deviations) of the improvement in a 100-mm VAS and are not significantly different ($T_{30} = 1.30, P = 0.20$). A sample VAS is shown in Table 1 as it was presented to the subjects.

A number of other items showed no correlation with improvement in pain in any group. These included ranges of motion and VAS relating to activities (sleep, work, etc.). Data were analysed to identify any features which might have prognostic utility for patients presenting with neck pain.

The Middlesex Hospital Questionnaire showed normal means for the study population on all scales (anxiety, phobia, obsession, somatization, depression, and hysteria). A modified Social Readjustment Rating Scale of 35 neck-pain patients was not significantly different from the mean of 20 patients with rheumatoid arthritis, though markedly higher than the mean of 11 patients admitted for elective cholecystectomy. The mean ages of the three groups were 48, 53, and 51 years, respectively.

Neither the Middlesex Hospital Questionnaire nor the Social Readjustment Rating Scale distinguished the 22 patients whose VAS had improved at three weeks from the 17 whose VAS had not. Nor did age, sex, history of trauma, tablet count, presence of arm pain, radiographic grade, or central nervous system symptoms correlate with outcome in any group. Multiple regression analysis showed only one item associated with prognosis: local tenderness on initial examination was associated ($P = 0.013$) with a high score on VAS for pain at three weeks. This finding did not correlate with initially higher pain scores.

As tests of efficacy of the double-blind design, 37 patients were asked (1) to identify which treatment was used and (2) if they remembered having their necks manipulated. Six claimed to remember a manipulation, when in fact five of these had received none. The one subject who answered correctly reported marked improvement. Untoward effects occurred in four patients. Two had superficial phlebitis following diazepam injection and recovered uneventfully. Two patients reported a new discomfort in their necks, followed by improvement in their chronic neck pain. Both had had manipulations.

DISCUSSION

A larger proportion of manipulation-group patients than control-group patients improved. However, this difference was not statistically significant, and subsequent manipulation of ten unimproved control patients was not associated with improvement in any of them.

This small and relatively heterogeneous sample did not reveal any subpopulation of neck-pain sufferers peculiarly responsive to manipulation. A significant therapeutic effect of manipulation was not demonstrable in the study group as a whole. With one exception, favorable or unfavorable outcome did not correlate with any positive findings in the patients' histories or examinations. This single correlation occurred between the finding of local tenderness and the outcome of continued pain.

The questionnaires used to assess personality and situational factors provided no insight into the cause or the prevention of chronic neck pain. More conventional kinds of historical items were not helpful.

An acknowledged difficulty with our experimental design, as in the others we reviewed, is the lack of standardization of the technique of manipulation. The accumulation of controlled data of the results of other practitioners of manipulation might circumvent this difficulty. The diazepam-induced amnesia allows a double-blind design, an advance that now can be used by other investigators for further testing of the hypothesis that manipulation of the spine has therapeutic value.

With the important exception of the double-blind design, some features of the present study resemble those in a recent report of cervical manipulation in migraine.²⁰ The migraine patients, when they were receiving manipulations by chiropractors, showed improved VAS for intensity of pain but not frequency of attacks. Two comparison groups of migraine patients, having had manipulations by nonchiropractors, improved significantly less. The authors discussed the likelihood that this isolated positive finding represented a placebo effect relating to the relative "enthusiasm" of different groups of therapists.

We considered the "enthusiasm" factor in our own setting. A nine-point NVS was completed by 24 of 27 consecutive patients who had received both medical management and neck manipulations by our therapist-rheumatologist three to six months beforehand. Eight (33%) responded that they were "much better," compared with ten of 33 (30%) in our prospective double-blind series at three months. Both of these figures are lower than our clinical impressions had led us to expect; they are also lower than the literature on the natural history of this condition predicts.² Among the many possible explanations of these data is our impression that we have studied a particularly refractory

population of neck-pain sufferers. This in turn might help to explain our unexpectedly negative results.

Meanwhile, personal experiences of many patients and therapists, like our impressions prior to this study, give them confidence in manipulation as a means of relieving pain, and the intriguing speculations¹² about vertebral manipulation continue.

This study of 21 patients, treated with a single intravenous injection of diazepam and a single cervical manipulation, showed no greater improvement in signs or symptoms than a control group given only diazepam. Thirty percent of chronic-neck-pain patients were symptomatically improved three months after manipulation, comparing unfavorably with results expected from less aggressive measures. Marked nuchal tenderness on presentation is a sign that pain will persist. Numerous other physical findings, symptoms, and various psychologic, historical, and radiographic features appear to have no predictive value. The use of intravenous diazepam is helpful in the study of vertebral manipulation because its amnesic effect allows a double-blind study design. Further investigation may reveal clinical features that will allow selective use of vertebral manipulation and minimization of its risks.

We conclude on the basis of our own experience and review of the literature that the value of a single manipulation of the cervical spine has not been established. Further refinements in the selection of patients and documentation of results are still needed to establish the role of manipulation of the spine for relief of pain. The double-blind method described in this report may be helpful toward this end.

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