JAOA

ORIGINAL CONTRIBUTION

Osteopathic manipulative treatment in conjunction with medication relieves pain associated with fibromyalgia syndrome: Results of a randomized clinical pilot project

RUSSELL G. GAMBER, DO; JAY H. SHORES, PHD; DAVID P. RUSSO, BA; CYNTHIA JIMENEZ, RN; BENARD R. RUBIN, DO

Osteopathic physicians caring for patients with fibro-myalgia syndrome (FM) often use osteopathic manipu-lative treatment (OMT) in conjunction with other forms of standard medical care. Despite a growing body of evi-dence on the efficacy of manual therapy for the treatment of selected acute musculoskeletal conditions, the role of OMT in treating patients with chronic conditions such as FM remains largely unknown.

Twenty-four female patients meeting American Col-lege of Rheumatology criteria for FM were randomly assigned to one of four treatment groups: (1) manipulation group, (2) manipulation and teaching group, (3) moist heat group, and (4) control group, which received no addi-tional treatment other than current medication. Partici-pants' pain perceptions were assessed by use of pain thresholds measured at each of 10 bilateral tender points using a 9-kg dolorimeter, the Chronic Pain Experience Inventory, and the Present Pain Intensity Rating Scale. Patients' affective response to treatment was assessed using the Self-Evaluation Questionnaire. Activities of daily living were assessed using the Stanford Arthritis Center Disability and Discomfort Scales: Health Assess-ment Questionnaire. Depression was assessed using the Center for Epidemiological Studies Depression Scale.

Significant findings between the four treatment groups on measures of pain threshold, perceived pain, attitude toward treatment, activities of daily living, and per-ceived functional ability were found. All of these findings favored use of OMT. This study found OMT combined with standard medical care was more efficacious in treating FM than standard care alone. These findings need to be replicated to determine if cost savings are incurred when treatments for FM incorporate nonpharmacologic ap-proaches such as OMT.

(Key words: osteopathic manipulative treatment, orthopedic manipulation, fibromyalgia, clinical trials)

Fibromyalgia (FM) syndrome is a common nonarticular, rheumatic musculoskeletal pain disorder for which a definite cause has yet to be identified.[1] Diffuse muscu-loskeletal pain and aching, the presence of multiple tender points (TP), disturbed sleep, fatigue, and morning stiffness characterize the syndrome. Central to the American College of Rheumatology's FM diagnostic criteria are the presence of reproducible TPs on physical examination. These TPs must be located in all four quadrants of the body, including the axial skeleton, and must elicit pain—not mere subjective dis-comfort or tenderness—to palpation with a force of 4 kg.[2]

Approximately 10% to 12% of the general population suffers from chronic pain, and FM is the second most common diagnosis in rheumatology clinics.[3] Fibromyalgia syndrome appears to be more common in women and exhibits increasing prevalence as a function of age and comor-bidity.[4] Medical service use and disability rates are high among patients in whom fibromyalgia is diagnosed.[5] Simi-larly, use of a variety of complementary and alternative modes of therapy also appears to be common among patients with FM.[6]

The prevalence of psychiatric symptoms among patients in whom FM is diagnosed is high. A lifetime history of depression has been reported in up to 70% of patients with FM.[7] Psychological stress has been shown to exacerbate the expression of primary FM symptoms. Moreover, it appears that FM is often associated with several other recently described "functional somatic syndromes" such as irritable bowel syndrome, chronic fatigue syndrome, and multiple chemical sensitivity.[8]

Medication therapy, including the use of antidepres-sants and nonsteroidal anti-inflammatory drugs, has been the mainstay of treatment for FM. Of these pharmacologic inter-ventions, tricyclic antidepressants, such as amitriptyline hydrochloride, have been the most widely studied and eval-uated. In general, use of these medications has resulted in relief of symptoms, but these benefits are modest and decrease over time.[9] Nonpharmacologic approaches, including fitness training programs,[10-12] biofeedback,[13] elec-

troacupuncture,[14] and cognitive-behavioral psychotherapy,[15] have demonstrated some overall efficacy.

Osteopathic physicians involved in the care of patients with FM often use osteopathic manipulative treatment (OMT) in conjunction with standard medical care. Despite a growing body of evidence on the efficacy of manual therapy for the treatment of selected acute musculoskeletal conditions, the role of OMT in treating chronic conditions such as FM remains largely unknown. Manual modes of therapy such as OMT have been promoted as therapeutic options for chronic rheumatic diseases on theoretical grounds,[16] but rigorously controlled studies are lacking. One pilot study of the effectiveness of chiropractic management on FM symptoms demonstrated improved cervical and lumbar range of motion but failed to effect any of the primary clinical signs and symptoms defining FM, such as reduction in TP burden, overall pain, or perceived functional ability.[17] Another retrospective case study review of 20 patients with FM unresponsive to standard treatment showed immediate benefit in terms of decreased pain and increased function from strain-counterstrain techniques, a common form of OMT.[18]

The purpose of the present study was to assess the efficacy of OMT as an adjunct to standard medical care in a university clinic–based population of rheumatology patients in whom FM was diagnosed. Of particular interest was the question of what effect OMT might have on functional outcomes and psychological well-being. These therapeutic endpoints have been documented as missing in previous randomized clinical trials (RCT) for fibromyalgia.[19]

Methods
Experimental design
This was a randomized, observer-masked, placebo-controlled clinical trial of OMT in patients in whom FM was diagnosed who received medical care in a university-based rheumatology clinic at the University of North Texas Health Science Center in Fort Worth, Texas. The study assessed all outcomes using a repeated-measures design. The clinic is a training site for osteopathic medical students and internal medicine residents at the University of North Texas Health Science Center and a regional referral center for patients requiring specialized management of rheumatic and musculoskeletal diseases. The institutional review board of the University of North Texas Health Science Center approved all procedures and interventions used in this study.

Study population
Participants in this study were patients presenting to the rheumatology clinics at the University of North Texas Health Science Center in Fort Worth, Texas. A research technician screened all patients and offered admission to those who met the following criteria: (1) a diagnosis of FM based on the 1990 American College of Rheumatology criteria for FM; (2) absence of concurrent illnesses of consequence (eg, peptic ulcer disease,

cardiac arrythmias, disease requiring CNS suppression); (3) aged between 30 and 65 years old; (4) no concurrent participation in other physical or manual modalities such as therapeutic massage, chiropractic services, physical therapy, or OMT with a concurrent physician. A research coordinator reviewed medical records to confirm study eligibility and obtained verbal and written informed consent. As part of their participation in this study, patients received free medical treatment and laboratory tests related to their FM for the duration of the 6-month study as well as a $100 stipend to defray travel expenses.

Randomization and interventions
Precoded cards in sealed envelopes were used to randomly allocate 24 female patients to one of four treatment groups: (1) manipulation group receiving OMT; (2) manipulation and teaching group receiving OMT in addition to instruction at every visit on how to self-treat their TPs at home; (3) moist heat group receiving moist heat packs applied to their most troublesome TPs on each physician visit; and (4) control group receiving only their current medication.

All participants remained on any medications prescribed to them before enrollment in the study and met with two physicians on each visit to discuss medication management and general medical concerns. Both the study rheumatologist and the study OMT specialist were encouraged to discuss medical problems and medication management issues with all enrolled patients. On each visit, subjects received identical clinical assessments conducted by a trained research nurse-specialist unaware of participant group assignment. A single OMT specialist delivered all manipulative interventions.

Manipulative treatments were done according to the following guidelines: (1) one treatment per week, (2) 15 to 30 minutes in duration, and (3) a combination of Jones strain/counterstrain techniques and other osteopathic modalities applied to those TPs the patient identified as most troublesome. Other modalities available to the treating physician at his discretion included myofascial release, muscle energy, soft tissue treatment, and craniosacral manipulation. These techniques all represent well-accepted modalities within the osteopathic profession. Treatment was individualized with respect to sequence and number of modalities used per session because it is generally accepted that patients may have differential responses to a given technique.

Measures and outcomes
This study used a control group and repeated-measures design in which all of the participants were assessed on weeks 1, 2, 4, 7, 11, 15, 19, and 23. The participants were assessed in several ways. Pain thresholds were measured at each of 10 bilateral TPs using a 9-kg dolorimeter. Pain indices were obtained using the Chronic Pain Experience Inventory and the Present Pain Intensity Rating Scale (PPI). The Chronic Pain Experience Inventory is an instrument comprising visual-analog Likert

scales assessing the current status of 24 specific affective attributes of pain. The PPI is a single-item anchored scale assessing current overall pain at six levels of severity. Affective response to treatment was assessed using the Self-Evaluation Questionnaire (SEQ). The SEQ is an instrument comprising anchored four-point scales assessing the participant's current status on each of 20 affective attributes. Activities of daily living were assessed using the Stanford Arthritis Center Disability and Discomfort Scales: Health Assessment Questionnaire (HAQ). The HAQ is an instrument comprising anchored four-point scales assessing the subject's ability to perform 20 activities of daily living. Depression was assessed using the Center for Epidemiological Studies Depression Scale. The Center for Epidemiological Studies Depression Scale is an instrument comprising reports on the frequency of occurrence of 20 specific psychological attributes related to pain.

Statistical analysis

A two-way (occasion by group) analysis of variance (ANOVA) was performed on the pain threshold data to test for differences among the treated and untreated subjects. A significant ($P <$ .05) group effect was found for 3 of the 20 tender points. Subsequent analyses were run to identify differences among the four groups using Sheffe's post hoc contrasts ($P <$ .01). Five of the contrasts favored the manipulation and teaching group, 5 favored the manipulation group, and 1 favored the moist heat group. Two of the contrasts mitigated against the heat treatment group, and 9 mitigated against the untreated group.

A two-way ANOVA was performed on data obtained from the SEQ. A significant ($P <$ .05) group effect was found for 5 of the 20 affective attributes. Subsequent Sheffe's post hoc contrasts identified significant ($P <$ .01) differences among the four groups. Ten of the contrasts favored the manipulation and teaching group, and 14 favored the manipulation group. Five of the contrasts mitigated against the heat treatment group, and 11 mitigated against the untreated group.

A two-way ANOVA was performed on the HAQ. A significant ($P <$ .05) group effect was found for 9 of the 20 activities of daily living. Subsequent Sheffe's post hoc contrasts found significant ($P <$ .01) differences among the groups. Five of the contrasts favored the manipulation and teaching group, 26 favored the manipulation group, and 6 favored the control group. Eight of the contrasts mitigated against the manipulation and teaching group in favor of the manipulation group, 23 mitigated against the moist heat group, and 6 mitigated against the control group.

A two-way ANOVA was performed on the CPI data. A significant ($P <$ .05) group effect was found for 11 of the 24 attributes. Subsequent Sheffe's post hoc contrasts identified significant ($P <$ .01) differences among the four groups. Eleven of the contrasts favored the manipulation and teaching group, 31 favored the manipulation group, and 12 favored the control group. Eight of the contrasts mitigated against the manipulation and teaching group in favor of the manipulation group,

36 mitigated against the moist heat group, and 10 mitigated against the control group in favor of the manipulation group.

A two-way ANOVA of the single measure of pain provided by the PPI Rating Scale and Center for Epidemiological Studies Depression Scale resulted in no significant main effect findings.

Results

All patients completed the study. Significant findings were found between the four treatment groups on measures of pain threshold, perceived pain, attitude toward treatment, activities of daily living, and chronic pain attributes. All of these findings favored the patients' receiving OMT. Patients assigned to one of the two manipulated groups had significantly higher pain thresholds at the left and right second costochondral junction and the left medial epicondyle TPs postintervention. They were significantly more satisfied, more comfortable, more relaxed as well as less strained, and less confused compared to patients not receiving OMT. They were also better able to stand alone, cut meat, open a milk carton, walk, open doors, open jars, turn faucets, go shopping, and get in and out of a car compared to control subjects who did not receive OMT. Moreover, they reported fewer symptoms related to failure, frustration, inhibition, struggling, helplessness, guilt, incapacity, wakefulness, and tiredness associated with pain. They were significantly more likely to endorse items indicating that they felt less bothered, had good appetites more often, were less frequently depressed, had less frequent losses of energy, were less often restless, and were less often lonely. The *Figure* presents a summary of the findings of this study that may aid in clinical interpretation. It is a frequency polygon in which each positive finding is weighted +1 and each negative finding is weighted −1.

Comment

This study found that OMT combined with standard medical care was more efficacious in the treatment of FM than standard care alone. If the *Figure* is treated as a model of the effects of clinical treatment on patient outcomes, then the relative contribution of the treatments to outcomes is clearly seen. Medication alone sometimes made a contribution to the relief of pain. Medication with manipulation contributed to pain relief. Similarly, the addition of teaching patients OMT sometimes contributed. Moist heat, however, did not contribute to pain relief. An identical pattern of contribution is seen in the patients' activities of daily living. Again, medication with manipulation contributed to pain relief, whereas medication with combined manipulation and teaching, and medication alone occasionally contributed. Moist heat did not contribute to increases in the activities of daily living. Contributors to feelings of well-being ("has positive affect") were medication alone and medication with moist heat. Neither medicine with OMT nor medicine with OMT and teaching contributed to this outcome measure. Thus, it may be inferred that OMT offered
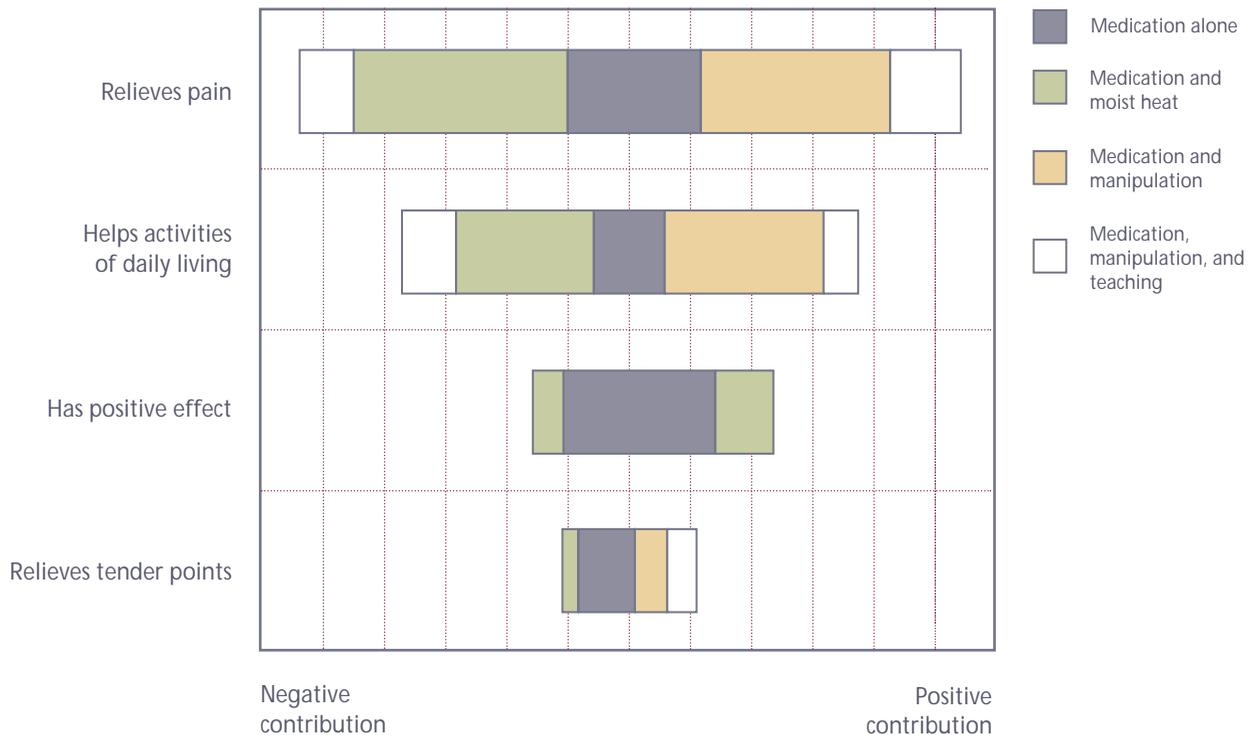
Figure. *Histogram of the frequency of significant findings by treatment and outcome measure. Frequency polygon with positive findings weighted +1 and negative findings weighted −1. Combined medication and manipulation and combined medication, manipulation, and teaching improved perceptions of pain, activities of daily living, and relieved tender points. Medication alone did not relieve tender points.*

more to patients than simple nonspecific effects such as satisfaction with treatment or effects only attributable to elements of the physician-patient relationship. Both forms of manipulation (with and without teaching) combined with medication significantly increased patients' threshold to pain at TPs. Medication alone and medication with moist heat did not contribute to this outcome measure.

In this study, OMT also appeared to affect other symptoms associated with FM in a variety of ways. Use of OMT raised pain thresholds, improved comfort levels and affective components related to chronic illness, and increased the perceived functional abilities of treated patients. This finding contrasts those in a recent metanalysis of 49 FM treatment outcome studies, which showed that physically-based treatments, such as exercise therapy and prescribed home stretching regimens, did not significantly improve daily functioning.[20] Explanations for differences in daily functioning outcomes between physically-based treatments such as OMT and exercise therapy are unclear.

The methodologic aspects of our study were evaluated by adapting two sets of criteria for assessing the quality of RCTs of spinal manipulation for low back or neck pain.[21,22] Scores of 59 and 90 were achieved for the present study using the criteria of Koes et al[21] and Anderson et al,[22] respectively. This study addressed a weakness identified in previous RCTs for FM by measuring functional and psychological variables and incorporating the use of well-validated data collection instruments.[19]

The prevalence of FM in the general population is estimated at 2% to 12%.[4] If that estimated prevalence is accurate, then the cost to our economy in lost work time may exceed the cost of many better-documented illnesses.[23] There is an emerging consensus that the most effective disease management programs for FM are multimodal and incorporate a blend of treatment strategies targeting both physical and psychological aspects of the syndrome.[24] Future investigations with larger sample sizes at multiple centers are needed to determine if cost savings are incurred when treatments for FM incorporate nonpharmacologic approaches such as OMT.

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