Supplemental Care With Medication-Assisted Manipulation Versus Spinal Manipulation Therapy Alone for Patients With Chronic Low Back Pain

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Abstract

Objectives: To measure changes in pain and disability for chronic low-back pain patients receiving treatment with medication-assisted manipulation (MAM) and to compare these to changes in a group only receiving spinal manipulation.

Study Design: Prospective cohort study of 68 chronic low-back pain patients.

Methods: Outcomes were measured using the 1998 Version 2.0 American Association of Orthopaedic Surgeons/Council of Musculoskeletal Specialty Societies/Council of Spine Societies Outcomes Data Collection Instruments. The primary outcome variable was change in pain and disability. All patients received an initial 4- to 6-week trial of spinal manipulation therapy (SMT), after which 42 patients received supplemental intervention with MAM and the remaining 26 patients continued with SMT.

Results: Low back pain and disability measures favored the MAM group over the SMT-only group at 3 months (adjusted mean difference of 4.4 points on a 100-point scale, 95% confidence interval [CI] −2.2 to 11.0). This difference attenuated at 1 year (adjusted mean difference of 0.3 points, 95% CI −8.6 to 9.2). The relative odds of experiencing a 10-point improvement in pain and disability favored the MAM group at 3 months (odds ratio 4.1, 95% CI 1.3-13.6) and at 1 year (odds ratio 1.9, 95% CI 0.6-6.5).

Conclusion: Medication-assisted manipulation appears to offer some patients increased improvement in low back pain and disability. Further investigation of these apparent benefits in a randomized clinical trial is warranted. (J Manipulative Physiol Ther 2005;28:245-252)

Key Indexing Terms: *Manipulation, Chiropractic; Low Back Pain; Medication-Assisted Manipulation; Manipulation Under Anesthesia*

Studies of medication-assisted manipulation (MAM) techniques have appeared in the literature since 1930.[1] Manipulation under anesthesia (MUA),[2-5] manipulation under joint anesthesia/analgesia,[6,7] manipulation under epidural anesthesia,[8] and various injection procedures combined with manipulation therapy[9,10] represent examples of MAM techniques. These protocols have been recommended for a variety of spine-related pain conditions, including chronic lumbosacral and sacroiliac strain,[1,11] acute and chronic low back pain,[9,10,12-15] recalcitrant low back pain and lumbar radiculopathy,[6,8] spinal arthritis,[1,16] sciatica,[1,17] lumbar disk syndrome,[16,18-22] myofibrositis with and without disk herniation,[16,19] postoperative stiffness,[16,23] spondylolisthesis,[16] constant intractable pain,[24] and failed back surgery syndrome.[25]

Osteopaths and orthopedic practitioners typically administered early MAM techniques using long-lever (ie, using the leg or thigh to increase the rotatory force) spinal maneuvers performed with the patient under general anesthesia. Current protocols use specific short-lever (ie, hand to spine) spinal adjustments and mobilization, characteristic of chiropractic and modern osteopathic adjustive techniques, after the administration of shorter acting intravenous sedation and analgesia.[26] Recent studies have investigated currently used MAM protocols, but none have included long-

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term follow-up using a comprehensive set of previously validated measures.

The objectives of this study are (1) to measure immediate and long-term changes in pain and disability for chronic low-back pain patients receiving supplemental treatment with a MAM protocol combining mobilization, spinal manipulation therapy (SMT), and traction therapy of the sacrococcygeal structures; and (2) to compare changes in pain and disability for chronic low-back pain patients receiving supplemental care with MAM to changes in pain and disability for chronic low-back pain patients receiving only a course of usual SMT.

Methods

Study Design and Source Population

Chronic low-back pain patients presenting at 2 private chiropractic practices were recruited for participation in a prospective observational cohort study. Recruitment targeted existing patients and was augmented by radio and newspaper advertisements as well as direct mailings to local physicians requesting referral of appropriate patients. All patients enrolled in the study received an initial 4- to 6-week course of SMT and then followed 1 of 2 potential treatment options: (1) continued care with usual SMT or (2) continued SMT supplemented with MAM procedures.

Allocation to study group was based on clinician recommendation and patient self-selection following re-evaluation after the initial course of SMT. Study participants were followed up for 1 year, with data collected at baseline, 6 weeks, 3 months, 6 months, and 1 year. The source population was made up of adults in the areas served by the 2 chiropractic practices (one located in an urban area of Southern California, the other located in a rural area of Northern California).

Patient Selection

Patients were eligible for the study if they (1) sought care at 1 of the 2 private chiropractic practices from August 20, 2000, to February 5, 2002, (2) presented with chronic (duration >3 months) nonspecific low back pain with or without back-related leg pain, (3) had reduced lumbopelvic flexibility as shown by an inability to touch their fingertips to the floor while maintaining a straight-legged standing posture, and (4) were between the ages of 18 and 60 years.

Potential participants were excluded if they (1) had back pain caused by fracture, tumor, infection, severe spondyloarthropathy, or other nonmechanical cause, (2) had active rheumatoid disease, (3) had any active infectious disease, (4) had a current history of smoking or tobacco use (must not have used tobacco products for at least 6 months before presentation), (5) had a current history of drug and/or alcohol abuse, (6) had severe coexisting disease, (7) had a blood coagulation disorder or were using corticosteroids or anticoagulant medications, (8) were using any form of medication that would conflict with sedating medication as determined by board-certified anesthesiologist members of the treatment team, (9) had any conditions that would preclude the use of manipulation and MAM procedures, (10) lacked the ability to read English, or (11) had low back pain involving third-party liability or worker's compensation.

Patient Screening and Enrollment Protocol

A field coordinator interviewed all patients presenting with chronic low back pain to identify those meeting selection criteria. A brief explanation of study goals and treatment protocols was given to all patients satisfying inclusion criteria. Eligible patients were asked if they were willing to participate in a study designed to help determine effective care for people with low back pain by assessing 2 treatment strategies aimed at reducing pain, improving physical function, and increasing patient satisfaction with treatment. The field coordinator explained that all study participants would receive an initial course of SMT that might be followed by supplemental care with MAM. It was explained that final decision regarding treatment rested with the patient and treating doctor. Patients agreeing to participate in the study received a medical history interview and physical examination. Plain film radiographs and magnetic resonance imaging radiographs were performed before treatment.

Informed Consent

All eligible patients electing to participate in the study were asked to read and sign an informed consent form. The 5-page informed consent form provided explicit detail regarding treatment protocols, potential benefits, potential complications, and possibility of treatment failure. The informed consent form clearly stated that participation in the study was voluntary and that the patient could withdraw from the study or choose alternative treatment at any time. The institutional review board at the Southern California University of Health Sciences approved the study protocol and informed consent form. A field coordinator administered the informed consent form and was available to answer study-related questions. In addition, a clinician met with all eligible patients to provide a detailed explanation of the MAM protocol.

Cohort Selection

All study patients received a 4- to 6-week course of SMT. Patients were then reevaluated after the initial treatment period. Based on the patient's clinical progress, treating clinicians made recommendations regarding additional care that included continued spinal manipulation or supplemental care with MAM. Ultimate decisions regarding choice of treatment group resided with the patient.

Treatment Protocols

Care was provided by 2 chiropractors using similar treatment protocols. For the initial 4 to 6 weeks, SMT was provided to all patients, as well as information about posture and body mechanics and 1 or more of the following, as appropriate: flexibility, aerobic, and strengthening exercises. On average, patient visits were scheduled 2 to 3 times per week during this initial phase of treatment.

Patients were reevaluated at the end of the initial 4 to 6 weeks. Based on the results of this reevaluation, the clinician had 3 options: (1) recommend continued care with spinal manipulation, (2) recommend supplemental care with MAM, or (3) discharge the patient. Supplemental care with MAM was recommended if the initial clinical goals (eg, range of motion, muscle strength, and pain relief) were not met with the course of SMT and the clinician felt further gains likely with the addition of MAM.

Spinal manipulation therapy only. Patients in this group continued to receive SMT similar to the initial phase of treatment. Spinal manipulation involves a controlled dynamic thrust, applied with high velocity and low amplitude, directed at 1 or more joints of the spine using short-lever contacts. Continued care was provided based on clinical evaluation and patient feedback for an additional period of 4 to 12 weeks.

Medication-assisted manipulation. After the initial 4 to 6 weeks of spinal manipulation, patients in this group received 1 to 3 treatments with MAM. Typically, these sessions were provided in consecutive weeks. Medication-assisted manipulation incorporates the intravenous administration of sedative and analgesic medication. The rationale for the addition of sedative and analgesic medication to SMT is that it helps to eliminate or reduce pain and muscle spasm that hinder the effective use of traditional manipulation and mobilization. It is perceived that these procedures allow the practitioner to break up joint adhesions and reduce segmental dysfunction to a greater extent than if medication had not been used. A medical physician with board certification in anesthesiology carefully examined the patients to determine if relaxation and pain-controlling medication were appropriate.

The medication (ketamine hydrochloride and midazolam hydrochloride) delivered enough relaxation and pain relief to make the treatment comfortable, but was designed to wear off quickly. The examination and treatment while under medication took approximately 10 to 20 minutes. While in the relaxed state, the patients underwent a series of spinal and pelvic mobilization maneuvers targeted at increasing joint flexibility and overall range of motion. Cautious administration of SMT was used as indicated. In addition to these elements common to current medication under anesthesia protocols, patients received traction therapy with the intention of improving the movement of sacrococcygeal structures.[27] Patients in this group also continued office visits in support of the MAM results.

Data Collection and Variables

Data were collected using the 1998 Version 2.0 American Association of Orthopaedic Surgeons/Council of Musculoskeletal Specialty Societies/Council of Spine Societies Outcomes Data Collection Instruments.[28] Working with other specialty societies, the American Association of Orthopaedic Surgeons developed a series of instruments designed to collect patient-based data within clinical practices to assess the effectiveness of treatment regimens and in musculoskeletal research settings to study the clinical outcomes of treatment. The lumbar spine module (as well as 10 other primary instruments included in the normative data study and outcomes instruments) is designed to assess the degree to which a patient's condition affects physical and emotional functioning, self-image, and symptom status. In addition, the lumbar spine instruments include the Short-Form 36-Item (SF-36) Health Status Questionnaire.[29] Scales in the instruments rely on multitrait/multi-item response analysis and exhibit high levels of internal reliability and discriminant and convergent validity.[30] Each instrument contains a number of questions; some may be assessed individually, and others may be combined to form scales. Each summated outcomes scale is composed of the scores from related items that are averaged and then rescaled so that each is scored from 0 (poor outcome) to 100 (best possible outcome).

The following data were collected at baseline.

Low back pain and related disability. The pain/disability scale consisted of 11 items, 2 of which questioned the patient about frequency and magnitude of back pain symptoms. The remaining 9 items pertained to impact of these symptoms on activities of daily living (ADLs). Responses to these 11 items were averaged and rescaled to a 100-point scale with a score of 0 representing the most possible pain and disability and a score of 100 representing least possible pain and disability.

Treatment expectations. The treatment expectations scale was derived from responses to 5 items that queried the patient regarding expectations of treatment at baseline in terms of impact on ADLs. On the baseline questionnaire, these items were prefaced by the question, "What results do you expect from your treatment?" In response to the specific ADL items, the patient circled a number from 1 to 5 that represented their belief in the level of likelihood that the treatment would provide improvement. Patients were also given the choice of "not applicable" for these items. The index was scaled so that a score of 0 represents the lowest level of treatment expectations and 100 represents the highest level of treatment expectations.

Comorbidity. The comorbidity index is composed of the scores from related items that were averaged and rescaled so

that each is scored from 0 (no comorbidities) to 100 (highest level of comorbidities). Patients provided information regarding presence of major comorbidities, treatment status regarding any comorbidities, and whether existing comorbidities limited activities.

Health-related quality of life. The lumbar spine module contains the SF-36 Health Survey, Version 2 (SF-36v2), which measures general health-related quality of life.[29] Five of 8 subscales measuring domains of health were used: (1) physical functioning, (2) role limitations caused by physical health, (3) role limitations caused by emotional problems, (4) general health perceptions, and (5) mental health. All 5 measures are scored on a 0- to 100-point scale.

Sociodemographic data. Sociodemographic variables included age, sex, race/ethnicity, education, household income, marital status, and current employment status.

Follow-up questionnaires addressed the same items measured at baseline. Repeated presentation of the various questions and scales provided information about change from baseline. Visit frequency was tracked by review of study patient files in both offices.

Outcome Variables

The primary outcome variable was change in pain and disability measured with a 0-point (most pain and disability) to 100-point (least pain and disability) scale. The pain and disability outcome was treated as a continuous variable when measured with the pain/disability index. This outcome was also used as a dichotomous variable. Cut points of 10 points or more (vs <10 points) on the 100-point scale were used as dichotomous outcomes. The 10-point cut point was chosen a priori as the smallest change felt to be clinically meaningful for pain and disability.

Statistical Analysis

The primary comparison was MAM versus SMT alone. Descriptive statistics were used to summarize the patient characteristics measured at baseline for both treatment groups. Mean values, SDs, and medians were computed for continuous variables, and frequency distributions were generated for categorical variables. Time trends of continuous outcome variables within each group were graphed, and differences from baseline measurements were computed and plotted by time. Adjusted mean differences and 95% confidence intervals (CIs) (controlling for potential differences between groups suggested by comparison of baseline data) between groups on continuous variables were computed at each data collection point.

Logistic regression was used to estimate odds ratios (ORs) and 95% CIs for the likelihood of experiencing at least a 10-point improvement in pain and disability between baseline and the 3-, 6-, and 12-month follow-up intervals. Sample size justification was based on detecting a 10-point difference in pain/disability index scores between groups. An a priori judgement was made that a difference less than 10 points on the pain/disability index would not be clinically meaningful. Sample size calculations suggested that an overall sample size of 80 subjects, 40 subjects per treatment group, would be sufficient to detect between-group differences of 10 points in pain and disability (80% power and $\alpha = .05$). The sample size necessary to detect smaller and probably not clinically significant differences would be substantially larger (eg, detection of 5-point between-group differences would require an overall sample size of 260 subjects with 80% power and $\alpha = .05$).

Results

Screening, Enrollment, and Follow-up

A total of 314 patients were screened. Two hundred eighteen were excluded for failure to meet selection criteria. Of the 96 patients eligible for the study, 70 elected to participate. Two dropped out, 1 from each office, after completing the consent form, but before receiving treatment. Total enrollment in the study consisted of 68 patients with both sites contributing 34 patients each. Forty-two patients elected to receive supplemental care with MAM, whereas 26 patients elected to continue with SMT alone.

Six-week and 3-month follow-up questionnaires with complete outcome data were returned by all 68 (100%) patients. Sixty-two (91.2%) patients returned the 6-month questionnaires, and 63 (92.7%) patients completed the 1-year questionnaires.

Baseline Characteristics

Table 1 shows baseline distributions of sociodemographic, health status, and low-back pain characteristics by treatment group and for all patients. Some variable categories were collapsed to facilitate statistical comparison between groups. Overall, 62% of the participants were men, and the mean age of all patients was approximately 41 years. Study patients were predominantly white, non-Hispanic (83.8%), married (64.7%), employed (91.2%), and had at least some college education (87.8%). The mean pain/disability score for all patients was 65 (on a 0- to 100-point scale, 100 representing least pain and disability).

Table 1 suggests that both groups appear similar for most characteristics measured. The overall mean treatment expectations score was 82.5 (on a 0- to 100-point scale, 100 points signifying greatest optimism regarding treatment results) with very similar expectations reported by both treatment groups (83.9 vs 80.0 for MAM and SMT groups, respectively). Age, general health status, marital status, employment status, income, comorbidity, satisfaction with current symptoms, and SF-36 scores across all subscales were not appreciably different (P values ranging from .13 to .89).

Table 1. *Frequency distributions and mean values and medians for selected sociodemographic and baseline health status and back pain variables, by treatment group*

	Total (n = 68), n (%)	Treatment group		Significance level
		MAM (n = 42)	SMT (n = 26)	
Age, y				
21-29	10 (14.7)	8 (19.0)	2 (7.7)	
30-39	21 (30.9)	13 (31.0)	8 (30.8)	
40-49	23 (33.8)	15 (35.7)	8 (30.8)	$P = .303$
50-59	14 (20.6)	6 (14.3)	8 (30.8)	
Mean (SD)	41.2 (9.33)	40.0 (9.38)	43.2 (9.08)	
Median	42.7	39.1	44.2	
Sex				
Male	42 (61.8)	22 (52.4)	20 (76.9)	$P = .043$
Female	26 (38.2)	20 (47.6)	6 (23.1)	
Race/ethnicity*				
White, non-Hispanic	57 (83.8)	38 (90.5)	19 (73.1)	
Black or African American	1 (1.5)	0 (0)	1 (3.8)	
Hispanic	5 (7.4)	3 (7.1)	2 (7.7)	–
Asian or Pacific Islander	2 (2.9)	0 (0)	2 (7.7)	
Other	3 (4.4)	1 (2.4)	2 (7.7)	
Education				
High school grad/some college	33 (50.0)	22 (53.7)	11 (44.0)	$P = .447$
College grad/postgraduate school or degree	33 (50.0)	19 (46.3)	14 (56.0)	
Marital status				
Married	44 (64.7)	24 (57.1)	20 (76.9)	
Living with significant other	9 (13.2)	6 (14.3)	3 (11.5)	$P = .359$
Divorced/separated	6 (8.8)	5 (11.9)	1 (3.8)	
Single (never married)	9 (13.2)	7 (16.7)	2 (7.7)	
Employment status				
Currently working, homemaker, student	63 (92.6)	38 (90.5)	25 (96.2)	$P = .383$
Unemployed, leave of absence, retired	5 (7.4)	4 (9.5)	1 (3.8)	
Household income				
Less than US$20 000	4 (7.1)	3 (9.1)	1 (4.3)	
US$20 000 to US$39 999	14 (25.0)	11 (33.3)	3 (13.0)	
US$40 000 to US$59 999	16 (28.6)	10 (30.3)	6 (26.1)	$P = .134$
US$60 000 to US$79 999	9 (16.1)	5 (15.2)	4 (17.4)	
US$80 000 or more	13 (23.2)	4 (12.1)	9 (39.1)	
General health status				
Excellent	12 (17.6)	7 (16.7)	5 (19.2)	
Very good	29 (42.6)	14 (33.3)	15 (57.7)	$P = .155$
Good	22 (32.4)	17 (40.5)	5 (19.2)	
Fair	5 (7.4)	4 (9.5)	1 (3.8)	
Comorbidity index (0- to 100-point scale), mean (SD)	8.8 (4.77)	8.8 (4.86)	8.7 (4.72)	$P = .897$
Treatment expectations (0- to 100-point scale), mean (SD)	82.5 (17.9)	83.9 (17.7)	80.0 (18.5)	$P = .398$
Pain/disability index (0-100 scale), mean (SD)	65.0 (14.6)	60.7 (13.3)	72.0 (14.0)	$P = .001$
Satisfaction with symptoms				
Very dissatisfied	48 (70.6)	31 (73.8)	17 (65.4)	
Somewhat dissatisfied	13 (19.1)	7 (16.7)	6 (23.1)	$P = .889$
Neutral	5 (7.4)	3 (7.1)	2 (7.7)	
Somewhat satisfied	2 (2.9)	1 (2.4)	1 (3.8)	
SF-36, mean (SD)				
Physical function	70.1 (20.4)	68.7 (19.1)	72.5 (22.5)	$P = .457$
Role-physical	47.8 (39.1)	44.5 (38.5)	52.9 (40.2)	$P = .397$
Role-emotional	72.6 (38.9)	71.5 (38.4)	74.4 (40.3)	$P = .775$
Mental health	73.1 (15.8)	72.4 (16.6)	74.2 (14.8)	$P = .649$
General health	71.7 (20.8)	71.7 (20.8)	74.0 (21.5)	$P = .471$

Some patients refused to provide data for some variables. Percentages were calculated using total number of nonmissing responses provided for each variable.

* Lack of racial diversity in study patients precluded meaningful analysis comparing differences between groups.

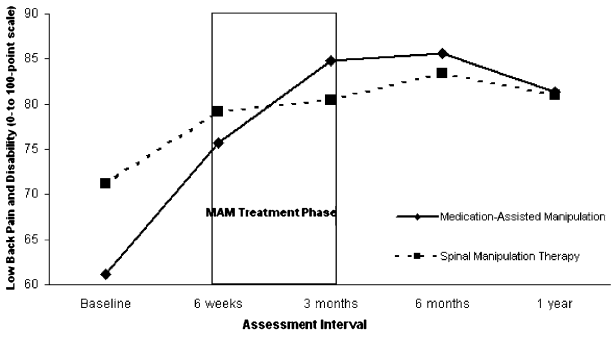

Fig 1. *Adjusted mean levels of pain and disability, by follow-up assessment and treatment group.*

Table 2. *Adjusted mean values, mean differences, and 95% CIs for pain and disability at baseline and each follow-up assessment, by treatment group: results of ordinary least squares regression analysis*

Follow-up interval	Mean pain/disability		Mean difference*	95% CI*
	MAM	SMT		
Baseline	61.2	71.2	−10.0	−16.9 to −3.1
6 wk	75.7	79.2	−3.6	−10.8 to 3.7
3 mo	84.8	80.4	4.4	−2.2 to 11.0
6 mo	85.6	83.4	2.1	−6.1 to 10.4
1 y	81.3	81.0	0.3	−8.6 to 9.2

Baseline pain and disability mean scores, mean difference, and 95% CI for the MAM and SMT groups are unadjusted. Follow-up pain and disability means, mean differences, and 95% CIs are adjusted for baseline pain/disability and sex.

* Negative values indicate higher scores for the SMT group relative to the MAM group.

Some differences in clinical and sociodemographic variables were noted between the 2 treatment groups at baseline. The MAM group reported a mean pain/disability score of 60.7, whereas the SMT-only group reported a mean pain/disability score of 72.0 (mean difference −11.3, 95% CI −18.1 to −4.6). Differences between the treatment groups for sex also appear statistically significant with a higher proportion of women opting to supplement SMT with MAM. Subsequent analyses comparing pain/disability outcomes between groups controlled for baseline differences in pain/disability and sex.

Pain/Disability Outcomes

Adjusted mean pain/disability scores for both groups are presented for all assessment intervals in Fig 1 and Table 2 (adjusted for baseline pain/disability and sex). Improvement in adjusted mean pain/disability scores during the initial 4- to 6-week trial of therapy was 8.0 points for the patients choosing to continue with SMT alone, whereas the patients opting for supplemental care with MAM experienced a gain of 14.5 points during the initial SMT phase. During the subsequent active care phase (from week 6 to 3 months), the group receiving additional care with SMT alone experienced a slight further improvement of 1.2 points, whereas the group receiving supplemental care with MAM experienced a substantially larger additional improvement in pain and disability scores of 9.1 points. At 3 months, the adjusted mean pain and disability score for the MAM group increased to 84.8, whereas the usual care group score remained virtually unchanged at 80.4 (adjusted mean difference of 4.4 points, 95% CI −2.2 to 11.0). Slight increases in adjusted mean pain and disability scores occurred between 3 and 6 months for both groups, with scores dropping a little for both groups at 1-year follow-up.

Table 3. *ORs for improvement in pain and disability for MAM versus SMT, by follow-up interval: results of logistic regression analysis*

Follow-up interval	OR*	95% CI*
0-3 mo	4.1	1.3-13.6
0-6 mo	2.5	0.7-9.9
0-12 mo	1.9	0.6-6.5

Odds of improvement in pain/disability scores from baseline to each follow-up assessment point for the MAM group versus the SMT group. Improvements of ≥10 points (vs <10 points) on the pain and disability index were used as dichotomous outcomes.

* ORs and 95% CIs are adjusted for baseline pain/disability and sex.

About 66% of all patients experienced improvement in pain and disability by 10 points or more during the first 3 months, and approximately 64% of study participants reported improvement of at least 10 points at 1 year. Eighty-one percent of the MAM group had a 10-point or more improvement in pain and disability scores between baseline and 3 months compared with 42% of SMT-only patients. At 1 year, 74% of the MAM group reported an improvement of at least 10 points over baseline scores compared with 48% of the patients continuing with SMT alone. Table 3 lists the adjusted ORs measuring the odds of improvement by at least 10 points for pain and disability in the MAM group versus the SMT group. The relative odds of experiencing a 10-point improvement in pain and disability favored the MAM group at 3 months (adjusted OR 4.1, 95% CI 1.3-13.6) and at 1 year (OR 1.9, 95% CI 0.6-6.5).

There were no known study-related adverse events requiring institutional review board notification for participants in either group.

Discussion

This effort represents the first multisite long-term study of MAM using a comprehensive set of previously validated outcome measures. A recent review of MAM lists at least

25 studies appearing in the English-language literature since 1930.[26] The vast majority of these studies are case reports or case series,[2-4,16,18-20,23-25,31-34] with only 1 cohort[35] and 2 randomized clinical trials.[9,10] One additional cohort study has appeared since the review was published.[36] Although our findings of patient improvement with MAM are similar to the findings of prior investigations, significant differences between many of those trials and this present study, perhaps most notably differences in treatment protocols, limit meaningful comparisons.

Most reported MAM studies involve MUA techniques, and virtually all MUA reports published before the mid-1990s included protocols using general anesthesia. More current protocols, including the one used in this investigation, use shorter acting agents that induce moderate sedation/analgesia (conscious sedation) to deep sedation/analgesia rather than general anesthesia, which causes loss of consciousness during which patients are not arousable, even by painful stimulation.

In addition, these earlier studies used long-lever manipulation techniques rather than the short-lever techniques currently used. The earlier studies did use passive range of motion stretching similar to current techniques. The 2 MAM randomized clinical trials reported protocols differing even more substantially. One studied the use of long-lever manipulation accompanied with the injection of a proliferant solution into spinal ligaments,[9] and the other investigated the combination of manual therapy with steroid injections of the piriformis muscle.[10]

Two recent studies used treatment protocols quite similar to this observational trial. One reported results from a case series of 177 patients,[2] and the other reported results from a cohort study with 38 MUA patients compared with 49 MUA-eligible patients not receiving such treatment because of failure to obtain insurance precertification.[36] The case series outcome measures were range of motion, Visual Analog Scale rating, medication use, and work status assessed before MUA, after MUA, and 6 months after MUA. The cohort study outcome measures assessed low back pain and disability using the Roland-Morris Questionnaire and a numerical pain scale given before MUA, after the final MUA, and again 4 weeks later. Findings from our study are consistent with these 2 prior investigations regarding improvement in reported pain and disability. A pattern common to the recently published cohort study and our study is that mean baseline pain and disability scores were worse in the MAM cohort relative to the SMT-only cohort.

Treatment group selection was dependent on insurance approval in the recently published MUA cohort study. Impact of financial constraints was limited in our study by the existence of a funding source that provided for care at subsidized rates. In our study, group determination was the result of patient choice following clinical recommendations made at reevaluation after the initial trial of usual chiropractic care. Clinicians did not have access to pain/disability index scores at any time during the study, but mean pain/disability score differences at baseline between MAM and SMT-only groups appear to agree with the clinicians' assessments as well as underscore a theme in the MAM literature. This procedure has been recommended as an additional treatment option for patients with greater levels of pain and disability that are not adequately resolved with manual therapy alone.

The primary limitation of the present investigation is that treatment was not randomly allocated. This limitation was partially addressed by collecting extensive patient characteristics data and controlling for observed differences between the 2 groups during analysis. Baseline data indicate that the 2 groups are quite similar across most variables, with the notable exception of level of initial pain and disability and potential differences in age and sex, which were used as a covariates in all subsequent analyses. Resource limitations resulted in an enrollment lower than original recruitment targets resulting in less precise estimates of effect. Results from our study may not be generalized to other populations in which patient populations differ from our sample or clinicians use different techniques. The MAM protocol applied in this study is very similar to those taught at postgraduate courses in the United States, although the additional component of traction therapy for sacrococcygeal structures is unique. Both clinicians serve as or have served as faculty for postgraduate MAM courses. The use of previously validated comprehensive outcome measures instruments, long-term follow-up, and high 1-year response rate represent strengths of this study relative to prior MAM investigations.

Conclusion

Chronic low-back pain patients presenting with greater levels of pain and disability appear more likely to pursue supplemental care with MAM after a course of SMT alone. Medication-assisted manipulation appears to offer these patients increased improvement in low back pain and disability. These improvements may not endure over the long term, and the clinical changes observed are not necessarily caused by MAM. This study does suggest that certain subpopulations of chronic low-back pain patients may be suitable candidates for MAM and that additional studies assessing treatment effectiveness appear warranted. A larger-scale, multisite, randomized, controlled trial represents the next logical step for subsequent investigations of MAM.

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