JAOA

ORIGINAL CONTRIBUTION

A Randomized Controlled Trial of Osteopathic Manipulative Treatment Following Knee or Hip Arthroplasty

John C. Licciardone, DO, MS; Scott T. Stoll, DO, PhD; Kathryn M. Cardarelli, MPH; Russell G. Gamber, DO; Jon N. Swift, Jr, DO; William B. Winn, DO

Context: Preliminary study results suggest that osteopathic manipulative treatment (OMT) may reduce pain, improve ambulation, and increase rehabilitation efficiency in patients undergoing knee or hip arthroplasty.

Objective: To determine the efficacy of OMT in patients who recently underwent surgery for knee or hip osteoarthritis or for a hip fracture.

Design: Randomized controlled trial involving hospital and postdischarge phases.

Setting: Hospital-based acute rehabilitation unit.

Patients: A total of 42 women and 18 men who were hospitalized between October 1998 and August 1999.

Intervention: Patients were randomly assigned to groups that received either OMT or sham treatment in addition to standard care. Manipulation was individualized and performed according to study guidelines regarding frequency, duration, and technique.

Main Outcome Measures: Changes in Functional Independence Measure (FIM) scores and in daily analgesic use during the rehabilitation unit stay; length of stay; rehabilitation efficiency—defined as the FIM total score change per rehabilitation unit day; and changes in Medical Outcomes Study Short Form-36 scores from rehabilitation unit admission to 4 weeks after discharge.

Results: Of 19 primary outcome measures, the only significant difference between groups was decreased rehabilitation efficiency with OMT (2.0 vs 2.6 FIM total score points per day; P=.01). Stratified analyses demonstrated that poorer OMT outcomes were confined to patients with osteoarthritis who underwent total knee arthroplasty (length of stay, 15.0 vs 8.3 days; P=.004; rehabilitation efficiency, 2.1 vs 3.4 FIM total score points per day; P<.001).

Conclusion: The OMT protocol used does not appear to be efficacious in this hospital rehabilitation population.

From the University of North Texas Health Science Center at Fort Worth–Texas College of Osteopathic Medicine (Licciardone, Stoll, Gamber); the University of Texas School of Public Health, Houston (Cardarelli); Mayo Clinic, Rochester, Minn (Swift); and the College of Education and Health Professions, University of Arkansas (Winn).

Supported by grants from the American Osteopathic Association, the Osteopathic Health System of Texas Foundation, and the Carl Everett Charitable Lead Trust Fund.

Address correspondence to John C. Licciardone, DO, MS, University of North Texas Health Science Center at Fort Worth–Texas College of Osteopathic Medicine, 3500 Camp Bowie Blvd, Fort Worth, TX 76107.

E-mail: jlicciar@hsc.unt.edu

Spinal manipulation can be helpful for patients with acute low back problems without radiculopathy when initiated within the first month of symptoms.[1] A clinical trial of osteopathic manipulative treatment (OMT) in patients with low back pain for at least 3 weeks, but less than 6 months, failed to demonstrate a benefit in primary outcomes in 12 weeks. However, patients who received OMT required less medication and less physical therapy than patients who received standard care.[2] Despite growing evidence on the efficacy of OMT in certain acute and subacute musculoskeletal conditions, the role of OMT in treating chronic conditions remains largely unknown.

Osteopathic manipulative treatment has been advocated as a therapy for patients with rheumatic diseases,[3,4] though definitive evidence of efficacy is lacking. In addition, manipulation is believed to play an important part in the management of each stage of osteoarthritis, from early conservative to postsurgical treatment.[5] Osteopathic manipulative treatment has also been advocated in the treatment of patients with hip fractures for pain control and to facilitate patients' return to a nonhospital environment in the geriatric population.[6]

The rehabilitation setting provides an opportunity to learn more about the efficacy of OMT in patients with debilitating conditions, such as osteoarthritis and hip fracture. The two preliminary studies that suggest OMT's efficacy in the postsurgical period in patients undergoing knee or hip arthroplasty are limited by methodologic shortcomings.[7,8] In a clinical outcome study, decreases in pain perception and increases in ambulation in patients who received OMT were reported; however, it is not clear whether outcomes were

Table 1
Description of Osteopathic Manipulative Treatment Techniques Allowed in the Research Protocol*

Technique	Description
Myofascial release	Involves passive palpatory feedback by the operator to achieve release of myofascial tissues. This may involve a direct technique in which the restrictive barrier is engaged and then loaded with a constant force by the operator until release occurs, or it may involve an indirect technique in which myofascial tissue is guided along the path of least resistance until release occurs.
Strain/counterstrain	Involves a gentle, passive force to inhibit inappropriate strain reflexes that are manifested by specific point tenderness.
Muscle energy	Involves directed patient movement from a precisely controlled position against a defined resistance by the operator. This technique may be used to mobilize restricted joints, stretch tight muscles and fascia, improve local circulation, and balance neuromuscular relationships to alter muscle tone.
Soft tissue	Involves tissues other than skeletal or arthrodial elements. This usually involves lateral stretching, linear stretching, deep pressure, traction, or separation of muscle origin and insertion, while monitoring tissue response and motion changes by palpation.
High-velocity low-amplitude	Involves the application of a passive force by the operator over a short distance to mobilize a restricted joint.
Craniosacral	Involves the primary respiratory mechanism based on the interdependent functions of the cranial bones, brain and spinal cord, intracranial and intraspinal membranes, cerebrospinal fluid, and the sacrum.

*Adapted from the *Glossary of Osteopathic Terminology*, available at http://www.osteopathic.org/index.cfm?PageID=ost_glossary.

measured by blinded investigators, and controls did not receive any type of placebo.[7] The other study found significant improvements in locomotion and in rehabilitation efficiency in patients who received OMT.[8] Patients in the latter study were not randomly assigned to groups, and controls—selected from different hospitals than patients who received OMT—did not receive a placebo intervention.

The purpose of the present study was to further assess the efficacy of OMT in patients who recently underwent knee or hip surgery for chronic osteoarthritis or hip fractures.

Methods

Experimental Design

This was a randomized, double-blind, placebo-controlled trial of OMT in patients who recently underwent knee or hip surgery for chronic osteoarthritis or a hip fracture. The study was conducted between October 1998 and August 1999 in the rehabilitation unit of the Osteopathic Medical Center of Texas, Fort Worth. This hospital is a medical training site for the University of North Texas Health Science Center.

The rehabilitation unit was managed by a proprietary entity that administered acute inpatient facilities nationwide.

Therefore, all patients received care that was consistent with the national standard for acute inpatient rehabilitation. The only experimental intervention was the addition of either OMT or sham treatment to standard care in rehabilitation. The institutional review board of the University of North Texas Health Science Center approved all procedures.

Patients

The admissions director of the rehabilitation unit screened patients who were 50 years of age or older to determine whether they met study inclusion criteria: (1) hospitalized with a primary diagnosis of knee or hip osteoarthritis, or hip fracture; and (2) underwent any of the following surgical procedures within 1 week before rehabilitation unit admission: arthroplasty for knee or hip osteoarthritis; arthroplasty for a hip fracture; open reduction–internal fixation for a hip fracture; or revision of a previous knee or hip arthroplasty. Patients who met these screening criteria were interviewed by the research coordinator. This evaluation included a review of the medical record to confirm study eligibility and an assessment of cognitive performance using the Mini-Mental State Examination.[9] The research coordinator administered verbal and written informed consent to all eligible patients judged to be mentally competent to participate within 72 hours of admission.

Randomization and Interventions

Participants were evaluated by an OMT specialist to identify areas of somatic dysfunction, defined as "impaired or altered function of related components of the somatic (body framework) system; skeletal, arthrodial, and myofascial structures; and related vascular, lymphatic, and neural elements."[10] This evaluation served as the basis for an individualized OMT plan for the rehabilitation unit stay. These individualized plans focused on the anatomic region surrounding the surgical site but allowed for manipulation of secondary regions if indicated.

Treatments were performed by undergraduate fellows within the Department of Osteopathic Manipulative Medicine at the University of North Texas Health Science Center at Fort Worth–Texas College of Osteopathic Medicine. Although these select medical students complete an additional year of training in osteopathic principles and OMT before receiving their osteopathic medical degree, students were still in the training process while providing OMT in this study.

These fellows provided OMT according to the following guidelines: (1) 2 to 5 sessions weekly; (2) no more than 2 days between sessions; (3) 10- to 30-minute sessions; (4) one or a combination of the following techniques: myofascial release; strain/counterstrain; muscle energy; soft tissue; high-velocity low-amplitude (not at the surgical site); or craniosacral manipulation. Treatment guidelines reflect an intensity of OMT that may be available in most hospital rehabilitation units. These techniques, described in *Table 1*, are well-accepted modes of OMT.[11] Treatment was individualized, as there are no absolute rules regarding frequency, dose, technique, and sequence of OMT. Individual treatment was also used because patients may respond to a given technique in different ways.[11]

Precoded cards in sealed envelopes were used to randomly allocate patients to groups that received either OMT or sham treatment, with both procedures performed by the same undergraduate fellows according to the preceding guidelines. Sham treatment consisted of range-of-motion activities and light touch. These placebo techniques were applied to anatomic regions identified in the osteopathic evaluation and treatment plan; however, these manually applied forces were of substantially decreased magnitude and were purposely aimed at avoiding key areas of somatic dysfunction.

Measures and Outcomes

Baseline data, collected on admission to the rehabilitation unit, included demographic characteristics, health insurance coverage, medical diagnoses, type of surgery, health status before admission, functional assessment, and daily analgesic medication use. Demographic variables included age, gender, race, and marital status.

Standardized health measures were derived using the Medical Outcomes Study Short Form-36 (SF-36) and the Functional Independence Measure (FIM). The SF-36 is a valid, reliable, and widely used measure of health that provides scores in eight health scales. These scales include physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health.[12] In osteoarthritis patients, following total knee arthroplasty, SF-36 scores for physical functioning and role limitations due to physical problems are significantly correlated with the condition-specific Knee Society function score.[13] The SF-36 is equal or superior to the Sickness Impact Profile, a more established and longer instrument, in detecting physical and global health changes associated with hip arthroplasty.[14]

During the hospital phase of the study, the research coordinator conducted SF-36 face-to-face interviews at admission to and discharge from the rehabilitation unit. The discharge interview addressed only general health perceptions, vitality, and mental health, as the five remaining SF-36 health scales are based on physical or social activities that cannot be done in a hospital rehabilitation unit. The research coordinator subsequently conducted SF-36 telephone interviews 4 weeks after discharge from the rehabilitation unit. Patient responses were transformed using established scoring algorithms to generate standardized health scale scores ranging from 0 to 100 (worst to best possible health).[12]

The FIM instrument is the functional assessment measure of the Uniform Data System for Medical Rehabilitation.[15,16] Because of its use in hospital rehabilitation settings, the instrument was used in the current study to complement the SF-36's generic measures of health. The FIM includes 18 items that measure functional independence in 6 subscales: self-care,

Table 2
Baseline Characteristics of Study Participants*

Characteristic	All Participants (n=60)	OMT Group (n=30)	Sham Treatment Group (n=30)	*P*
Age, y	69.2 (10.3)	68.2 (10.7)	70.2 (10.0)	.46
Sex, No. (%)				.57
Female	42 (70)	20 (67)	22 (73)	
Male	18 (30)	10 (33)	8 (27)	
Race, No. (%)				.77
White	45 (75)	22 (73)	23 (77)	
Nonwhite	15 (25)	8 (27)	7 (23)	
Marital status, No. (%)				.60
Married	26 (43)	14 (47)	12 (40)	
Not married	34 (57)	16 (53)	18 (60)	
Health insurance, No. (%)				.42
Medicare	25 (42)	11 (37)	14 (47)	
HMO or PPO	23 (38)	11 (37)	12 (40)	
Other	12 (20)	8 (27)	4 (13)	
Primary diagnosis, No. (%)				.08
Osteoarthritis (knee or hip)	44 (73)	25 (8)	19 (63)	
Hip fracture	16 (27)	5 (17)	11 (37)	
Comorbidities, No.	4.2 (2.1)	4.2 (2.3)	4.2 (1.8)	.95
Surgery, No. (%)				.07
Knee arthroplasty	30 (50)	19 (63)	11 (37)	
Hip arthroplasty	27 (45)	9 (30)	18 (60)	
Open reduction-internal fixation	3 (5)	2 (7)	1 (3)	
Hospital stay before rehabilitation, d	4.2 (3.7)	3.7 (2.1)	4.6 (4.8)	.35

(continued)

* Values are expressed as mean (SD) unless otherwise indicated. A higher score represents better health or functioning on both the SF-36 and FIM scales. *P* values are for the differences between OMT and sham treatment groups.
OMT indicates osteopathic manipulative treatment; HMO, health maintenance organization; PPO, preferred provider organization.

sphincter control, mobility, locomotion, communication, and social cognition.[17,18] Each item is rated on a seven-point scale that represents different gradations of independence and reflects the amount of assistance the patient requires to perform a specific activity. Independence is categorized and scored as complete independence, 7; modified independence, 6; requires supervision or setup, 5; requires minimal contact assistance, 4; requires moderate assistance, 3; requires maximal assistance, 2; and requires total assistance, 1.[18]

These ordinal-scale responses closely approximate interval-scale data except at the endpoints of the scales.[19] The scores on each scale may be summed to generate a total score, and changes over time may be used to measure rehabilitation outcomes.[19] Functional Independence Measure performance has been validated in rehabilitation inpatients, including those with orthopedic conditions.[20] Trained rehabilitation unit personnel, including nurses and speech, occupational, and physical therapists, scored the FIM items on admission to and discharge from the rehabilitation unit.

The primary outcome measures were changes in FIM subscale and total scores and in daily analgesic use during the rehabilitation unit stay; length of stay; rehabilitation efficiency—defined as the FIM total score change per rehabilitation unit day[15]; and changes in SF-36 health scale scores from rehabilitation unit admission to 4 weeks after discharge. All study personnel who were responsible for developing OMT

Table 2
Baseline Characteristics of Study Participants* (continued)

Characteristic	All Participants (n=60)	OMT Group (n=30)	Sham Treatment Group (n=30)	*P*
Analgesic medication, mg/d†				
Acetaminophen	2801 (1829)	2899 (1642)	2699 (2030)	.68
Hydrocodone	30.1 (17.3)	31.0 (14.8)	29.0 (20.4)	.71
SF-36 health scale score‡				
Physical functioning	38.1 (27.1)	39.0 (27.6)	37.1 (27.1)	.79
Role limitations, physical	19.9 (35.9)	21.7 (37.6)	18.1 (34.7)	.71
Bodily pain	38.5 (31.6)	31.0 (27.5)	46.3 (34.2)	.06
General health	61.2 (25.1)	60.7 (24.6)	61.8 (26.1)	.86
Vitality	32.5 (22.2)	32.5 (20.7)	32.5 (24.0)	.99
Social functioning	53.4 (30.9)	52.5 (30.4)	54.3 (31.9)	.82
Role limitations, emotional	53.7 (47.1)	50.0 (47.7)	57.5 (47.1)	.55
Mental health	67.6 (20.8)	62.1 (22.2)	73.1 (18.0)	.04
FIM subscale score§				
Self-care	4.5 (0.7)	4.6 (0.8)	4.4 (0.6)	.35
Sphincter control	4.5 (1.8)	4.4 (1.8)	4.6 (1.8)	.62
Mobility	3.4 (1.1)	3.4 (1.1)	3.4 (1.0)	.91
Locomotion	1.5 (0.7)	1.3 (0.5)	1.8 (0.8)	.01
Communication	6.6 (0.7)	6.7 (0.6)	6.6 (0.7)	.77
Social cognition	6.6 (0.6)	6.6 (0.7)	6.6 (0.6)	.58
FIM total score at admission§	82.0 (11.3)	81.8 (11.9)	82.3 (10.9)	.86
FIM total score discharge goal§	108.5 (7.8)	107.7 (8.1)	109.3 (7.6)	.45

* Values are expressed as mean (SD) unless otherwise indicated. A higher score represents better health or functioning on both the SF-36 and FIM scales. *P* values are for the differences between OMT and sham treatment groups.
† Acetaminophen (29 patients in the OMT group, 28 patients in the sham treatment group) and hydrocodone (25 patients in the OMT group, 20 patients in the sham treatment group) were the two analgesics used by most of the patients. Most patients used multiple analgesics.
‡ The SF-36 health scales were scored from 0 to 100 (worst to best possible score).
§ The FIM subscales and total were scored from 1 to 7 and 18 to 126, respectively (worst to best possible score).
OMT indicates osteopathic manipulative treatment; HMO, health maintenance organization; PPO, preferred provider organization; SF-36, Medical Outcomes Study Short Form 36; FIM, Functional Independence Measure.

plans or measuring primary outcomes were blinded to group assignments. The only personnel aware of these assignments were the undergraduate fellows who performed OMT and sham treatments; however, they did not measure any of the study outcomes.

Statistical Analysis

Baseline measures were summarized using descriptive statistics. Comparisons of patients who completed the hospital phase of the study, eligible patients who refused to participate or who did not complete the hospital phase, and patients who were ineligible because of dementia were made using the chi-square test for categorical variables and analysis of variance, with Tukey's post-hoc test, for continuous variables. Differences between OMT and sham-treatment patients were assessed using the chi-square test for categoric variables and the Student *t*-test for continuous variables. As the SF-36 general health perceptions, vitality, and mental health scales were measured three times (at rehabilitation unit admission, discharge, and 4 weeks after discharge), repeated measures analysis of variance was used to assess these outcomes. Analysis of covariance was used to adjust for potential confounding of study outcomes. Stratified analyses were used to determine the efficacy of OMT in patients with osteoarthritis or hip fracture and for each surgical site among patients with osteoarthritis.

Table 3
Primary Outcome Measures*

Measure	OMT Group (n=30)	Sham Treatment Group (n=30)	*P*
Change from rehabilitation unit admission to discharge			
FIM subscale score†			
Self-care	1.6 (0.6)	1.7 (0.5)	.33
Sphincter control	2.1 (1.6)	1.6 (1.7)	.28
Mobility	2.3 (0.9)	2.3 (0.9)	.93
Locomotion	2.9 (1.1)	2.8 (1.1)	.64
Communication	0.0 (0.1)	0.1 (0.4)	.47
Social cognition	0.1 (0.2)	0.0 (0.1)	.39
FIM total score†	26.5 (7.0)	26.2 (6.5)	.86
Analgesic medication, mg/d			
Acetaminophen	−741 (1471)	−371 (1715)	.39
Hydrocodone	−9.9 (16.9)	−8.0 (13.3)	.68
At rehabilitation unit discharge			
Length of stay, d	15.4 (6.6)	12.3 (7.4)	.09
Rehabilitation efficiency‡	2.0 (0.7)	2.6 (1.1)	.01
Change from rehabilitation unit admission to 4 weeks after discharge			
SF-36 health scale score§			
Physical functioning	−10.0 (31.3)	−15.0 (27.2)	.55
Role limitations, physical	−16.3 (42.4)	−7.0 (37.9)	.41
Bodily pain	22.9 (36.7)	13.3 (38.0)	.37
General health	4.9 (19.9)	3.3 (17.9)	.76
Vitality	9.2 (23.2)	9.0 (33.7)	.98
Social functioning	16.4 (41.5)	1.0 (32.5)	.15
Role limitations, emotional	24.4 (58.5)	22.7 (45.9)	.91
Mental health	10.6 (23.4)	4.8 (12.7)	.27

* Values are expressed as mean (SD). Positive changes on the SF-36 and FIM represent improvements. Negative changes for analgesic medication represent decreased use.
† The FIM subscales and total were scored from 1 to 7 and 18 to 126, respectively (worst to best possible score).
‡ Rehabilitation efficiency was computed as the FIM total score change per rehabilitation unit day.
§ The SF-36 health scales were scored from 0 to 100 (worst to best possible score).
OMT indicates osteopathic manipulative treatment; FIM, Functional Independence Measure; SF-36, Medical Outcomes Study Short Form 36.

Based on well-established data, we estimated the sample size to have 80% power in detecting 11- to 20-point or greater group differences in the SF-36 health scales.[12] Using more preliminary experience,[8] we estimated that the sample size provided 80% power in detecting 9-point or greater group differences in FIM total score change and 7-day or greater group differences in length of stay. Any of these outcomes is considered not only to be statistically significant, but also clinically relevant.[12,20] All hypotheses were tested at the .05 level of significance using two-tailed statistics. Statistical analyses were performed using SYSTAT 7.0 for Windows (Systat Software Inc, Richmond, Calif).

Results

Recruitment and Follow-up of Patients

Patient flow and retention are summarized in the *Figure*. Of 96 potentially eligible patients, 16 were excluded because of dementia. Among the remaining 80 patients, 11 refused to

Table 4
Primary Outcome Measures in Osteoarthritis Patients*

Measure	All Osteoarthritis Patients: OMT Group (n=25)	All Osteoarthritis Patients: Sham Treatment Group) (n=19	*P*	Knee Osteoarthritis Patients: OMT Group (n=19)	Knee Osteoarthritis Patients: Sham Treatment Group (n=11)	*P*
Change from rehabilitation unit admission to discharge						
FIM subscale score†						
Self-care	1.6 (0.6)	1.6 (0.5)	.95	1.5 (0.6)	1.7 (0.6)	.43
Sphincter control	2.1 (1.6)	1.4 (1.7)	.19	2.4 (1.5)	1.2 (1.8)	.07
Mobility	2.3 (0.9)	2.3 (0.9)	.95	2.3 (0.9)	2.5 (0.9)	.62
Locomotion	3.1 (1.0)	3.2 (0.9)	.70	2.9 (1.0)	3.3 (1.1)	.42
Communication‡	0.0 (0.1)	0.0 (0.0)	NA	0.0 (0.1)	0.0 (0.0)	NA
Social cognition‡	0.1 (0.2)	0.0 (0.0)	NA	0.1 (0.2)	0.0 (0.0)	NA
FIM total score†	27.0 (7.3)	25.6 (7.7)	.56	27.1 (7.8)	26.6 (8.1)	.89
Analgesic medication, mg/d						
Acetaminophen	−782 (1574)	10 (1889)	.15	−857 (1617)	433 (1919)	.07
Hydrocodone	−10.1 (17.7)	−6.7 (16.8)	.59	−11.4 (18.3)	−9.2 (12.0)	.79
At rehabilitation unit discharge						
Length of stay, d	14.9 (6.4)	9.3 (3.4)	.001	15.0 (6.7)	8.3 (3.0)	.004
Rehabilitation efficiency§	2.1 (0.7)	3.0 (1.0)	.001	2.1 (0.8)	3.4 (1.0)	<.001
Change from rehabilitation unit admission to 4 weeks after discharge						
SF-36 health scale score¶						
Physical functioning	−1.0 (26.3)	−9.0 (26.6)	.37	−4.3 (28.9)	−3.8 (28.9)	.96
Role limitations, physical	−9.5 (38.3)	5.0 (34.3)	.25	−15.0 (41.0)	9.4 (18.6)	.13
Bodily pain	29.0 (29.0)	23.4 (31.0)	.58	21.5 (28.4)	23.0 (26.7)	.91
General health	7.5 (19.8)	5.8 (18.4)	.80	2.5 (16.4)	5.3 (10.4)	.67
Vitality	9.8 (21.2)	21.3 (33.4)	.21	8.3 (19.2)	29.4 (29.9)	.05
Social functioning	25.6 (40.1)	8.0 (27.7)	.15	16.3 (41.9)	17.2 (25.9)	.96
Role limitations, emotional	34.9 (57.2)	17.8 (45.2)	.34	26.7 (45.8)	29.2 (51.8)	.91
Mental health	14.3 (22.6)	4.0 (13.1)	.11	14.4 (20.6)	3.0 (10.0)	.16

* Values are expressed as mean (SD). All knee osteoarthritis patients had arthroplasty. Positive changes on the SF-36 and FIM represent improvements. Negative changes for analgesic medication represent decreased use.
† The FIM subscales and total were scored from 1 to 7 and 18 to 126, respectively (worst to best possible score).
‡ The *t*-test could not be performed because there were no changes reported by any of the patients in the sham treatment group.
§ Rehabilitation efficiency was computed as the FIM total score change per rehabilitation unit day.
¶ The SF-36 health scales were scored from 0 to 100 (worst to best possible score).
OMT indicates osteopathic manipulative treatment; FIM, Functional Independence Measure; SF-36, Medical Outcomes Study Short Form 36.

participate, 3 were admitted during nonrecruitment intervals (holidays during which study personnel were not available), 3 were randomly assigned but discharged before initial osteopathic evaluation or before receiving any treatment, and 3 were randomly assigned but prematurely transferred out of the rehabilitation unit for extraneous reasons (2 were transferred because of inadequate health insurance coverage and 1 was transferred because of a cardiac complication). Patients with dementia were significantly older than those who completed the hospital phase of the study (78.1 vs 69.2 years; P=.01) and,

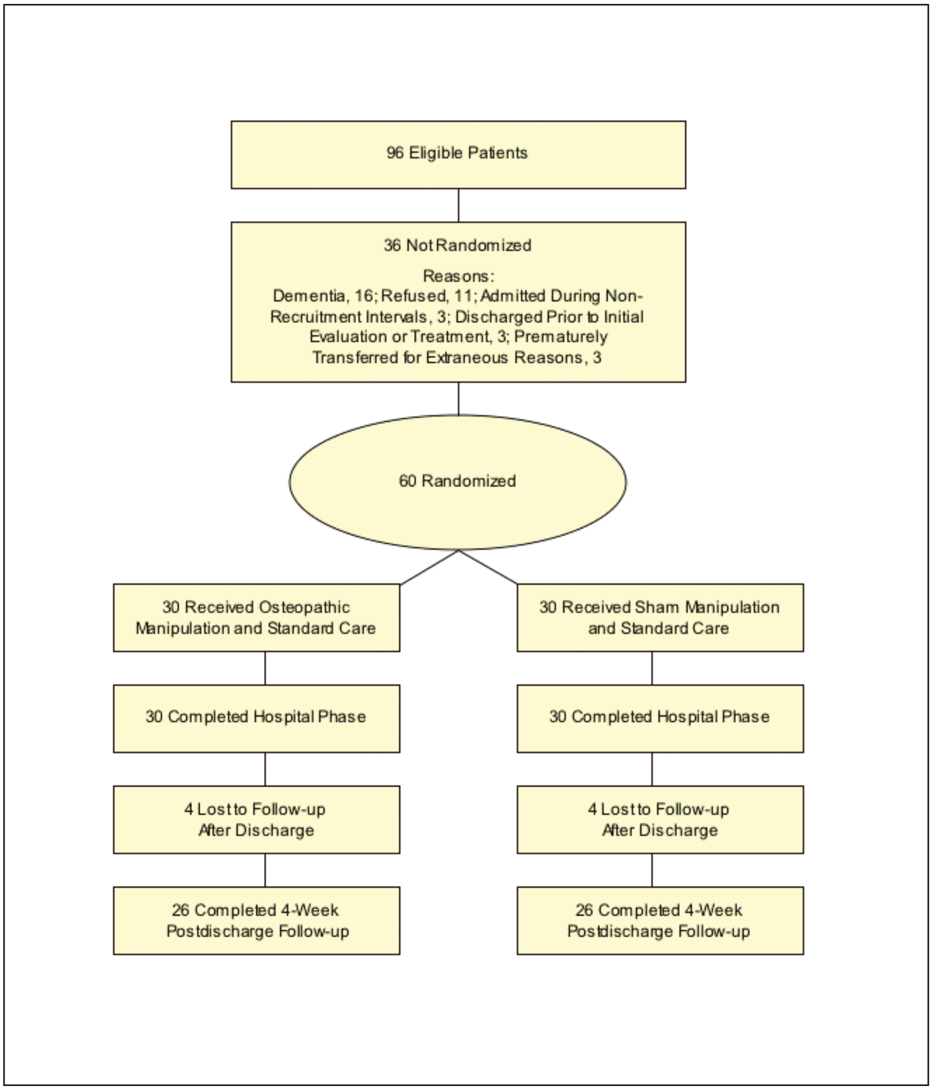

Figure. *Profile of the randomized controlled trial.*

consequently, were more likely to have Medicare insurance (80% vs 42%; $P = .02$), a primary diagnosis of hip fracture (81% vs 27%; $P < .001$), and surgery other than a knee or hip arthroplasty (44% vs 5%; $P < .001$).

There were no significant differences in any of the aforementioned characteristics, nor in gender, race, marital status, or number of comorbid conditions between the 20 eligible patients who refused to participate or did not complete the hospital phase of the study and the 60 participants who completed the hospital phase. Four patients in each group were lost to follow-up after discharge. When these lost patients were compared on 36 baseline characteristics and rehabilitation unit outcomes, they differed significantly only in the baseline SF-36 vitality score, which favored OMT patients (35.0 vs 10.0; $P = .02$).

Baseline Characteristics

The typical participant was 69 years old, female, white, and had four comorbid conditions (*Table 2*). Osteoarthritis was the predominant diagnosis (73%), with the knee being the surgical site approximately twice as often as the hip. All patients with knee osteoarthritis had undergone total knee arthroplasty. The mean scores on all SF-36 health scales were significantly below national norms[12]; however, the FIM total score was identical to that reported for rehabilitation inpatients with orthopedic conditions.[20] Most patients used acetaminophen (95%) and hydrocodone (75%) for analgesia at admission.

Patients with hip fractures had significantly longer rehabilitation unit length of stay than patients with osteoarthritis (17.6 vs 12.5 days; $P = .01$). Rehabilitation efficiency was also lower in patients with hip fracture (1.8 vs 2.5 FIM total score points daily; $P = .02$). Age was directly related to length of stay ($P = .002$) and inversely related to rehabilitation efficiency

($P=.001$). Sex, race, marital status, health insurance coverage, and number of comorbid conditions had no significant associations with primary outcomes.

Baseline characteristics favored the sham treatment group in the SF-36 mental health scale (73.1 vs 62.1; $P=.04$) and in the FIM locomotion subscale (1.8 vs 1.3; $P=.01$). Nevertheless, it seems that patients were adequately randomized because under the null hypothesis the likelihood of observing two or more significant differences between groups in the 27 baseline variables tested can be attributed to chance ($P=.39$). There was also a trend toward better health in the sham treatment group in the SF-36 bodily pain scale (46.3 vs 31.0; $P=.06$).

Outcomes

Patients in the OMT and sham treatment groups had a similar number (5.4 vs 4.7; $P=.39$) and frequency (2.4 vs 2.6 weekly; $P=.18$) of treatments. The mean change in FIM total score exceeded that previously reported for orthopedic patients (26 vs 22 FIM total score points).[20]

Patients in both groups improved in all FIM subscales and decreased their daily analgesic use during the rehabilitation unit stay, though neither group had significantly greater improvement than the other (*Table 3*). Similarly, both groups improved to a comparable degree on the three SF-36 health scales measured at discharge from the rehabilitation unit.

Osteopathic manipulative treatment was associated with lower rehabilitation efficiency (2.0 vs 2.6 FIM total score points daily; $P=.01$) and a trend toward greater length of stay (15.4 vs 12.3 days; $P=.09$). In the postdischarge phase, patients in both groups had similar changes in SF-36 health scale scores when compared with those at admission; scores in physical functioning and role limitations due to physical problems declined because of curtailment of work and other activities in the postsurgical period. Osteopathic manipulative treatment was not significantly better than sham treatment in any primary outcome, even after simultaneously adjusting for baseline group differences in the SF-36 mental health and bodily pain scales and in the FIM locomotion subscale.

Among patients with osteoarthritis, OMT was associated with greater length of stay (14.9 vs 9.3 days; $P=.001$) and lower rehabilitation efficiency (2.1 vs 3.0 FIM total score points daily; $P=.001$) (*Table 4*). These poorer outcomes were limited to patients with knee osteoarthritis (length of stay, 15.0 vs 8.3 days, $P=.004$; rehabilitation efficiency, 2.1 vs 3.4 FIM total score points daily, $P<.001$). Among patients with a hip fracture, there were no significant differences in primary outcomes between patients who received OMT or sham treatments.

Discussion

Two to three OMT sessions weekly, performed by undergraduate fellows, were not efficacious in acute rehabilitation patients who recently underwent surgery for knee or hip osteoarthritis or a hip fracture. Overall, the only significant difference between groups was decreased rehabilitation efficiency with OMT. In patients who underwent arthroplasty for knee osteoarthritis, OMT resulted in significantly poorer outcomes in length of stay, rehabilitation efficiency, and vitality. The reasons for these findings are unclear, and none is explained by demographic characteristics, health insurance coverage, or number of comorbid conditions.

The methodologic aspects of our study were evaluated by adapting two sets of criteria for assessing the quality of randomized clinical trials of spinal manipulation for low back or neck pain.[21,22] Scores of 67 and 82 were achieved in the current study using the criteria of Koes et al[21] and Andersson et al,[22] respectively. These scores exceed those of other studies of manipulation reported in original papers,[21,22] in derivative works,[23-25] and in a recent clinical trial of OMT.[2]

The major methodologic problems in the present study identified through this process are its sample size and the presence of a comprehensive, multidisciplinary treatment program as a standard cointervention in the rehabilitation unit. However, given the significantly poorer outcomes associated with OMT in length of stay and rehabilitation efficiency, it seems unlikely that greater sample size would have uncovered significant benefits associated with our OMT protocol in this rehabilitation population.

Intention-to-treat analysis was not used because our unpublished data from a previous study indicated that only one of 20 patients who received OMT in this setting discontinued treatment. Further, using the criteria of Koes et al,[21] intention-to-treat analysis is not considered to be critical in our research methodology because there was no loss to follow-up during the hospital phase of the study, which included 11 of the 19 primary outcomes. Lack of OMT efficacy cannot be attributed to losses to follow-up after discharge because the rehabilitation unit outcomes of lost patients in each group were similar. Further, the number of patients lost to follow-up were not excessive and were similar in magnitude to those in a recent clinical trial of OMT.[2] The benefits of sessions of OMT lasting between 10 and 30 minutes 2 or 3 times weekly may have been obscured by the other modes of rehabilitation therapy that were provided to all patients several times daily.

The sample size in this study, while limited, allows us to reasonably exclude moderate to large treatment effects attributable to student-performed OMT. However, we cannot rule out more subtle, yet clinically significant, effects. Such effects may have been apparent had we used condition-specific or surgical site–specific outcome measures. Such measures include the Arthritis Impact Measurement Scales, the Western Ontario and McMaster Universities Osteoarthritis Index, the Knee Society clinical rating scale, and the Oxford Hip Score.[26,27] Also, we cannot exclude the possibility that greater efficacy may have been observed had OMT been provided more frequently, for longer duration, or by more experienced practitioners.

It is known that experienced osteopathic physicians record fewer, but more significant, diagnostic findings than trained student examiners.[28] Thus, predoctoral examiners using inefficient filtering processes for palpatory data may translate into less optimal treatment in a time-constrained environment. Despite the additional cost factor, which was prohibitive in this study, the use of osteopathic physicians with more experience must be considered in future research involving the efficacy of OMT.

Findings from the present study also support the theory that a spectrum of conditions exists with varying degrees of responsiveness to OMT. At one end of the spectrum, relatively healthy patients with acute, uncomplicated medical conditions seem to respond most favorably to OMT.[1] Patients with subacute conditions may respond less favorably. For example, they may have only marginal improvements in primary outcomes, but they may be maintained on less medication or may use fewer ancillary services.[2] Patients with chronic musculoskeletal conditions who respond least favorably (ie, the rehabilitation patients in the present study) may represent the other end of the spectrum. Additional research should assess the use of OMT at various stages in the natural history of disease and as a complement to standard treatment over time.

Acknowledgment

The authors thank Kimberly Fulda, MPH, and David P. Russo, DO, MPH, for their assistance in this study.

References

1. Bigos S, Bowyer O, Braen G, et al. *Acute Low Back Problems in Adults. Clinical Practice Guideline No. 14.* Rockville, Md: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, 1994.

2. Andersson GB, Lucente T, Davis AM, Kappler RE, Lipton JA, Leurgans S. A comparison of osteopathic spinal manipulation with standard care for patients with low back pain. *N Engl J Med*. 1999;341:1426-1431.

3. Rubin BR. Rheumatology. In: Ward RC, ed. *Foundations for Osteopathic Medicine*. Baltimore, Md: Williams & Wilkins; 1997:459-466.

4. Rubin BR, Gamber RG, Cortez CA, Wright TJ, Shores J, Davis G. Treatment options in fibromyalgia syndrome [abstract]. *J Am Osteopath Assoc*. 1990;90:844-845.

5. Tucker WE. Treatment of osteoarthritis by manual therapy. *Br J Clin Pract*. 1969;23:3-8.

6. Scott RA. Orthopaedics. In: Ward RC, ed. *Foundations for Osteopathic Medicine*. Baltimore, Md: Williams & Wilkins; 1997:329-347.

7. 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.

8. Brittain PD, Stoll ST, Dickey JA, Licciardone JC, Romanski VV. 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.

9. Folstein MF, Folstein SE, McHugh PR. "Mini-Mental State": a practical method for grading the cognitive state of patients for the clinician. *J Psychiat Res*. 1975;12:189-198.

10. Rumney IC. Basic terminology for osteopathic procedures. *J Am Osteopath Assoc*. 1971;70:1275-1288.

11. Ward RC, ed. *Foundations for Osteopathic Medicine*. Baltimore, Md: Williams & Wilkins; 1997.

12. Ware JE Jr, Snow KK, Kosinski M, Gandek B. *SF-36 Health Survey: Manual and Interpretation Guide*. Boston, Mass: New England Medical Center; 1993.

13. Kantz ME, Harris WJ, Levitsky K, Ware JE Jr, Davies AR. Methods for assessing condition-specific and generic functional status outcomes after total knee replacement. *Med Care*. 1992;30:MS240-252.

14. Katz JN, Larson MG, Phillips CB, Fossel AH, Liang MH. Comparative measurement sensitivity of short and longer health status instruments. *Med Care*. 1992;30:917-925.

15. Granger CV, Hamilton BB. UDS report. The Uniform Data System for Medical Rehabilitation Report of First Admissions for 1990. *Am J Phys Med Rehabil*. 1992;71:108-113.

16. Granger CV, Hamilton BB. The Uniform Data System for Medical Rehabilitation report of first admissions for 1991. *Am J Phys Med Rehabil*. 1993;72:33-38.

17. Granger CV, Hamilton BB, Linacre JM, Heinemann AW, Wright BD. Performance profiles of the functional independence measure. *Am J Phys Med Rehabil*. 1993;72:84-89.

18. Linacre JM, Heinemann AW, Wright BD, Granger CV, Hamilton BB. The structure and stability of the Functional Independence Measure. *Arch Phys Med Rehabil*. 1994;75:127-132.

19. Long WB, Sacco WJ, Coombes SS, Copes WS, Bullock A, Melville JK. Determining normative standards for functional independence measure transitions in rehabilitation. *Arch Phys Med Rehabil*. 1994;75:144-148.

20. Dodds TA, Martin DP, Stolov WC, Deyo RA. A validation of the functional independence measurement and its performance among rehabilitation inpatients. *Arch Phys Med Rehabil*. 1993;74:531-536.

21. Koes BW, Assendelft WJ, van der Heijden GJ, Bouter LM, Knipschild PG. Spinal manipulation and mobilisation for back and neck pain: a blinded review. *BMJ*. 1991;303:1298-1303.

22. Anderson R, Meeker WC, Wirick BE, Mootz RD, Kirk DH, Adams A. A meta-analysis of clinical trials of spinal manipulation. *J Manipulative Physiol Ther*. 1992;15:181-194.

23. Assendelft WJ, Koes BW, van der Heijden GJ, Bouter LM. The efficacy of chiropractic manipulation for back pain: blinded review of relevant randomized clinical trials. *J Manipulative Physiol Ther*. 1992;15:487-494.

24. Koes BW, Assendelft WJ, van der Heijden GJ, Bouter LM. Spinal manipulation for low back pain. An updated systematic review of randomized clinical trials. *Spine*. 1996;21:2860-2871.

25. Shekelle PG, Adams AH, Chassin MR, Hurwitz EL, Brook RH. Spinal manipulation for low-back pain. *Ann Intern Med*. 1992;117:590-598.

26. Kreibich DN, Vaz M, Bourne RB, et al. What is the best way of assessing outcome after total knee replacement? *Clin Orthop*. 1996:221-225.

27. Dawson J, Fitzpatrick R, Murray D, Carr A. The problem of 'noise' in monitoring patient-based outcomes: generic, disease-specific and site-specific instruments for total hip replacement. *J Health Serv Res Policy*. 1996;1:224-231.

28. Kappler RE, Larson NJ, Kelso AF. A comparison of osteopathic findings on hospitalized patients obtained by trained student examiners and experienced osteopathic physicians [abstract]. *J Am Osteopath Assoc*. 1971;70:1091-1092.

Bone and Joint
DECADE
2002 - USA - 2011