SPINE Volume 28, Number 13, pp 1355–1362

Osteopathic Manipulative Treatment for Chronic Low Back Pain

A Randomized Controlled Trial

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Study Design. A randomized controlled trial was conducted.

Objective. To determine the efficacy of osteopathic manipulative treatment as a complementary treatment for chronic nonspecific low back pain.

Summary of Background Data. Osteopathic manipulative treatment may be useful for acute or subacute low back pain. However, its role in chronic low back pain is unclear.

Methods. This trial was conducted in a university-based clinic from 2000 through 2001. Of the 199 subjects who responded to recruitment procedures, 91 met the eligibility criteria. They were randomized, with 82 patients completing the 1-month follow-up evaluation, 71 completing the 3-month evaluation, and 66 completing the 6-month evaluation. The subjects were randomized to osteopathic manipulative treatment, sham manipulation, or a no-intervention control group, and they were allowed to continue their usual care for low back pain. The main outcomes included the SF-36 Health Survey, a 10-cm visual analog scale for overall back pain, the Roland–Morris Disability Questionnaire, lost work or school days because of back pain, and satisfaction with back care.

Results. As compared with the no-intervention control subjects, the patients who received osteopathic manipulative treatment reported greater improvements in back pain, greater satisfaction with back care throughout the trial, better physical functioning and mental health at 1 month, and fewer cotreatments at 6 months. The subjects who received sham manipulation also reported greater improvements in back pain and physical functioning and greater satisfaction than the no-intervention control subjects. There were no significant benefits with osteopathic manipulative treatment, as compared with sham manipulation.

Conclusions. Osteopathic manipulative treatment and sham manipulation both appear to provide some benefits when used in addition to usual care for the treatment of chronic nonspecific low back pain. It remains unclear whether the benefits of osteopathic manipulative treatment can be attributed to the manipulative techniques themselves or whether they are related to other aspects of osteopathic manipulative treatment, such as range of motion activities or time spent interacting with patients, which may represent placebo effects. [Key words: low back pain, orthopedic manipulation, osteopathic manipulative treatment, osteopathic medicine, patient satisfaction, physical functioning, randomized controlled trial] **Spine 2003;28:1355–1362**

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Partially supported by Grant 99-11-487 from the American Osteopathic Association.

Acknowledgment date: July 23, 2002. First revision date: November 8, 2002. Second revision date: November 22, 2002. Acceptance date: December 10, 2002.

The submitted manuscript does not contain information about medical devices or drugs.

Institutional and professional organization funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this article.

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It is estimated that 15% to 20% of the U.S. population experiences low back pain annually, and that at any given time, 2% of the population is disabled because of back problems.[1] Historically, low back symptoms have been the second leading cause of office visits to primary care physicians and the most common reason for visits to osteopathic physicians.[2] The total annual costs of back pain in the United States have been estimated at $20 to $50 billion,[3] despite efforts by managed care organizations to control access to health care and to contain costs.[4]

A comprehensive evaluation of spinal manipulation for low back pain was undertaken by the Agency for Healthcare Research and Quality.[5] This organization recommended that spinal manipulation can be helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms.[5] A recent review of this clinical practice guideline found that only minor updating is needed, involving primarily recommendations for back schools, lumbar corsets, and epidural steroid injections.[6]

Two major studies have investigated osteopathic manipulative treatment (OMT) for low back pain in the United States administered by osteopathic physicians who are fully qualified medical practitioners. The first study, a randomized controlled trial involving patients referred to a university-based back clinic in California from 1973 to 1979, found significant benefits with the first manipulative treatment, as compared with a combined treatment involving soft tissue massage and a sham manipulation technique.[7] However, no significant benefits were attributed to manipulation at discharge, which occurred an average of 30 days after the initial treatment.

Another randomized controlled trial, performed at two medical offices of an Illinois-based health maintenance organization from 1992 to 1994, involved patients with "subacute" low back pain lasting at least 3

weeks but less than 6 months.[8] This trial compared OMT using a variety of techniques, each at the discretion of the treating provider, with usual care for low back pain. There were no significant differences in primary clinical outcomes between the OMT group and the usual-care group at 12 weeks. However, the OMT group used significantly less medication and physical therapy.

Studies of spinal manipulation for chronic low back problems are inconclusive.[9] Furthermore, no studies specifically address the use of OMT for chronic low back pain. The purpose of this trial was to study the efficacy of OMT in ambulatory subjects with chronic nonspecific low back pain.

■ Methods

A randomized controlled trial was conducted at the University of North Texas Health Science Center at Fort Worth to study the efficacy of OMT for chronic nonspecific low back pain. Subjects were recruited from January 2000 through February 2001 using advertising in local newspapers and referrals from university-based clinics and other local physicians. Subjects with constant or intermittent, nonspecific low back pain for at least 3 months composed the target population. The research protocol was approved by the Institutional Review Board of the University of North Texas Health Science Center.

A clinical research technician performed a brief telephone screening of recruitment responders. Screened subjects were excluded from participation if they were younger than 21 years or older than 69 years, had any of six possible underlying causes of low back symptoms in their history (spinal osteomyelitis, spinal fracture, herniated disc, ankylosing spondylitis, cauda equina syndrome, or cancer, excluding nonmalignant skin cancer), had undergone surgery involving the low back within the preceding 3 months, had received workers' compensation benefits within the preceding 3 months or were potentially involved in litigation relating to back problems, were pregnant, had ever been a patient at the trial clinic site, were an employee of the trial clinic site, or had received spinal manipulation for back pain within the preceding 3 months or on more than three occasions during the preceding year.

Eligible screened subjects were subsequently interviewed by the clinical research technician, who explained the research protocol and obtained verbal and written informed consent. These participating subjects then underwent a more thorough clinical assessment adapted from the Clinical Practice Guideline on Acute Low Back Problems in Adults.[5] This baseline assessment included a focused medical history and physical examination, including neurologic evaluation, performed by a predoctoral osteopathic manipulative medicine fellow. Subjects with "red flags" for any of the six aforementioned underlying causes of low back symptoms were identified, given appropriate recommendations for follow-up evaluation, and excluded from further participation. The red flags for each of the six conditions were as follows[5]:

spinal osteomyelitis: intravenous drug use, urinary tract infection, or skin infection within the preceding year, or corticosteroid use of more than 3 months duration within the preceding year

spinal fracture: spinal trauma within the preceding year or corticosteroid use exceeding 3 months duration within the preceding year

herniated disc: history of leg pain radiating below the knee, history of persistent numbness or weakness in the leg or legs, or history of claudication

ankylosing spondylitis: morning back stiffness in persons younger than 40 years

cauda equina syndrome: history of bladder dysfunction, saddle anesthesia, or fecal incontinence

cancer: history of previous cancer, excluding nonmalignant skin cancer, unexplained weight loss of at least 10 pounds or 5% of body weight within the preceding year, or no relief of low back symptoms with bed rest for persons older than 50 years.

Because approximately 12% of ambulatory patients with back pain have symptoms of sciatica or leg pain without neurologic compromise related to lumbar disc herniation,[5] the authors sought to include such subjects in the trial. However, to minimize the likelihood of including subjects with a lumbar disc herniation, subjects with sciatica were included only if they tested negative for all of the following: 1) ankle dorsiflexion weakness; 2) great toe extensor weakness; 3) impaired ankle reflexes; 4) loss of light touch sensation in the medial, dorsal, and lateral aspects of the foot; 5) ipsilateral straight-leg-raising test (positive result: leg pain at $<60°$); 6) crossed straight-leg-raising test (positive result: reproduction of contralateral pain).

These six neurologic tests allow detection of most clinically significant nerve root compromises resulting from L4–L5 or L5–S1 disc herniations, which together make up more than 90% of all clinically significant radiculopathies attributable to lumbar disc herniations.[5] All eligible subjects then received an osteopathic structural evaluation performed by a predoctoral osteopathic manipulative medicine fellow to identify areas of somatic dysfunction that might potentially be associated with low back pain, and to develop an initial treatment plan for these areas.[10]

At the baseline assessment, data were collected on each subject's age, gender, race and ethnicity, marital status, education, occupation, type of insurance coverage, and comorbid medical conditions within the preceding 3 months. The Medical Outcomes Study Short Form-36 Health Survey (SF-36) was used to measure the self-reported health status of the subjects. The SF-36 is a valid and reliable instrument widely used to measure generic health status, particularly for monitoring clinical outcomes after medical interventions.[11,12] The SF-36 provides data on health concepts using the following scales[11]: physical functioning, role limitations because of physical problems, bodily pain, general health, vitality, social functioning, role limitations because of emotional problems, and mental health.

Each subject's overall perception of back pain was assessed using a 10-cm horizontal visual analog scale. Findings have shown that the data derived from such written scales among patients with chronic low back pain are normally distributed, even when the scales are used without verbal instructions.[13] Pain at the two extremes of this scale was labeled as "not noticeable at all" and "worst pain possible." During clinic visits, OMT and sham manipulation subject responses to this scale were collected before treatment was received. The scale was scored by a blinded clinical research technician using a standard ruler.

Functional status and disability resulting from back pain were measured with the Roland–Morris Disability Questionnaire.[14] This questionnaire is short and simple to complete, and appears to be well suited for studies involving patients with

mild to moderate disability.[15] Empirical research suggests that the Roland–Morris Disability Questionnaire poses fewer problems involving blank or multiple responses than either the Oswestry Disability Index or the Jan van Breemen Institute pain and functional capacity questionnaire, and therefore may be the preferred instrument for assessing change over time in patients with low back pain.[16] Additional data specific to back pain also were collected on the number of current cotreatments using a checklist of 12 possible treatments, current medication use, the number of lost work or school days within the preceding 4 weeks, and global satisfaction with back care as measured by Likert scale responses. Together, the trial data include the five domains of patient-based outcomes recommended for evaluating the treatment of spinal disorders[17]: 1) generic health status, 2) pain, 3) back-specific function, 4) work disability, 5) back-specific patient satisfaction.

After baseline assessment and data collection, the subjects were assigned randomly to one of three treatment groups in an approximate 2:1:1 ratio: OMT, sham manipulation, or no intervention as a control condition. The intent of this allocation strategy was to enroll comparable numbers of subjects receiving OMT and not receiving OMT, and subsequently to combine the sham manipulation and no-intervention control groups should no statistically significant differences be observed between the latter groups.

Randomization was performed using sequential sealed envelopes prepared by the clinical research technician before enrollment of the subjects. The treating predoctoral osteopathic manipulative medicine fellows subsequently opened the sealed envelopes and recorded the allocation of subjects as they entered the trial. The osteopathic manipulative medicine fellows responsible for the baseline assessments, structural evaluations, initial treatment plans, randomization, and OMT and sham manipulation interventions all were third- or fourth-year medical students in the process of completing an additional year of medical training devoted entirely to osteopathic theory and practice. All the trial personnel, with the exception of these fellows, were blinded to treatment group assignments throughout the trial.

Osteopathic and sham manipulation subjects were treated for a total of seven visits over 5 months, including visits 1 week, 2 weeks, and 1 month after baseline assessment, and then monthly thereafter. Each subject in these two groups was to receive his or her assigned treatment at all seven visits regardless of previous treatment responses. The 6-month visit was designed to collect exit data and did not include any treatment. Follow-up data on the SF-36 scales, visual analog scale for back pain, Roland–Morris Disability Questionnaire, and global satisfaction with back care were collected using each at the 1-, 3-, and 6-month visits. Data on back-specific cotreatments, current medication use, and lost work or school days were collected at the 1- and 6-month visits. No-intervention control subjects provided these data on the same timetable as the OMT and sham manipulation subjects, but did so through postal questionnaires instead of during a clinic visit.

The following protocol was used for OMT treatments. The OMT sessions lasted 15 to 30 minutes, and the OMT was performed by predoctoral osteopathic manipulative medicine fellows. The techniques included one or a combination of the following: myofascial release, strain–counterstrain, muscle energy, soft tissue, high-velocity–low-amplitude thrusts, and cranial–sacral. The OMT was aimed at somatic dysfunction in the low back or adjacent areas.

Because this trial was intended to assess the efficacy of OMT as practiced in actual clinical encounters, the research protocol allowed for discretion in OMT interventions and techniques across subjects and time.[10] Two cohorts of predoctoral osteopathic manipulative medicine fellows provided baseline structural evaluations and treatments for 3-month intervals on a rotating basis during the trial. A 1-hour trial-specific training session for new and returning fellows was provided by an osteopathic manipulative medicine specialist every 3 months to facilitate consistent protocol implementation throughout the trial, including the provision of both OMT and sham manipulation techniques.

Sham manipulation subjects received "treatments" according to the same protocol guidelines and timetable described previously for OMT subjects. These sham treatments included range of motion activities, light touch, and simulated OMT techniques. The latter consisted of manually applied forces of diminished magnitude aimed purposely to avoid treatable areas of somatic dysfunction and to provide minimal likelihood of therapeutic effect. The third group received no trial interventions. All the subjects, regardless of group assignment, were allowed to receive usual or other low back care to complement the trial interventions, with the exception of other OMT or chiropractic manipulation. Data were collected on each subject's use of cotreatments throughout the trial including prescription and over-the-counter medications, physical therapy, massage therapy, hydrotherapy, transcutaneous electrical nerve stimulation, spinal and epidural injections, acupuncture, herbal therapies, and meditation.

Baseline demographic and clinical characteristics were summarized using descriptive statistics. Analysis of variance was used to test for differences among the groups in continuous variables, and the χ^2 test was used for dichotomous or categorical variables. Crude SF-36 data were transformed and standardized using recommended procedures.[11] The Roland–Morris Disability Questionnaire was scored as the sum of positive responses on each of its 24 items.[14] The Likert scale responses for global satisfaction were transformed by assigning relative weights to each of the possible response options. Repeated measures analysis of variance[18] was used to identify significantly different changes over time among the treatment groups in each of 14 primary outcomes: eight SF-36 health scale scores, visual analog scale score for back pain, Roland–Morris Disability score, number of cotreatments, current back pain-specific medication use, lost work or school days related to back pain, and global satisfaction with back care. Outcomes for which baseline data were collected were tested for significance using the treatment group by time interaction term. For a given outcome, such analysis compares the cumulative experience of the treatment groups to the relevant point in time. The treatment group main effects were used to test for significance related to global satisfaction with back care because it was not possible to collect baseline data for this variable. The χ^2 test was used to identify differences among the treatment groups in the percentages of subjects currently using medication for back pain.

The numbers of subjects receiving OMT and not receiving OMT (the latter including the sham manipulation subjects and the no-intervention control subjects combined) to be included in the trial to achieve a power of approximately 80% in detecting moderate to large differences between groups were determined using the SF-36 scales. The latter were used because they comprised the majority of primary outcomes, and because ex-

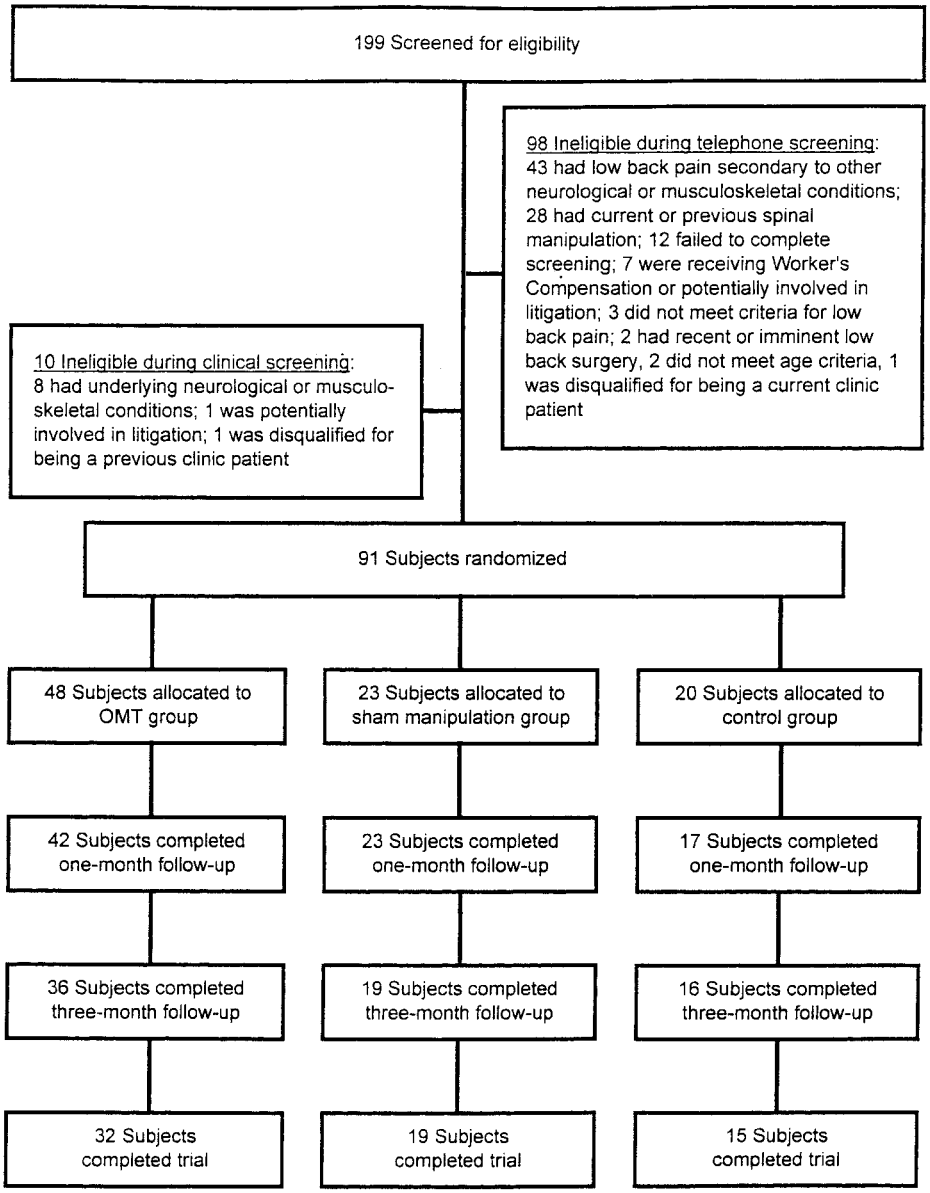

Figure 1. Flow of subjects through the clinical trial.

tensive data were available to estimate sample sizes for a repeated measures design.[11] All hypotheses were tested at the 0.05 level of statistical significance. Data management and analyses were performed using the SYSTAT software package (Systat Software, Richmond, CA).

■ Results

The flow of subjects through the trial is shown in Figure 1. Altogether, 91 (46%) of the 199 persons who responded to recruitment procedures were randomized. The three treatment groups were comparable with regard to baseline characteristics (Table). At trial entry, 46 (51%) subjects had experienced low back pain for more than 1 year, 22 (24%) were currently using multiple treatments for back pain, and 70 (77%) had used medication for back pain within the preceding 4 weeks. As determined by mean SF-36 scale scores and available normative data,[11] the subjects were comparable with the general U.S. population in terms of general health (71 *vs* 72) and mental health (72 *vs* 75); had deficiencies involving role limitations because of emotional problems (74 *vs* 81), social functioning (73 *vs* 83), and vitality (48 *vs* 61); and had substantial deficits involving role limitations because of physical problems (36 *vs* 81), bodily pain (45 *vs* 75), and physical functioning (62 *vs* 84). Nevertheless, specifically with regard to low back pain, the mean Roland–Morris Disability score of 7.5 ± 4.6 among the trial subjects suggests lower levels of functional disability than reported by patients with nonspecific low back pain of more than 6 weeks duration (normative mean, 12.1 ± 4.7).[15,19]

Overall, 82 subjects (90%) completed the 1-month follow-up assessment, 71 (78%) the 3-month assessment, and 66 (73%) the 6-month assessment. There were no significant differences in attrition among the treatment groups. Of the 25 patients who did not complete the study, two were removed by trial personnel for med-

Table 1. Baseline Characteristics of Subjects According to Treatment Group*

Characteristic	Treatment Group: OMT N = 48	Sham Manipulation N = 23	No Intervention Control N = 20	*P*
Age, y	49 ± 12	52 ± 12	49 ± 12	0.48
Gender, % women	69	57	65	0.60
Race/ethnicity, % non-Hispanic white	90	83	80	0.52
Education, y	15.1 ± 2.5	15.1 ± 1.8	14.8 ± 2.9	0.88
Health insurance, %	83	87	95	0.43
Comorbid conditions, no.	1.0 ± 1.2	1.2 ± 1.3	1.6 ± 1.6	0.30
Duration of back pain, % >1 y	52	39	63	0.29
Medication use for back pain in past four weeks, %	79	70	80	0.62
Current cotreatments for back pain, no.	1.3 ± 0.6	1.2 ± 0.8	1.3 ± 0.9	0.82
Work or school days lost in past four weeks, d	0.3 ± 0.8	0.2 ± 0.6	0.2 ± 0.6	0.80
SF-36 scale scores				
Physical functioning	60 ± 22	61 ± 21	65 ± 28	0.77
Role limitations–physical	39 ± 38	24 ± 37	45 ± 40	0.17
Bodily pain	44 ± 18	44 ± 18	47 ± 18	0.84
General health	71 ± 19	67 ± 20	64 ± 22	0.40
Vitality	49 ± 18	49 ± 21	47 ± 20	0.90
Social functioning	73 ± 22	70 ± 27	77 ± 24	0.66
Role limitations–emotional	76 ± 40	75 ± 37	67 ± 42	0.64
Mental health	72 ± 15	72 ± 20	70 ± 21	0.95
Overall back pain score on 10-cm. visual analogue scale, cm.	3.6 ± 2.2	3.7 ± 2.7	3.1 ± 2.3	0.64
Roland-Morris Disability score	7.4 ± 4.4	8.0 ± 4.5	7.3 ± 5.4	0.86

* Plus–minus values are means and standard deviations.

ical reasons after randomization but before receiving any treatment: one because of suspected spinal stenosis and another because of broken ribs sustained during a fall.

As shown in Figure 2, there were significantly different trends over time among the treatment groups on the SF-36 physical functioning scale. At 1 month, the OMT subjects reported more improvement in physical functioning than the no-intervention control subjects ($P = 0.03$). However, at 3 and 6 months, only sham manipulation subjects improved more than the no-intervention controls subjects ($P = 0.01$ and $P = 0.03$, respectively). The only other significant findings with regard to the SF-36 scales were that the OMT subjects reported greater mental health improvement than no-intervention control subjects at 1 month ($P = 0.04$), and that the sham manipulation subjects reported

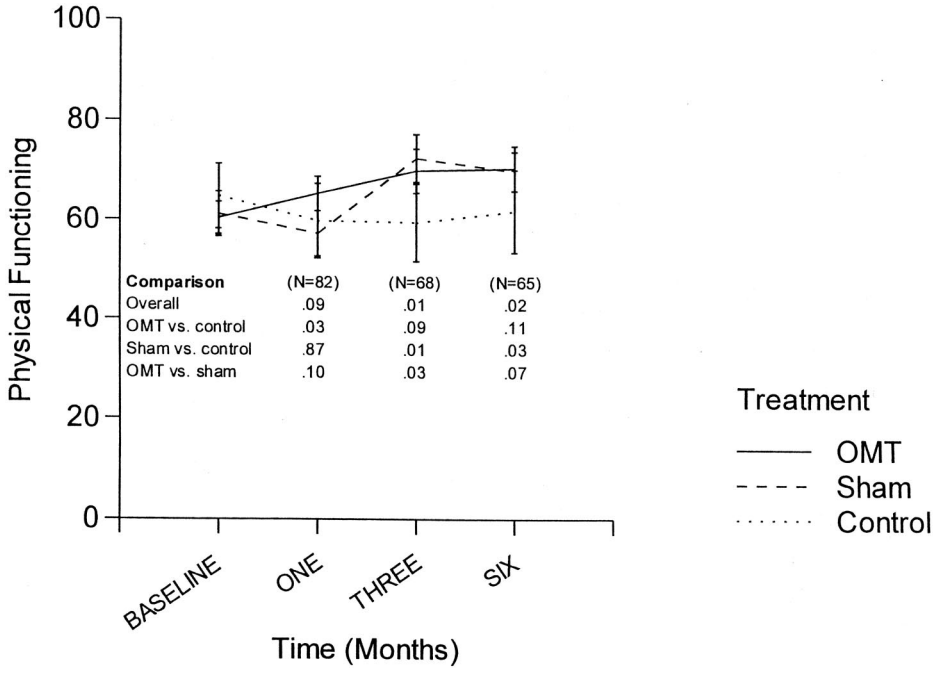

Figure 2. SF-36 physical functioning scale scores over time (mean ± SE). The table entries represent *P* values for the cumulative experience from baseline to the applicable point in time. Higher scores represent better physical functioning.

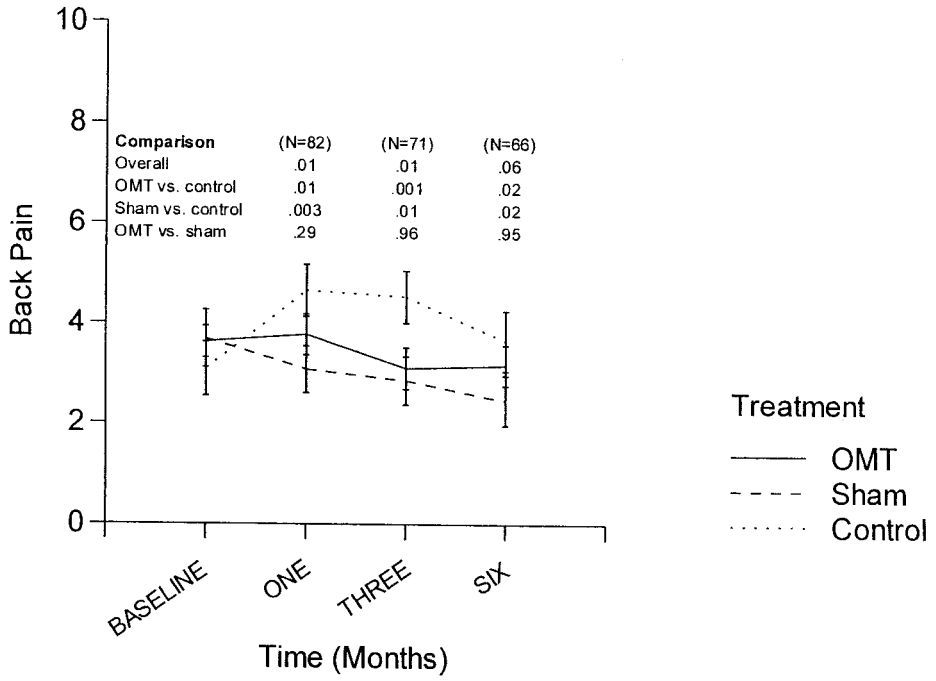

Figure 3. Visual analogue scale scores for back pain over time (mean ± SE). The table entries represent *P* values for the cumulative experience from baseline to the applicable point in time. Higher scores represent greater pain.

fewer role limitations because of physical problems than the no-intervention control subjects at 6 months ($P = 0.04$).

Figure 3 also demonstrates significantly different trends over time among the treatment groups with regard to visual analog scale scores for back pain. Both the OMT and sham manipulation subjects reported greater improvements in back pain than the no-intervention control subjects at 1 ($P = 0.01$ and $P = 0.003$, respectively), 3 ($P = 0.001$ and $P = 0.01$, respectively), and 6 ($P = 0.02$ and $P = 0.02$, respectively) months. Despite these findings, there were no significant differences over time among the treatment groups in the Roland–Morris Disability scores.

As shown in Figure 4, the OMT subjects used fewer cotreatments than the no-intervention control subjects at 6 months ($P = 0.03$). However, there were no significant differences among the treatment groups in back pain-specific medication use or lost work or school days over time. Figure 5 demonstrates that both OMT ($P = 0.001$) and sham manipulation ($P = 0.02$) subjects reported significantly greater satisfaction with their back care than the no-intervention control subjects.

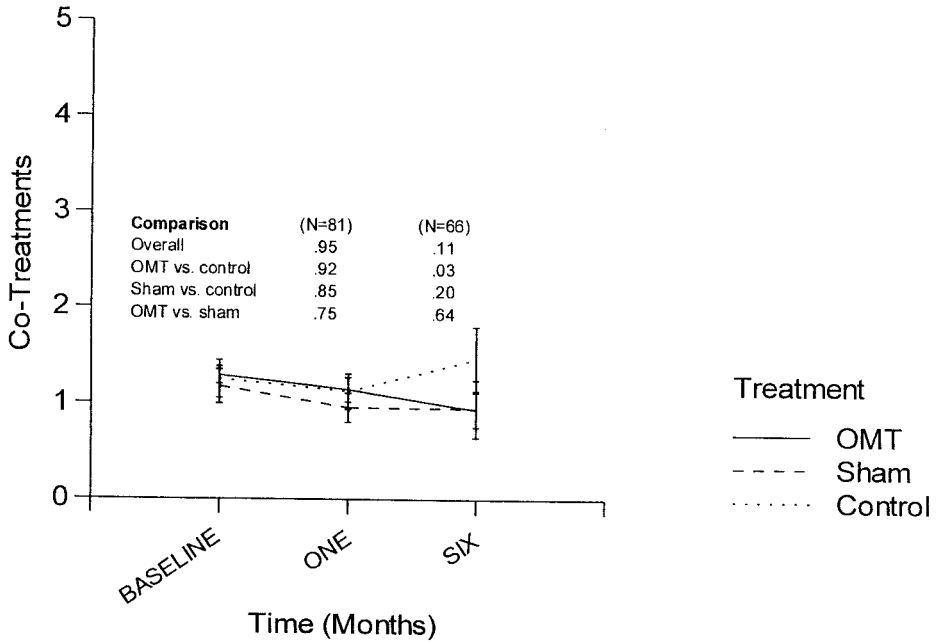

Figure 4. Number of cotreatments for back pain over time (mean ± SE). The table entries represent *P* values for the cumulative experience from baseline to the applicable point in time.

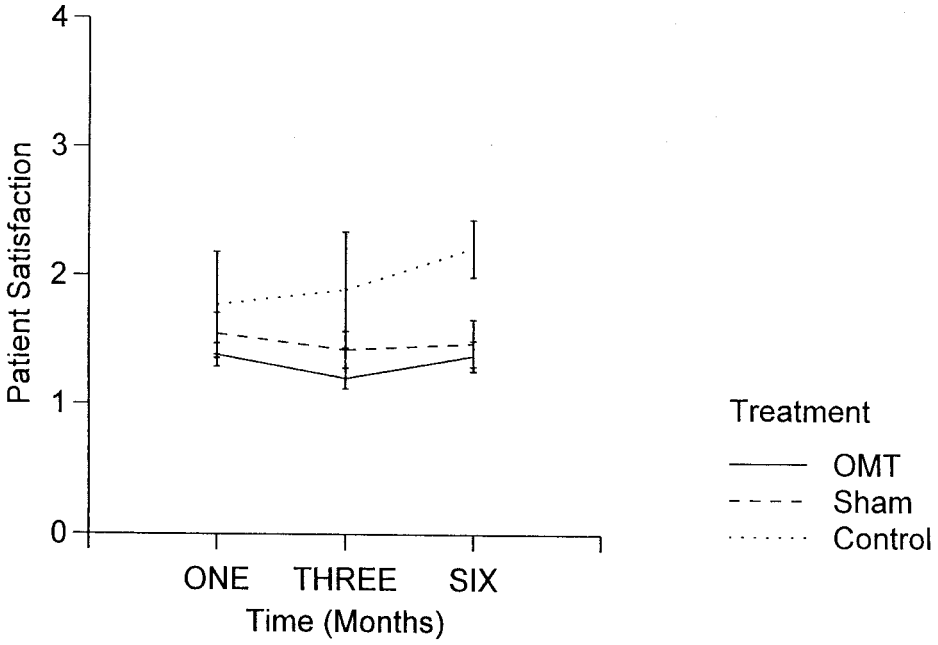

Figure 5. Global satisfaction with back care over time (mean ± SE). Higher scores represent less satisfaction with back care. Significant differences in main effects were observed between OMT subjects and no intervention controls ($P = 0.001$) and between sham manipulation subjects and no intervention controls ($P = 0.02$).

■ Discussion

This trial is unique in being the first to address the efficacy of OMT for chronic nonspecific low back pain. Despite several favorable findings among comparisons of OMT subjects and no-intervention controls subjects, the observation of similar favorable findings among comparisons of sham manipulation subjects and no-intervention control subjects and the lack of any significant differences in outcomes between the OMT and sham manipulation subjects raise questions about the inherent effects of the OMT techniques. In addition to the possibility of placebo effects, there are several important methodologic considerations that may help explain the findings of this trial.

The issue of appropriate control treatments in OMT research is controversial. Clinical trials that include only a no-intervention control condition are likely to bias their results in favor of OMT for at least three reasons: 1) the "laying on of hands," 2) greater attention from and interaction with the treating provider, and 3) expectation of a therapeutic effect. Indeed, a recent systematic review found evidence that placebos had a significant beneficial effect, as compared with no treatment, in trials that used self-reported continuous outcomes,[20] such as those commonly used in this trial.

This review further found that the significant benefits of placebo were evident in studies that investigated pain as an outcome, and estimated the placebo effect to be 0.65 cm on a 10-cm visual analogue scale such as that used in this trial or one third the effect of nonsteroidal antiinflammatory drugs.[20,21]

Several factors may have attenuated the potential benefits of OMT in this trial. First, the fellows used to provide OMT and sham manipulation in this trial were third- and fourth-year medical students in the process of completing an additional year of training devoted to osteopathic theory and practice. It is possible that such predoctoral fellows may not have had sufficient practical experience to provide OMT with the same efficacy as more seasoned practitioners or to provide nontherapeutic sham manipulation. With regard to knee or hip osteoarthritis, a randomized controlled trial using predoctoral fellows to provide treatment failed to demonstrate any clinical benefits attributable to OMT,[22] although previous studies using osteopathic residents found such benefits.[23,24]

Second, although the three treatment groups were comparable with regard to back pain–specific cotreatments and medication use at baseline, the no-intervention control group showed more use of cotreatments than the OMT group at 6 months. The use of more cotreatments may have improved the outcomes of the no-intervention controls, thereby attenuating differences in clinical outcomes in comparisons with the OMT subjects.

Third, to make the current findings more generalizable, the authors sought to include as many subjects with chronic nonspecific low back pain as possible. Thus, 46% of the recruits met eligibility criteria and were randomized to the trial, as compared with 5%[7] and 15%[8] who met eligibility criteria in previous trials of OMT. The relatively low baseline Roland–Morris Disability scores likely were manifestations of the more inclusive criteria used in the current trial and suggest that the subjects were not highly selected to demonstrate large clinical improvements in response to treatment. When studies operate at the low (healthy) end of the Roland–Morris Disability scale, smaller thresholds exist for determining clinically important improvements over baseline scores.[25] Consequently, larger sample sizes are needed to power a trial adequately for such end points. The relatively small sample sizes in this clinical trial impeded its ability to detect small to moderate treatment effects. It is

possible that such OMT benefits may exist and that they are clinically relevant, but that larger trials will be needed to demonstrate them.

Fourth, 10% of the subjects were lost to follow-up evaluation at 1 month, 22% at 3 months, and 27% at 6 months. This slightly exceeds the criterion of 10% to 20% loss to follow-up evaluation used to assess randomized controlled trials of manipulation for back and neck pain,[26,27] although this criterion is somewhat arbitrary and does not allow for greater losses to follow-up evaluation in lengthier trials such as this one. By comparison, in the two OMT trials cited earlier, attrition was 27% at discharge (mean of 30 and 20 days after baseline for OMT and control groups, respectively), 39% at trial completion (mean of 51 and 41 days after baseline for OMT and control groups, respectively),[7] and 13% at trial completion (mean of 12 weeks after baseline).[8]

In summary, this clinical trial found that in comparison with usual care alone, usual care and OMT provided better 1-month outcomes in physical functioning, mental health, and back pain, but that only the latter finding persisted over 6 months. Osteopathic manipulative treatment also resulted in the use of fewer cotreatments at 6 months and provided greater satisfaction throughout the trial. Nevertheless, usual care and sham manipulation also provided better outcomes than usual care alone in back pain, greater satisfaction throughout the trial, and better physical functioning at 3 and 6 months. Methodologically, larger and more powerful studies with more experienced OMT providers and better control of cotreatments are needed to determine whether OMT benefits in chronic nonspecific low back pain are inherently attributable to the manipulation techniques or whether they may be the result of placebo effects.

■ Key Points

- This clinical trial found that in comparison with usual care alone, usual care and OMT provided better outcomes in back pain, physical functioning, mental health, use of cotreatments, and satisfaction with back care.
- Usual care and sham manipulation also provided better outcomes in back pain and physical functioning and greater satisfaction than usual care alone.
- Usual care and OMT did not provide significantly better low back outcomes than usual care and sham manipulation.
- Larger and more powerful studies with more experienced OMT providers and better control of cotreatments are needed to determine whether the benefits of OMT benefits for chronic nonspecific low back pain are inherently attributable to the manipulation techniques or whether they may be the result of placebo effects.

Acknowledgments

The authors express their gratitude to the other faculty, predoctoral fellows, clinic personnel, and employees who assisted in this project.

References

1. Andersson GBJ. The epidemiology of spinal disorders. In: Frymoyer JW, ed. *The Adult Spine: Principles and Practice*. 2nd ed. Philadelphia: Lippincott-Raven, 1997:93–141.
2. Cypress BK. Characteristics of physician visits for back symptoms: a national perspective. *Am J Public Health* 1983;73:389–95.
3. Nachemson AL. Newest knowledge of low back pain: a critical look. *Clin Orthop* 1992;279:8–20.
4. Hanchak NA, Murray JF, Hirsch A, et al. USQA health profile database as a tool for health plan quality improvement. *Manag Care Q* 1996;4:58–69.
5. Bigos S, Bowyer O, Braen G, et al. *Acute Low Back Problems in Adults*. Clinical Practice Guideline No. 14. Rockville, MD: Agency for Healthcare Research and Quality, Public Health Service, U.S. Department of Health and Human Services, 1994.
6. Shekelle PG, Ortiz E, Rhodes S, et al. Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated? *JAMA* 2001;286:1461–7.
7. Hoehler FK, Tobis JS, Buerger AA. Spinal manipulation for low back pain. *JAMA* 1981;245:1835–8.
8. Andersson GB, Lucente T, Davis AM, et al. A comparison of osteopathic spinal manipulation with standard care for patients with low back pain. *N Engl J Med* 1999;341:1426–31.
9. Shekelle PG, Adams AH, Chassin MR, et al. Spinal manipulation for low back pain. *Ann Intern Med* 1992;117:590–8.
10. Ward RC, ed. *Foundations for Osteopathic Medicine*. Philadelphia: Lippincott Williams & Wilkins, 1997.
11. Ware JE, Snow KK, Kosinski M, et al. SF-36 *Health Survey: Manual and Interpretation Guide*. Boston: New England Medical Center, 1993.
12. Ware JE, Gandek B. Overview of the SF-36 health survey and the International Quality of Life Assessment (IQOLA) Project. *J Clin Epidemiol* 1998; 51:903–12.
13. Ogon M, Krismer M, Söllner W, et al. Chronic low back pain measurement with visual analogue scales in different settings. *Pain* 1996;64:425–8.
14. Roland M, Morris R. A study of the natural history of back pain: Part I. development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983;8:141–4.
15. Roland M, Fairbank J. The Roland–Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine* 2000;25:3115–24.
16. Stratford PW, Binkley J, Solomon P, et al. Assessing change over time in patients with low back pain. *Phys Ther* 1994;74:528–33.
17. Bombardier C. Outcome assessments in the evaluation of treatment of spinal disorders: summary and general recommendations. *Spine* 2000;25:3100–3.
18. Wilkinson L, Coward M. Analysis of variance. In: *SYSTAT 7.0: Statistics*. Chicago: SPSS, 1997:119–223.
19. Beurskens A, de Vet HCW, Koke AJA. Responsiveness of functional status in low back pain: a comparison of different instruments. *Pain* 1996;65:71–6.
20. Hróbjartsson A, Gøtzsche PC. Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. *N Engl J Med* 2001;344: 1594–602.
21. Gøtzsche PC. Sensitivity of effect variables in rheumatoid arthritis: a meta-analysis of 130 placebo controlled NSAID trials. *J Clin Epidemiol* 1990;43: 1313–8. [erratum, 1991;44:613]
22. Licciardone JC, Stoll ST, Herron KM, et al. A randomized controlled trial of osteopathic manipulation following knee or hip arthroplasty [abstract]. *J Am Osteopath Assoc* 2000;100:520.
23. Brtain PD, Stoll ST, Dickey JA, et al. Efficacy of osteopathic manipulative treatment in improving clinical outcomes in patients with orthopedic diagnoses admitted to a hospital-based rehabilitation unit [abstract]. *J Am Osteopath Assoc* 1999;99:422.
24. Jarski RW, Loniewski EG, Williams J, et al. The effectiveness of osteopathic manipulative treatment as complementary therapy following surgery: a prospective, match-controlled outcome study. *Altern Ther Health Med* 2000;6:77–81.
25. Beaton DE. Understanding the relevance of measured change through studies of responsiveness. *Spine* 2000;25:3192–9.
26. Koes BW, Assendelft WJ, van der Heijden GJ, et al. Spinal manipulation and mobilisation for back and neck pain: a blinded review. *BMJ* 1991;303: 1298–303.
27. Koes BW, Bouter LM, van der Heijden G. Methodological quality of randomized clinical trials on treatment efficacy in low back pain. *Spine* 1995; 20:228–35.