Spinal Manipulation for Low Back Pain

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• **A randomized clinical trial of rotational manipulation was conducted on 95 patients with low back pain selected for (1) the absence of any contraindications for vertebral manipulation, (2) the absence of any psychosocial problems that might affect the outcome of treatment, (3) the absence of any previous experience with manipulative therapy, and (4) the presence of palpatory cues indicating that manipulation might be successful. Patients were randomly assigned to one of two groups: an experimental group receiving manipulation therapy and a control group receiving soft-tissue massage. Comparison of the two groups indicated that (1) patients who received manipulative treatment were much more likely to report immediate relief after the first treatment, and (2) at discharge, there was no significant difference between the two groups because both showed substantial improvement.**

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ALTHOUGH back pain is not a life-threatening disorder, it is a pervasive one. Approximately 80% of adults will suffer from back pain at some point in their lives, and it is the most expensive ailment in the 30- to 60-year age group.[1] Spinal manipulation is among the oldest therapies for back pain, and it has numerous modern proponents,[2-4] but there has been a conspicuous absence of experimental evidence favoring this form of treatment.

The first major controlled clinical trial to be reported in the medical literature was conducted by Glover et al[5] on a population of British factory workers. A single rotational manipulation of the trunk produced significantly more subjective improvement than a placebo treatment (simulated diathermy), but only in a group of patients suffering from their first attack, which was of less than seven days' duration. Another early trial reported by Doran and Newell[6] compared manipulation, physiotherapy, corset, and analgesic treatments and found no differences in outcome.

Three more recent controlled studies have all reported spinal manipulation to be useful in the treatment of low back pain.[7-9] However, all of the studies that have shown positive effects may be criticized on the ground that they have not employed an adequate control for placebo effects. Evans et al[7] compared manipulation plus analgesics to analgesics alone, while others have utilized some form of diathermy as a control treatment.[5,8,9] Since manipulation involves considerable manual interaction between patient and physician, any therapeutic effect that is observed may easily be attributed to nothing more than a powerful placebo effect associated with "laying-on-of-hands." Prescriptions for analgesics or diathermy clearly are inadequate control procedures for a study on manual medicine. The trial reported by Doran and Newell[6] is not vulnerable to this criticism because manipulation was not found to be superior to the other treatments employed, but that study has been criticized on other grounds. For example, it has been claimed that the diagnostic criteria were insufficient to select those patients for whom manipulation was an appropriate treatment.[10,11]

The present clinical trial differs from previous studies of manipulation in that (1) a "placebo" manual treatment was employed, and (2) subjects were carefully selected from the patient population by a trained manipulator. Data presented in a previous report on this project[12] indicate that (1) patients with no knowledge of spinal manipulation probably cannot distinguish that therapy from soft-tissue massage, and (2) trained manipulators can, to some extent, select the patients most likely to benefit from manipulation.

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PATIENTS AND METHODS

Subjects for the study were selected from a group of 1,880 patients referred to the University of California, Irvine, Medical Center Back Clinic between June 1973 and June 1979. Of this group, 1,071 (57%) received some type of manipulative treatment in the clinic, while the remainder were referred elsewhere, either because manipulation was contraindicated or because alternative treatment was strongly indicated (eg, osteoporosis, bone infections, metabolic bone disease, fractures, carcinoma, ankylosing spondylitis, herniated nucleus pulposus, occlusive vertebral artery disease, etc). Pregnancy was also grounds for exclusion because radiography was contraindicated. Of the treated patients, 95 (5%) were selected for the study. Reasons for exclusion were previous experience with manipulation, disability income, pending litigation, previous back surgery, obesity, drug or alcohol abuse, and pain not treatable by manipulation of the lumbosacral area. The major indication for admission to the study was the presence of palpatory cues indicating hyperalgesia or a restricted or painful range of vertebral motion. This decision was made by the examining physician.

After being admitted to the trial and signing an informed consent statement approved by the institution's Human Subject's Review Committee, each patient was randomly assigned to either the experimental or the control group. Patients in the experimental group received rotational manipulations of the lumbosacral spine. In this maneuver, the patient lies on his or her side on a table facing the manipulator. The inferior leg is extended and the superior leg is flexed, tilting the superior aspect of the pelvis toward the manipulator. The superior shoulder is rotated away from the manipulator and the spine is "locked" in extension. A short, high-velocity thrust is then applied to the pelvis. This presumably has the effect of gapping the facet joints and stretching the paravertebral muscles of the lumbosacral area. This procedure has been described in more detail elsewhere.[3] When performed by qualified practitioners, lumbosacral manipulation is quite safe, although there have been occasional reports of injury produced by this form of treatment.[13] Patients assigned to the control group received only soft-tissue massage of the lumbosacral areas, with the rotational thrust omitted. The number of treatments received was variable, at the discretion of the treating physicians. On discharge, each patient was reexamined by the same physician who had performed the initial examination. This physician was not told which type of treatment the patient had received.

Most of the collected data were subjective, consisting of questionnaires filled out by the patients. Patients also filled out the Mini-Mult[14]—a short form of the Minnesota Multiphasic Personality Inventory. Objective measures used were straight-leg raising to pain, straight-leg raising to pelvic rotation as described by Fisk,[15] and distance of the fingertips from the floor on maximum forward flexion as used by Doran and Newell.[6]

Because most of the data were only measurable on an ordinal scale or were not normally distributed, nonparametric statistics were used. Unless otherwise indicated, all determinations of statistical significance were based on the Mann-Whitney *U* test, which is suitable for ranked data and makes none of the assumptions required for the use of parametric statistics.[16] Correlations were measured by the nonparametric Spearman rank-order correlation coefficient.[16] The criterion for statistical significance was a *P* value less than .05 for a one-tailed test.

Table 1.—Pretreatment Patient Characteristics and Length of Treatment*

	Manipulated	Control	Significance
No. of patients	56	39	. . .
% male	59	59	. . .
Age, yr†	30.1±8.4	32.1±9.8	NS
Pain patients reported, %			
Acute pain (<1 mo)	52	48	NS
Chronic pain (>6 mo)	17	29	NS
Moderate to very severe‡	79	74	NS
Severe to very severe‡	37	16	NS
Physician reporting, %			
Impaired gait	42	29	NS
Abnormal lumbar curvature	20	31	NS
No. of treatments†	4.8±2.7	3.9±2.5	$P<.05$
Duration of treatments, days†	30.0±27.7	19.6±20.4	$P<.05$

*Since some patients did not answer every question, the number of subjects may be lower for some comparisons.
†Mean±SD.
‡Scale of 1 to 5 where 1 is none; 2, slight; 3, moderate; 4, severe; and 5, very severe.

Table 2.—Short-term Effects of Manipulation*

First Manipulative Treatment	Manipulated	Control	Significance
No. of patients	56	39	. . .
Patients reporting improvement in, %			
Walking	66	55	NS
Bending or twisting	48	29	NS
Sitting down in a chair	66	37	$P<.01$
Sitting up in bed	63	34	$P<.01$
Reaching	51	22	$P<.01$
Dressing	43	19	$P<.01$
Amount of pain	84	68	$P<.05$
Improvement in straight-leg raising, degrees			
To pelvic rotation†	1.6±6.3	1.0±6.3	NS
To pain†	3.3±6.2	−.05±5.9	$P<.01$

*Since some patients did not answer every question, the number of subjects may be lower for some comparisons.
†Mean±SD. The *t* test was used to determine statistical significance.

RESULTS

Pretreatment comparisons, some of which are given in Table 1, indicate that, although there was a substantial difference in the number of subjects assigned to the two groups, the group receiving manipulative treatment was not significantly different from the control group on any of the pretreatment measures. In addition to the measures given in Table 1, these included origin of pain, rapidity of pain onset, the extent of pain on lateral bending, straight-leg raising to pain, straight-leg raising to pelvic rotation, and forward flexion. However, the group receiving manipulation did appear to have a somewhat higher proportion of patients reporting pain as "severe" or "very severe," as well as a somewhat lower proportion of patients with "chronic" pain, unimpaired gait, and abnormal spinal curvature. Although none of these differences reached statistical significance, they are potentially important as possible confounding variables. For example, regression toward the mean might tend to produce more

Table 3.—Long-term Effects of Manipulation*

	Manipulated	Control	Significance
Discharge Assessment			
No. of patients	41	28	. . .
Patients reporting, %			
Moderate to very severe pain	17	29	NS
Treatment was effective	88	86	NS
Physician reporting, %			
Impaired gait	5	0	NS
Palpatory signs	50	57	NS
Improvement in straight-leg raising, degrees			
To pelvic rotation†	8.0±9.3	4.1±8.6	NS
To pain†	7.8±7.4	8.6±8.4	NS
Improvement in forward flexion, cm†	11.4±15.9	10.7±14.2	NS
Assessment 3 Wk After Discharge			
No. of patients	33	25	. . .
Patients reporting, %			
Moderate to very severe pain	21	48	NS
Treatment was effective	88	68	$P<.05$
Treatment was manipulation	66	56	NS

*Since some patients did not answer every question, the number of subjects may be lower for some comparisons.

†Mean±SD. The *t* test was used to determine statistical significance.

improvement in patients with higher initial levels of pain, and it is generally believed that chronic cases of back pain yield a less favorable response to treatment.[2-4] Therefore, we directly examined the effects of these entry variables on the relevant outcomes. Patients who received manipulative therapy also tended to receive a significantly greater duration and number of treatments. This effect is difficult to interpret and presents problems for any analysis of postdischarge data.

Immediate effects of the first manipulative treatment are given in Table 2. The group receiving manipulation showed more improvement than the control group on four of the six subjective measures of spinal flexibility. The group receiving manipulative therapy also reported significantly more relief from pain. However, as given in Table 3, data on the relatively long-term effects of manipulation (at discharge and three weeks after discharge) are questionable. Apart from differences in the perceived effectiveness of treatment, manipulation did not appear to be significantly better than soft-tissue massage over the longer period of time. However, it should be noted that the two groups are similar because both have shown substantial improvement. Also, the two groups did not differ in the percentage of patients who felt they had received manipulation rather than massage. This suggests that the study succeeded in one of its primary objectives: to compare manipulation to an appropriate placebo treatment.

Objective measures of the effects of manipulation tended to parallel the subjective measures reported previously. Manipulative treatment produced greater increments in straight-leg raising, but this effect was statistically significant ($P<.01$) only on straight-leg raising to pain after the first treatment. This is somewhat different from the results presented in a preliminary report of these data,[17] which suggested a significant ($P<.01$) effect only on straight-leg raising to pelvic rotation. By the time of the discharge assessment, the patients who underwent manipulation were superior to the control patients only on straight-leg raising to pelvic rotation, but this effect was not statistically significant ($P>.05$), probably because of the reduced number of patients represented in that comparison. In agreement with Doran and Newell,[6] there was no difference between patients who received manipulation and control patients on distance from fingertips to floor on maximal forward flexion.

To investigate possible prognostic factors, correlations between all reported entry variables (Table 1) and all significant outcome variables were examined. Of 320 correlation coefficients, only 19 (6%) were statistically significant at the .05 level. This is little better than one would expect on the basis of chance alone.

Because of the possible confounding effects of the initial pain level and duration of pain, correlations between these variables and significant outcome variables are particularly important. The initial level of pain was not significantly correlated with any outcome variable in either the group receiving manipulation or the control group. In the group undergoing manipulative therapy, duration of pain was significantly ($P<.05$) correlated with the number and duration of treatments ($r_s=.34$ and .27, respectively), but no other significant correlations were found. In the control group, duration of pain was significantly (P values <.05) correlated with less improvement in "reaching" ($r_s=.37$) and with lower estimates of the effectiveness of treatment ($r_s=.47$), indicating that the tendency to report relief after a placebo treatment is greater in acute cases than in chronic ones. However, the exclusion of chronic cases (pain duration greater than six months) did not greatly affect the outcome variables. Differences between patients who received manipulative therapy and control patients in "reaching," "sitting down," "sitting up," "pain," and straight-leg raising to pain remained significant (P values <.05) despite the reduced number of subjects.

COMMENT

These data clearly show that spinal manipulation provides immediate subjective alleviation of low back pain. The amount of relief produced by manipulation is significantly (P values <.05) greater than the amount of relief produced by a placebo treatment consisting of soft-tissue massage of the affected areas. Because the study patients had no previous experience with manipulation and because these patients could not distinguish the experimental from the control treatments (see Table 3), we conclude that soft-tissue massage is an adequate control for the placebo effects of manipulation therapy.

In any clinical trial, three levels of "blinding" are possible: (1) the evaluating clinician may not know what treatment was received, (2) the patient may not know what treatment was received, and (3) the treating clinician may not know what treatment was received. Clinical

trials that achieve all three levels of blinding are widely referred to as "double-blind," and by this definition, double-blind trials of manipulation are impossible since the last condition cannot be met in any clinical trial involving manual interaction between the patient and the clinician. However, as the data reported herein suggest, it is possible to achieve the first two levels of blinding in a clinical trial of rotational manipulation. The physician who administers treatment may communicate enthusiasm (or lack of enthusiasm, if a control treatment is being administered) to the patient. However, the soft-tissue massage treatment provides control patients with a level of manual interaction that has not been provided in previous clinical trials of manipulation.[5-9]

The long-term effectiveness of manipulation is more difficult to assess, primarily because, given sufficient time, many patients with back pain will recover. Thus, in agreement with Sims-Williams et al,[9] we must conclude that, although manipulation may facilitate recovery, there is no evidence demonstrating that it affects the long-term prognosis.

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Malaria in the Tropics

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[p 1416]

Since 1898 I have served almost continuously in the tropics—four years in Cuba and two years at Panama—part of the time with troops, but most of this time being connected with municipal sanitation.

At Santiago, Cuba, I was with the army at the Base Hospital at Siboney, where all the seriously sick were sent during the entire campaign against Santiago until the army returned home.

In Havana I had charge of the yellow-fever wards at Las Animas Hospital. Las Animas was the hospital for contagious disease for the Sanitary Department of Havana, and, while a large majority of the patients treated by me there had yellow fever, a considerable number of malarial cases were also received, being mistaken for yellow fever.

Here at Panama I am in charge of the yellow-fever ward. All non-immunes with fever from any cause coming into Ancon Hospital are sent to these wards, and much the larger proportion of these cases are malaria. We treat something like two hundred cases of malaria each month in these wards.

I give here my experience in some detail so as to indicate what my opportunities for observing malaria in the tropics have been. This experience has impressed on me the fact that malaria in the tropics is by far the most important disease to which tropical populations are subject, either military or civil. While the percentage of fatalities is not nearly so great as from some other tropical disease, the amount of incapacity caused by malaria is very much greater than that due to all other disease combined. I was very much impressed with this at Santiago. While we had more deaths from yellow fever and typhoid fever than from malaria, the latter was the disease that prostrated our splendid little army. About the beginning of August there were very few individuals that were not suffering from fever, and the army, as a whole, was scarcely able to move. The mental depression caused by this general sickness can hardly be appreciated by any one who did not see it, and against a fresh enemy of greatly inferior strength our army at that time would have been entirely helpless. This campaign was a good illustration of what might occur to an army operating in the tropics and subjected to unchecked malaria. I have not at hand the statistics to which I can refer concerning the mortality from malaria during this campaign, but my recollection is that it was not very fatal. I recollect very few cases of pernicious malaria or black-water fever.