

A COMPARISON OF OSTEOPATHIC SPINAL MANIPULATION WITH STANDARD CARE FOR PATIENTS WITH LOW BACK PAIN

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ABSTRACT

Background The effect of osteopathic manual therapy (i.e., spinal manipulation) in patients with chronic and subchronic back pain is largely unknown, and its use in such patients is controversial. Nevertheless, manual therapy is a frequently used method of treatment in this group of patients.

Methods We performed a randomized, controlled trial that involved patients who had had back pain for at least three weeks but less than six months. We screened 1193 patients; 178 were found to be eligible and were randomly assigned to treatment groups; 23 of these patients subsequently dropped out of the study. The patients were treated either with one or more standard medical therapies (72 patients) or with osteopathic manual therapy (83 patients). We used a variety of outcome measures, including scores on the Roland-Morris and Oswestry questionnaires, a visual-analogue pain scale, and measurements of range of motion and straight-leg raising, to assess the results of treatment over a 12-week period.

Results Patients in both groups improved during the 12 weeks. There was no statistically significant difference between the two groups in any of the primary outcome measures. The osteopathic-treatment group required significantly less medication (analgesics, anti-inflammatory agents, and muscle relaxants) ($P < 0.001$) and used less physical therapy (0.2 percent vs. 2.6 percent, $P < 0.05$). More than 90 percent of the patients in both groups were satisfied with their care.

Conclusions Osteopathic manual care and standard medical care have similar clinical results in patients with subacute low back pain. However, the use of medication is greater with standard care. (N Engl J Med 1999;341:1426-31.)

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THE treatment of low back pain remains controversial in spite of a growing number of attempts to evaluate different therapeutic interventions and to develop clinical guidelines.¹⁻⁴ One stumbling block is the scientific evidence on which the guidelines are based. The results of randomized trials of some therapeutic interventions have been published, but the methodologic quality of many such studies is low.^{5,6} Many of the studies involve manual treatment of the spine (through manipulation or mobilization); millions of patients receive manual treatment every year.

Spinal manipulation as a treatment for back pain has been practiced for centuries. Over the past 150 years, different schools of manual treatment have evolved. In the United States, most spinal-manipulation ther-

apy is provided by chiropractors.⁷ Not surprisingly, therefore, most research on the efficacy of spinal manipulation assesses the chiropractic type of manipulation, which involves primarily short-lever, high-velocity spinal adjustments applied to specific contact points on the spinous process.⁸ Osteopathic manipulation has also been studied, but to a lesser degree. In osteopathy, the manipulation itself is only part of a philosophy of care; it is regarded as an adjunct to other medical care. The distinguishing hallmark of the osteopathic profession is the use of osteopathic manipulation. Osteopathic physicians make diagnoses on the basis of a combination of palpation and conventional diagnostic methods, and they use manual therapy in combination with conventional treatment methods, including pharmaceuticals and surgery. An emphasis on the importance of the musculoskeletal system in health and disease is a strong feature of the education of an osteopathic physician.⁹

Osteopathic medicine and chiropractic are different in terms of training and education and in their view of the musculoskeletal system.¹⁰ The focus of osteopathic medicine has been the need to optimize blood circulation to maintain or restore health. The chiropractic approach is focused more on the nervous system and advocates adjustments of the spinal vertebrae to improve neurotransmission.

Recent consensus reports have suggested that although manipulation may be effective in alleviating pain and improving function in patients with acute, uncomplicated back pain, its effectiveness has not been proved in patients with symptoms of longer duration.^{3,11} Koes and coworkers conducted a systematic review of randomized clinical trials; after applying criteria for methodologic rigor, they found insufficient evidence to prove the effectiveness of spinal manipulation in either acute or chronic low back pain.¹² Given that approximately 80 percent of primary care patients with low back pain have substantial improvement in the first month, regardless of therapy, it is difficult to demonstrate the value of any therapy in patients with acute symptoms.^{13,14}

We undertook this study to determine whether osteopathic care, including manipulative therapy, would

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benefit patients with low back pain (that had lasted for at least three weeks but less than six months) more than would standard allopathic care. The hypothesis tested was that osteopathic manipulation would result in more rapid relief of pain and recovery of function than that obtained with standard medical care.

METHODS

Selection of Patients

The study was conducted at two medical offices of a health maintenance organization (HMO). One office served 29,976 members, of whom 70 percent were members of minority groups (primarily black). The second office had 9682 members, with minimal minority representation.

The enrollment period was from August 1992 through August 1994, and the last follow-up was in December 1994. Patients between 20 and 59 years of age with low back pain that had lasted for at least three weeks but less than six months were identified by triage nurses. We determined preliminary eligibility and willingness to participate by reviewing charts and interviewing candidates over the telephone. We invited eligible patients to attend the base-line visit for further evaluation.

We excluded patients with nerve-root compression (dermatomal pain distribution, neurologic deficit, or both), a systemic inflammatory disorder, scoliosis, a serious medical illness such as cancer, recent myocardial infarction, diabetic neuropathy, neurovascular disease, alcohol or drug abuse, or a known psychiatric or psychological illness, as well as those with no lesion that could be manipulated. We also excluded patients who were pregnant, were involved in active litigation or receiving workers' compensation, had undergone manipulation treatment in the previous three weeks, or were considered unable to follow the protocol for any reason.

The study was approved by the institutional review committee of Rush University, and all subjects provided written informed consent.

Randomization and Treatment

At the base-line visit, we explained the study in detail and obtained informed consent. After eligibility was evaluated and the presence of a lesion suitable for manipulation was confirmed by a doctor of osteopathy, the patients were randomly assigned to one of two groups: that receiving osteopathic manipulation (the osteopathic-treatment group) or that receiving standard allopathic treatment (the standard-care group). The assignments, which were generated by a computer, were presented in sealed, sequentially numbered envelopes; each envelope was opened when the patient returned for the first appointment one week after enrollment. There was no stratification (blocking) according to treatment center.

The standard allopathic treatment was provided by physicians in the HMOs. The treatment included analgesics, antiinflammatory medication, active physical therapy, or therapies such as ultrasonography, diathermy, hot or cold packs (or both), use of a corset, or transcutaneous electrical nerve stimulation. All patients (including those in the osteopathic-treatment group) viewed a 10-minute educational videotape on back pain. The antiinflammatory agents that could be used were ibuprofen, naproxen, and piroxicam, and the approved analgesics were aspirin, acetaminophen, codeine, and oxycodone. Cyclobenzaprine was used as a muscle relaxant. Manual therapy in any form was not permitted as part of standard care.

For the osteopathic-treatment group, one of three osteopathic physicians from the Chicago College of Osteopathic Medicine provided additional treatment in the form of manipulation. In this study, osteopathic manipulation was applied to areas that the osteopathic physician determined to be related in some way to the patient's back pain; that is, treatment was individualized. A variety of techniques were used, including thrust, muscle energy, counterstrain, articulation, and myofascial release.¹⁵ The treating physician chose the techniques used. All treatment was documented

at each visit. All contacts with physicians occurred in the offices of the HMO.

At each of four weekly visits, and then four more visits at intervals of two weeks, patients in both groups were seen first by a certified nurse practitioner and then by the assigned physician. At 12 weeks, the patients were assessed by an evaluator who was blinded to the treatment assignments and had no relationship with either the HMO or the patients. Patients who reported before the 12th week that they had no pain were given a final evaluation at that time. For patients who chose to discontinue participation early, the reason for dropping out was documented.

Outcomes

At the base-line visit, we collected information on demographic characteristics, education, work, income, use of tobacco and medications, and the presence of other diseases. The evaluation of pain and function was based on a visual-analogue pain scale, the Roland-Morris questionnaire, the Oswestry questionnaire, selected questions from the North American Spine Society outcomes questionnaire, a pain drawing (the patient's indication of pain on a drawing of a person), and measurements of the range of motion and the degree to which the straight leg could be raised.

The visual-analogue pain scale consisted of a horizontal 10-cm line with the words "no pain" at one end and "worst pain" at the other.¹⁶ The Roland-Morris questionnaire is a validated 24-item adaptation of the Sickness Impact Profile, which assesses the loss of function due to back pain.^{17,18} Scores can range from 0 to 24; higher scores denote increasing severity of disease. To evaluate pain further, we used two items from the North American Spine Society Lumbar Spine Outcome Assessment Instrument: one on the frequency of pain and one on how "bothersome" the back pain was.¹⁹ The Oswestry questionnaire is a 10-item scale on which each item is scored from 0 to 5, with total scores ranging up to 50; higher numbers indicate worse pain. The first section deals with pain, and the other sections deal with various activities considered relevant to low back disability.²⁰ The Oswestry questionnaire was administered at the base-line and final visits, whereas the other evaluations were performed at every visit. The patients' acceptance of pain was determined at base line and at the final visit with a six-point scale. Range of motion was measured with a double inclinometer, and straight-leg raising was measured with a single inclinometer. Both measurements were performed by nurse practitioners who were not involved in the care of the patients. The use of standard care or osteopathic manipulation was documented at each visit.

Data were transferred to and analyzed by the Department of Preventive Medicine at Rush-Presbyterian-St. Luke's Medical Center. Double data entry was used for all key outcome variables.

Patients

A total of 1193 patients were identified by the triage nurses. Of these patients, 981 were ineligible — 39 percent for reasons related to their pain (the distribution of pain or the duration of pain), 26 percent for other reasons (unwillingness to participate, unavailability, or legal reasons), 19 percent because of other medical problems, and 16 percent for reasons pertaining to age. A total of 212 patients attended the base-line visit; 34 of these patients (16 percent) were found to be ineligible on the basis of the exclusion criteria. We randomly assigned the remaining 178 patients to the two treatment groups; we assigned 93 patients to the osteopathic-treatment group and 85 to the standard-care group. Twenty-three patients (13 percent) subsequently dropped out of the study: 2 (1 in each group) because of high sedimentation rates (an exclusion criterion) discovered after randomization, and 21 for unknown reasons (manifested in poor attendance at study visits). Of these 21 patients, 9 were in the osteopathic-treatment group and 12 were in the standard-care group. Six patients dropped out before any follow-up visits (two in the osteopathic-treatment group and four in the standard-care group), eight after one week (three in the osteopathic-treatment group and five in the standard-care

group), six after two weeks (three and three, respectively), and one (in the osteopathic-treatment group) after three weeks. In all, 155 patients completed the study; 83 were in the osteopathic-treatment group, and 72 were in the standard-care group.

Statistical Analysis

We summarized numerical variables as means \pm SD.²¹ Medians are shown for the Roland–Morris questionnaire, however, because the scores were distinctly skewed. Ninety-five percent confidence intervals for mean differences in outcome are shown for osteopathic-manipulation treatment minus standard care.

We compared the osteopathic-treatment group and the standard-care group using Wilcoxon rank-sum tests for numerical variables. For categorical variables, we used either a chi-square test or Fisher's exact test. We assigned values at the end of treatment using the last-value-carried-forward method of analysis, in which patients who had completed their treatment in fewer than 12 weeks were assigned the value at the final visit, whenever it occurred. Standard statistical software packages (6.09 and S-Plus, SAS, Cary, N.C.) were used for the analyses, which were performed on a Sun Sparcstation 10 (Sun Microsystems, Palo Alto, Calif.). All reported P values are two-tailed.

RESULTS

The osteopathic-treatment group and the standard-care group were similar with respect to demographic, socioeconomic, and work-related factors (Table 1). Education, income, and marital status were similar in the two groups. The severity of back pain and its functional effects were also similar between groups (Table 1). There was no difference between the groups in the frequency of nonmusculoskeletal diseases. Tobacco use was more common in the standard-care group (32 percent vs. 18 percent, $P=0.05$). About 90 percent of patients in both groups were satisfied with their work situation, and almost 30 percent were in physically demanding jobs.

Because we observed that the patients' condition continued to improve over the 12-week period, and because our primary measures were changes in scores, rather than occurrences of events, we excluded from the primary analyses the 23 patients who dropped out of the study. Tests in which large improvements were imputed for the 10 patients assigned to the osteopathic-treatment group and in which small improvements were imputed for the 13 patients assigned to the standard-care group showed that our conclusions from the primary analysis were not sensitive to the exclusion of these subjects, 8 of whom had no follow-up at all. Table 2 shows the changes in primary outcomes from base line to the final visit. Improvement occurred in both groups on every measure of outcome used. There were no statistically significant differences between treatment groups in terms of improvement, nor were there any statistically significant differences between the groups at the final evaluation.

Figure 1 shows the changes in the primary outcomes, as measured by the visual-analogue pain scale, the Roland–Morris questionnaire, and the Oswestry questionnaire, as a function of time. The curves for the standard-care and osteopathic-treatment groups

TABLE 1. BASE-LINE CHARACTERISTICS OF THE STUDY PARTICIPANTS.*

CHARACTERISTIC	OSTEOPATHIC-TREATMENT GROUP (N=83)	STANDARD-CARE GROUP (N=72)
Age — yr†	28.5 \pm 10.6	37.0 \pm 11.0
Sex — no. (%)		
Male	34 (41)	32 (44)
Female	49 (59)	40 (56)
Leg pain — no.		
Above knee	30	23
Below knee	9	10
Visual-analogue pain score — mm‡	49.0 \pm 23.6	45.0 \pm 20.6
Median Roland–Morris questionnaire score§	7	7
Oswestry questionnaire score¶	25.0 \pm 12.2	23.1 \pm 11.8
Flexion — degree	31.9 \pm 22.5	33.0 \pm 17.1
Extension — degree	7.2 \pm 7.8	6.9 \pm 7.8
Straight-leg raising — degree	75.5 \pm 9.8	75.4 \pm 9.3
Onset of pain — no. (%)		
Gradual	44 (53)	34 (47)
Sudden	37 (45)	36 (50)
Unknown	2 (2)	2 (3)

*There were no statistically significant differences between the groups. For all scales and questionnaires, the score increases with the severity of the pain or disease. Plus-minus values are means \pm SD.

†The P value for age was 0.091.

‡The visual-analogue pain scale was scored from 0 to 100.

§The Roland–Morris questionnaire was scored from 0 to 24.

¶The Oswestry questionnaire was scored from 0 to 50.

did not differ significantly. Forty-seven percent of the patients in the osteopathic-treatment group and 39 percent of those in the standard-care group completed all nine visits ($P=0.39$).

The use of medication was greater in the standard-care group than in the osteopathic-treatment group, with significant differences for nonsteroidal antiinflammatory drugs ($P<0.001$) and muscle relaxants ($P<0.001$). Nonsteroidal medication was prescribed at 54.3 percent of the patient visits to the standard-care physicians, as compared with 24.3 percent of the visits to the osteopathic-treatment physicians. A muscle relaxant was prescribed at 25.1 percent of the visits in the standard-care group and 6.3 percent in the osteopathic-treatment group. Physical therapy was also used more frequently in the standard-care group (2.6 percent vs. 0.2 percent, $P<0.05$).

More than 90 percent of the patients in each group were satisfied with their care (Table 3). There were no statistically significant differences between the groups. Answers to a quality-of-life question that was asked at the final visit — “If you had to spend the rest of your life this way, how would you feel?” — indicated that 80 percent of the patients in both groups accepted their back problem well.

TABLE 2. CHANGE IN PRIMARY OUTCOME MEASURES FROM THE FIRST TO THE FINAL VISIT AND PRIMARY OUTCOME MEASURES IN THE TWO GROUPS AT THE FINAL VISIT.*

MEASURE	OSTEOPATHIC-TREATMENT GROUP (N=83)	STANDARD-CARE GROUP (N=72)	P VALUE	95% CI OF THE DIFFERENCE†
Change from first to final visit				
Visual-analogue pain score (mm)‡	32.0±23.0	26.3±24.1	0.19	-1.8 to 13.2
Median Roland-Morris questionnaire score§	5	5	0.16	
Oswestry questionnaire score¶	13.6±13.4	12.9±13.4	0.97	-3.5 to 5.0
Flexion (degree)	1.9±22.0	4.2±21.3	0.64	-9.1 to 4.7
Extension (degree)	0.8±11.9	1.7±11.1	0.65	-4.6 to 2.8
Straight-leg raising (degree)				
Supine	2.8±9.7	1.3±9.1	0.40	-1.5 to 4.5
Sitting	6.6±12.7	5.2±10.4	0.94	-2.4 to 5.1
At the final visit				
Visual-analogue pain score (mm)‡	16.2±20.0	18.7±22.0	0.81	-9.2 to 4.1
Median Roland-Morris questionnaire score§	2	1	0.97	
Oswestry questionnaire score¶	11.9±12.2	9.9±12.1	0.23	-1.8 to 5.9
Flexion (degree)	35.9±15.2	37.2±18.6	0.64	-6.6 to 4.1
Extension (degree)	7.6±9.0	8.6±7.6	0.55	-3.6 to 1.8
Straight-leg raising (degree)				
Supine	78.7±7.9	76.6±9.6	0.24	-0.7 to 4.9
Sitting	81.6±9.1	81.5±11.4	0.48	-3.1 to 3.4

*All changes are improvements. All values are means ±SD, except those for the Roland-Morris questionnaire score, which are median values. For all scales and questionnaires, the score increases with the severity of the pain or disease.

†The confidence interval (CI) is for the difference between groups (the mean in the osteopathic-treatment group minus the mean in the standard-care group).

‡The visual-analogue pain scale was scored from 0 to 100.

§The Roland-Morris questionnaire was scored from 0 to 24.

¶The Oswestry questionnaire was scored from 0 to 50.

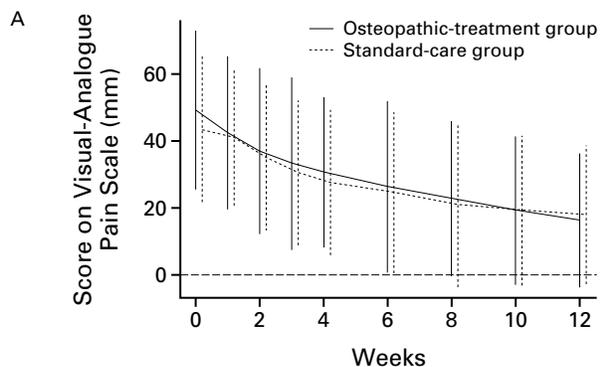
DISCUSSION

We found no difference in clinical outcome between standard care and osteopathic care among patients with low back pain of at least three weeks in duration. Because of the study design, we cannot determine whether the results reflect the natural history of subchronic-to-chronic low back pain or were modified by either standard or osteopathic care. We decided against using a placebo or nontreatment group because it is not possible to prevent patients with back pain from initiating self-care (by adjustment of activity and use of pain medication). Although the natural history of low back pain in patients with pain for more than three weeks and less than six months is not specifically known, previous studies indicate that the recovery rate is slower after three weeks than before.^{1,22,23} Most previous studies have focused on the first two to four weeks.^{6,8,24} Because most patients recover without specific treatment during this period, the additional effect of manipulation is difficult to determine. A few studies show a beneficial effect of manual treatment during that period, mainly in the form of a more rapid reduction in pain.^{25,26}

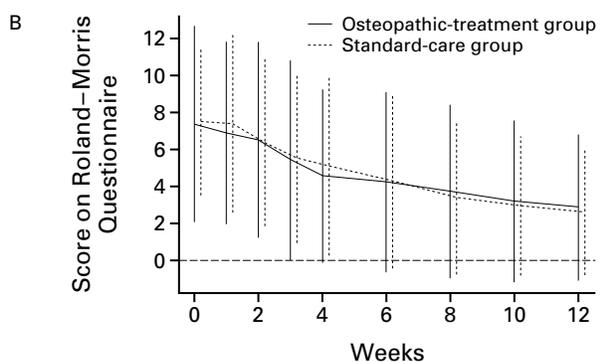
Koes et al.^{6,24} developed criteria for assessing the

quality of published studies of the efficacy of spinal manipulation. When those criteria were applied to our study, the study scored between 66 points (with the 1991 criteria) and 74 points (with the 1995 criteria) out of a possible 100. This compares favorably with the 30 trials of spinal manipulation or mobilization reviewed by Koes et al.,⁶ in which scores ranged from 20 to 56, with a median of 35. It also compares well with the 25 controlled trials of manipulation that were accepted for review by Shekelle et al.⁸ The main areas of methodologic weakness in our study, according to the criteria of Koes et al.,⁶ were the size of the study groups (72 in the smaller group, as compared with an ideal size of more than 100), the presence of other interventions, the lack of a placebo control group, and the lack of blinding of the patients. These four items constitute 24 points deducted from 100. Although rectifying these deficiencies would increase the value of a study from a methodologic perspective, we did not consider these items essential for addressing our hypothesis.

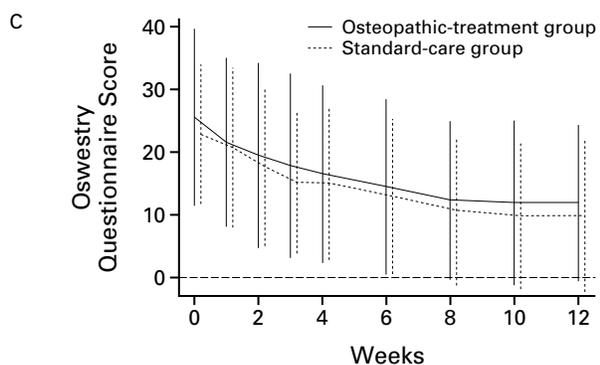
Other interventions are difficult to avoid when performing a pragmatic study comparing one treatment system (with several aspects) with standard care, which by its nature includes different alternatives for inter-



NO. OF PATIENTS		0	2	4	6	8	10	12		
Osteopathic-treatment group		83	82	79	75	72	64	53	41	83
Standard-care group		72	71	69	68	62	55	37	30	72



NO. OF PATIENTS		0	2	4	6	8	10	12		
Osteopathic-treatment group		83	82	79	75	72	64	53	41	83
Standard-care group		72	71	69	68	62	55	37	30	72



NO. OF PATIENTS		0	2	4	6	8	10	12		
Osteopathic-treatment group		83	82	79	75	72	64	53	41	83
Standard-care group		72	71	69	68	62	55	37	30	72

TABLE 3. PATIENTS' SATISFACTION WITH THEIR TREATMENT.

QUESTION AND RESPONSE	STANDARD-CARE GROUP	OSTEOPATHIC-TREATMENT GROUP
	percent	
Has the treatment you received met your expectations?		
Yes	92	95
No	8	5
Would you undergo this treatment again if you had the same illness?		
Yes	92	98
No	8	2
Would you recommend this treatment to a friend with a similar condition?		
Yes	100	97
No	0	3

vention. We chose not to evaluate the effect of manipulation separately because osteopathic manual care involves much more than manipulation, which should be viewed as one part of a larger philosophy of care. Several of the other interventions, including the informational videotape, were distributed equally between the two treatment groups.

We did not try to prevent the patients from knowing which type of treatment they were receiving; we believed that it would not be possible, because one type of treatment involved physicians who were not part of the HMO. It is difficult to develop a placebo for manipulation. The patients were unfamiliar with osteopathic manual care, but a few had undergone manipulation by other care providers in the past. None had received manual treatment for their current episode. A blinded assessment was made at the exit interview. Because most measures of outcome were completed by the patients themselves, the value of the blinded evaluation is limited.

Because of the study design, we could not determine differences in cost between treatment groups. Since the environment in which treatment occurs can influence the results of treatment, we decided that all

Figure 1. Mean (\pm SD) Changes in the Score on the Visual-Analogue Pain Scale (Panel A), the Roland-Morris Questionnaire Score (Panel B), and the Oswestry Questionnaire Score (Panel C) over the 12 Weeks of the Trial.

The visual-analogue pain scale is scored from 0 to 100; scores on the Roland-Morris questionnaire can range from 0 to 24; and the Oswestry questionnaire is a 10-item scale in which each item is scored from 0 to 5, with total scores ranging up to 50. Higher numbers denote worse pain or increasing severity of disease.

patients should be treated at the HMO offices, to which the osteopathic physicians traveled. This method was logistically complicated because of the limited hours and availability of the osteopathic physicians and contributed to the uneven distribution of patients among the three osteopathic physicians. The frequency of patient visits is typically greater when patients are undergoing manual therapy than when they are receiving standard allopathic care.^{19,27,28} We were concerned that the greater frequency of visits would introduce a placebo effect by itself in the osteopathic-treatment group; we therefore provided the same number of visits (eight) for both groups, on the basis of information from the osteopathic physicians.

The osteopathic-treatment group received less medication and less physical therapy than the standard-care group, and the differences in cost were significant. The value of drugs in the treatment of acute pain is supported in controlled trials.²⁹ However, as compared with those who wrote more prescriptions, physicians in managed-care settings — who wrote fewer prescriptions and emphasized education, continued physical activity, and self-care — obtained similar outcomes in terms of pain and function at one year, with lower cost and higher patient satisfaction.³⁰ Given the known and potentially serious adverse effects and costs of nonsteroidal antiinflammatory drug therapy,^{31,32} the achievement of equal outcomes in regard to pain relief, function, and satisfaction, with less use of medication and physical therapy, suggests an important benefit of osteopathic manipulative treatment; this type of treatment deserves careful examination through a formal cost–benefit analysis.^{33,34}

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