A Benefit of Spinal Manipulation as Adjunctive Therapy for Acute Low-Back Pain: A Stratified Controlled Trial

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Fifty-four subjects volunteered to participate in a controlled study contrasting spinal manipulation with spinal mobilization without the rotational forces and leverage required to move facet joints. All suffered from regional low-back pain for less than 1 month, were ages 18–40, had never previously undergone any form of spinal manipulation, and denied a prior episode of backache within the previous 6 months. Randomization was stratified at outset into those who suffered for less than 2 weeks and those whose discomfort had persisted for 2–4 weeks. Outcome was monitored by a questionnaire assessing functional impairment. A treatment effect of manipulation was demonstrated only in the strata with more prolonged illness at entry. In the first week following manipulation, these patients improved to a greater degree ($P = .009$, t test) and more rapidly ($P < .025$, Wilcoxon rank-sum test). [Key words: spinal manipulation, prospective randomized trial, acute low-back pain]

SPINAL MANIPULATION as a therapeutic maneuver can be traced to antiquity.[27] The imprint of this tradition can be discerned readily in Europe in the practice of general medicine,[6] orthopaedics,[3] and physiatry.[21] This is not to say that spinal manipulation is generally accepted in Europe; rather, its practice does not engender the polemics and polarization so common in this country. The development of osteopathy and the chiropractic, both in the United States near the turn of the century, fostered the practice of spinal manipulation but served to separate the practitioners from others who cared for patients with musculoskeletal illness.

The indications for and the techniques of spinal manipulation are not uniform between or within these clinical disciplines. For the purposes of discussion and of the study reported herein, spinal manipulation will designate the common practice of using a "manipulative thrust," the application of a high velocity arc with a short or long lever arm producing a torque that induces passive movement of one or more lumbar vertebral articulating surfaces.[12,21] The current study was designed to determine whether an important palliative maneuver has been relegated to the fringe of common medical practice or, to the contrary, whether many sufferers of acute uncomplicated low-back pain are being subjected to a worthless and costly intervention. The indication for spinal manipulation in this study was acute, uncomplicated, low-back pain in a patient between the age of 18 and 40.

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MATERIALS AND METHODS

Patients

Recruitment of subjects involved soliciting the cooperation of primary physicians in the local community and advertising in local newspapers. The latter proved more fruitful. Subjects were asked to volunteer without monetary or other compensation and with the understanding that all continuing care and undertaking of laboratory or radiographic studies would revert to their primary physician. The protocol was approved by our institutional Committee on the Protection of the Rights of Human Subjects and the subjects' consent was based on extensive verbal and written information.

Potential volunteers contacted the research secretary and were screened by telephone interview. There were six criteria for initial entry into the protocol: 1) age between 18 and 40, either sex; 2) subjects must be suffering from low-back pain for no more than 1 month; 3) subjects must have endured no other episode of back pain within the last 6 months; 4) neither workers' compensation nor disability insurance should be at issued and the acute low-back pain must not be considered work related; 5) subjects must never have undergone spinal manipulation previously; 6) subjects must be willing to travel to the Family Practice Center of the North Carolina Memorial Hospital and, if they chose to participate and were not eliminated on clinical criteria (*vide infra*), be available for repeated follow-up telephone interviews over the subsequent 2 weeks.

Over the course of two years, 57 subjects were so identified. All were entered into the next phase of the protocol within 4 days of initial telephone contact. Of these, two were considered ineligible because of clinical features suggesting inflammatory spondyloarthropathy and referred to their physicians. Another proved inaccessible to follow-up and was dropped from the analysis. Therefore, 54 subjects participated in this study with full compliance with follow-up.

The Experimental Protocol

At the appointed time volunteers were met in the Center by the research secretary. The very explicit informed consent form was read, reviewed, and discussed. It was made clear that there was no "placebo" arm to the protocol; two different interventions were to be compared, both of which are considered by their advocates to be effective. A questionnaire was administered. This instrument was developed and validated as a reliable and sensitive measure of disability in low-back pain by Roland and Morris.[24,25] The Roland–Morris instrument was constructed by choosing those items from the lengthy Sickness Impact Profile that seemed most relevant to

low-back pain. The Sickness Impact Profile itself has been successfully used to assess and follow patients with low-back pain.[4] The Roland–Morris modification is a series of 24 questions probing the impact of the backache on the physical functioning of the subject. The responses are scored 0 for a negative response, 0.5 if the response indicates intermittency and 1.0 for a positive response; a score of 24 is the extreme of illness on this instrument.

After verbal administration of the questionnnaire by the research secretary, the subjects were evaluated by one of the authors (NMH), a rheumatologist with a special interest in the conservative management of low-back pain whose approach does not include any form of spinal manipulation.[14] The protocol and consent form were reviewed and signed by the subject. The patients were subjected to a thorough history and physical examination. They were eliminated and referred to their primary physician if a strong suspicion of inflammatory disease was raised or if overt weakness or suggestions of cauda equina syndrome were apparent. In fact, no volunteer had demonstrable weakness, and few had reflex asymmetry although many had symptoms and some had signs of radiculopathy. The clinical evaluation included an appropriately reassuring discussion of the natural history and detailed advice as to conservative management including biomechanical considerations and the use of mild analgesics.[14] Subjects meeting the criteria for entry had no indications for laboratory or radiologic evaluations.[14]

Next the subjects met with the co-investigator (PC) experienced in the manipulative management of low-back pain. By training[3] and proclivity, this physician often uses physical modalities including spinal manipulation in his practice. However, in this protocol, he served as the experimental instrument rather than the ministering physician. He was assigned by random allocation the task of performing spinal "manipulation" or "mobilization" without a manipulative thrust on each volunteer.[12,13]

For mobilization without a manipulative thrust, the subject was positioned first on the right and then on the left side. In each position the operator stood facing the subject and firmly grasped both knees with one arm while pressing down on the subject's lower spine with the opposite hand. The subject's legs were then gently but firmly flexed on the hips twice. This functioned as a mobilization technique without the rotational forces and leverage required to move facet joints. For manipulation the subject was positioned first on the right side and then on the left side. The subject was then positioned in a spinal rotation position with shoulders and face to the ceiling, and pelvis rotated down toward the examining table. A long lever, high-velocity thrust was then applied to the lower spine while stabilizing the thorax. This maneuver, with positional variations, is one used by osteopathic physicians and chiropractors to manipulate facet and sacroiliac joints.

Interaction with the subject by coinvestigator PC was limited to a cursory focused examination and that necessary to perform these alternative maneuvers. The patient, the research secretary and the rheumatologist were all unaware of which alternative was assigned and remained totally unaware until the completion of data analysis. From the outset, randomization took into account the establishment of two strata: subjects whose backache had been present for less than 2 weeks and those who had suffered for 2–4 weeks.

Immediately after the maneuver, the subject was asked by the secretary to denote presence or absence of benefit by marking a horizontal analog scale. The subject was then contacted by telephone every 3 days (with a day's leeway) by the research secretary and the Roland–Morris questionnaire was administered at each contact.

RESULTS

Descriptive statistics for the study populations are presented in Table 1. No treatment group differences regarding patient characteristics can be detected. Table 2 is the distribution of responses o the scale presented to each subject immediately following the experimental maneuver. Clearly, the procedures were well tolerated and palliative, but there was no difference in benefit perceived between the two treatment modalities.

Table 1. Descriptive Statistics for the Study Population

	Treatment group	
	Mobilization (No.)	*Manipulation (No.)*
Number of patients	28	26
Sex		
Male	13	18
Female	15	8
Age		
20–29 years	10	14
30–40 years	18	12
Stratum		
≤2 weeks of symptoms	13	13
2–4 weeks of symptoms	15	13

Table 2. Distribution of Subjects by Response to "How Does Your Back Feel Now?" after Initial Treatment at Baseline Visit

Response	*Mobilization (No.)*	*Manipulation (No.)*
Much worse	0	0
Somewhat worse	0	0
Little worse	1	0
No different	5	4
Little better	7	11
Somewhat better	11	6
Much better	4	5

The populations subjected to alternative treatments did not differ in questionnaire score at entry (mobilization: mean 11.4, SE 0.93; manipulation: mean 10.6, SE 1.01). The vast majority of the subjects in both treatment groups improved dramatically over the 2-week course of follow-up. The average patient subjected to manipulation achieved a 50% reduction in score at the second questionnaire and an 80% reduction by the third. Neither by raw score nor by percent reduction in score did the two treatment populations differ at any follow-up point.

However, in the initial design of this study, randomization accommodated two strata: patients who suffered less than 2 weeks and those whose backache had been present for 2–4 weeks. The scores for all strata were indistinguishable at entry. Furthermore, the scores for the subjects suffering for 2 or fewer weeks were indistinguishable between treatment modalities at each follow-up point (Figure 1, upper frame). In contradistinction, patients who suffered for 2–4 weeks and who were treated with mobilization lagged behind those treated with manipulation in their rate of improvement (Figure 1, lower frame). The difference between mobilization and manipulation was most striking midway through the first week of follow-up, at the time of the first follow-up questionnaire (mobilization: mean 9.1, SE 1.37; manipulation: mean 3.9, SE 1.19; $P = .009$ for t test). Stated differently, the subjects in this stratum who underwent manipulation achieved a 50% reduction in score more rapidly than those who underwent mobilization ($P < .025$ by the exact method for the Wilcoxon rank-sum test). A multivariate analysis of variance supports this statistically significant treatment group difference as it provides a significant time × treatment × stratum interaction ($P = .040$). This significant interaction is caused by the manipulation advantage over mobilization at 3 days for the stratum with 2–4 weeks of illness.

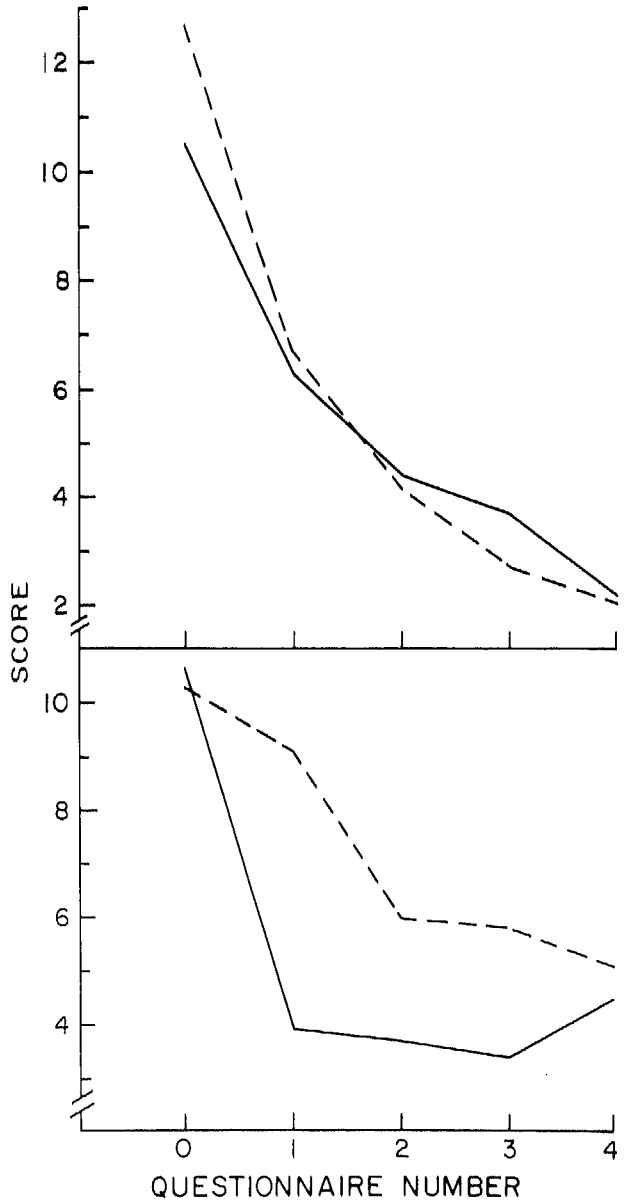

Fig 1. These plots are the mean score on the Roland–Morris instrument at entry (Questionnaire 0) and at the time of telephone follow-up every 3 (±1) days following treatment. Therefore, the fourth questionnaire was completed within 2 weeks of treatment. The broken lines represent the results for subjects treated by mobilization; the solid lines, spinal manipulation. All four groups were indistinguishable at entry and at 2 weeks. The top frame presents the results for the stratum wherein all subjects had suffered backache for less than 2 weeks at the time of entry into the protocol. The bottom frame represents the stratum for subjects that had suffered for 2–4 weeks. No treatment effect could be discerned for the more acute stratum. However, a treatment effect is apparent in the stratum illustrated in the lower frame. The mean scores for Questionnaire 1 differ ($P = .009$ for t test). To perform these calculations, equality of variances was assessed using F test. If F test was not significant at the .05 level, the equal variances t test was used to compare treatment groups; otherwise the approximate t test for unequal variances was used. The significance of this difference in mean score at Questionnaire 1 for those in the stratum that suffered for 2–4 weeks at entry was corroborated by examining the rate of improvement for the two treatment groups. Those who underwent manipulation achieved a 50% reduction in score more rapidly than those who underwent mobilization ($P < .025$ by the Wilcoxon rank-sum test.)

DISCUSSION

This is not the first attempt at a randomized controlled trial of spinal manipulation. Table 3 lists the salient features of a number of notable attempts. On several occasions, investigators noted immediate improvement in discomfort but in no prior study was benefit demonstrable beyond the hour of manipulation. In view of these data, why have clinicians persisted in practicing spinal manipulation and why does there appear to be no dearth of willing patients? The answer is that not only do these data run counter to their convictions, but also all of these studies are flawed and readily subjected to serious, if not telling, criticism:

1. Generally the manipulative technique is poorly described and no attempt is made to assure some uniformity of application even among multiple manipulators in a given trial.

2. Criteria for entry are either poorly defined or intentionally broad. This fact, coupled with the multicenter design of many of the trials, is responsible for the considerable heterogeneity of the populations studied. It is unreasonable to expect similar forms of outcome in groups as diverse as injured workers and ill housewives.

3. Outcome measures vary considerably between the trials, are generally contrived *a priori*, and seldom is their reliability, let alone validity, tested. This may be the most serious flaw in all these studies. For example, return to full function may be a less valid measure of palliation in an injured worker where job satisfaction may be more limiting than the back pain itself.[20] How can one assert lack of discernible benefit if the measures of benefit are inadequate?

4. Many of these trials suffer from errors in data acquisition and/or analysis[11] and most from Type II error.

5. Most clinicians are dubious about the validity of control maneuvers that do not take into account the intimacy involved in spinal manipulation. Furthermore, a fair trial of spinal manipulation demands that the maneuver be incorporated into a more general program of management.[22]

The current trial was designed with all these considerations in mind. We chose to study a young population least confounded by chronicity, comorbidities, or issues in disability or compensation insurance. It is also a population without precedent for complications of manipulation of the lumbar spine. The clinical interaction with the subjects was standardized and comprehensive. Irrespective of the independent treatment variable, the interaction was palliative (Table 2). The treatment, manipulation or mobilization, was administered by a single experienced practitioner in a standardized format that is familiar to all practitioners of spinal manipulation and acceptable to most. The evaluation of effect used a straightforward, sensitive, reliable, and valid instrument. Although our sample size ($N = 54$) was modest, we went to great lengths to avoid bias and confounders.

The natural history of backache in the population of patients thus selected is remarkably benign; it is generally asserted that 80% will be well within 2 weeks[14] as was our experience (Figure 1). In fact, it is likely that many of our volunteers would not have sought any professional assistance were it not for our recruitment.[15,16] The study design was to test, in two strata based on duration of backache, whether one of the maneuvers would discernibly hasten return to function and health. The sole difference detected was not only statistically significant but also clinically meaningful. Those subjects who had suffered a backache for 2–4 weeks prior to entry were afforded more rapid improvement if they were subjected to spinal manipulation. In view of the extraordinary prevalence of low-back pain and its pervasive impact in so many social spheres,[17] the ability to abrogate an episode of backache, even by a few days, has major ramifications.

As encouraging as we find this result, we feel compelled to offer strong caution. We have no confidence that this benefit will generalize to other populations. We have no confidence that any other form or frequency of manipulation can substitute for that used

Table 3. Randomized Controlled Trials of Spinal Manipulation or Mobilization for Low-back Pain

Experimental treatment (No)	*Control treatment (No)*	*Reference*
Manipulation (41)	Detuned diathermy (43)	9
Manipulation (116)	Corset (109) Analgesics (113) Physiotherapy (114)	5
Physiotherapy plus manipulation (47)	Detuned diathermy (47)	26
Physiotherapy plus back school (170)	Detuned diathermy (59)	1
Manipulation plus codeine (15)	Codeine (17)	7
Manipulation (12)	Diathermy (12)	23
Manipulation (48)	Massage (35)	2
Manipulation (94)	Physiotherapy (94)	19
Manipulation (56)	Massage (39)	18
Manipulation plus massage or electrostimulation (44)	Massage and/or electrostimulation (37)	10
Manipulation (41)	Diathermy (34)	8

even in the stratum in which we detected a treatment effect. Before we could condone such practices, we would demand further scientific demonstration of efficacy in relevant populations.

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