

CHRONIC LOW BACK PAIN: A STUDY OF THE EFFECTS OF MANIPULATION UNDER ANESTHESIA

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ABSTRACT

Objective: The objective of this project was to evaluate the efficacy of using self-reported questionnaires to study manipulation under anesthesia (MUA) for patients with chronic low back pain. Self-reported outcome assessment instruments were used to evaluate changes in patients receiving MUA versus those not receiving MUA.

Setting: Two ambulatory surgical centers and 2 chiropractic clinics.

Subjects: A total of 87 subjects participated in this study. The intervention group consisted of 38 patients and the nonintervention group consisted of 49 patients. Selection was made from a convenience sample of patients selected from doctors who perform MUA at 2 centers participating in the study.

Intervention: Patients in the intervention group received MUA. Patients in the nonintervention group received traditional chiropractic treatment.

Outcome Measures: A Numeric Pain Scale and the Roland-Morris Questionnaire were administered at baseline evaluation, after the procedure, and 4 weeks later. Results were documented and compared.

Results: The average Numeric Pain Scale scores in the MUA group decreased by 50%, and the average Roland-Morris Questionnaire scores decreased by 51%. The average Numeric Pain Scale changes in the nonintervention group decreased by 26%, and in the Roland-Morris Questionnaire group mean scores decreased by 38%.

Conclusions: In this sample of patients with chronic low back pain, self-reported outcomes improved after the procedure and at follow-up evaluation. There was more improvement reported in the intervention group than the nonintervention group. This study supports the need for large-scale studies on MUA. It also revealed that self-reported outcome assessments are easily administered and a dependable method to study MUA. (*J Manipulative Physiol Ther* 2002;25:e8)

Key Indexing Terms: *Chiropractic Manipulation; Low Back Pain; Outcome Measures; Chronicity*

INTRODUCTION

Low back pain is major public health problem. In the United States, low back pain affects between 60% to 80% of the population and costs from \$20 to \$50 billion annually.¹ Approximately 25% of low back pain cases become chronic but those cases represent approximately 90% of the costs.² Lack of diagnostic precision, poor correlation of symptoms and clinical findings, inconsistency of treatment methods, and poor study design have lead to

confusion and conflict in treatment methods for patients with low back pain. Although numerous treatments are available for patients with chronic low back pain, consensus regarding their effectiveness is lacking.^{3,4} Previous case studies have reported that manipulation under anesthesia (MUA) is effective in relieving low back pain.⁵ The procedure consists of spinal manipulation and stretching procedures performed while the patient receives intravenous anesthesia. This preliminary study was designed to test the practicality of a method to study the effects of MUA on self-reported low back pain and measure changes in self-reported outcomes in patients who received the procedure and those who received other treatment. Because a convenience sample was used, results cannot be directly attributed to the intervention. The results, however, will help generate hypotheses regarding MUA so future analytical studies can be performed.

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Background

Existing methods for managing nonpathologic chronic back pain include patient education, back schools, spinal injections, medications, physical therapy, exercise and rehabilitation, acupuncture, spinal mobilization and manipulation, behavioral modification, and work and lifestyle activity modification.⁶ The MUA procedure is typically performed on patients who have received some or all of these treatments without favorable results.⁷ The complexity of the MUA procedure, coupled with the complexity of chronic low back pain, makes studying these entities a challenge. With evidence-based health care practices emerging as state-of-the-art expectations, the study of patient-reported outcomes provides one method to evaluate the end-result of treatment methods. Treatment designed for a condition as complex as low back pain should be evaluated based on its ability to have an affect on a patient's health-related quality of life. Some health-related quality of life outcomes specifically relevant to the low back pain patient include relief of symptoms and improvement in functional ability. This study focuses on these outcomes specifically. The use of valid and reliable self-reported pain and disability questionnaires allows for measurement of such outcomes.

The MUA procedure is not new and can be traced to the 1930s.⁹ Attempts to generalize previous MUA studies are inappropriate because methods of patient selection, procedure protocols, anesthesia, and therapy after MUA is not always uniform. Previous studies on MUA have largely consisted of case studies and have generally examined short-term outcomes.⁸⁻¹¹

The National Academy of MUA Physicians (NAMUAP) is an organization developed for the purpose of standardizing, training, promoting, and reviewing MUA on a national level.¹² Consistent and standardized methods of carrying out the procedure must be recognized to study this procedure effectively.

This study focused on chronic low back pain syndromes with the cooperation of doctors and centers who perform the procedure according to the NAMUAP protocol. Patient-reported outcomes were measured.

Specific Aims

The specific aims of this pilot study include process issues associated with a method to study the MUA procedure (first specific aim) and outcome issues (second specific aim) related to measuring the results of the procedure. The goals of the process issues are to determine the feasibility of using pain and disability scales to study outcomes of the MUA procedure on chronic low back pain patients and to identify challenges in studying the MUA procedure. The goals of the outcome issues are to measure self-reported pain and disability before and after the MUA procedure and to determine if results at the 4-week follow-up evaluation

were different from those receiving traditional chiropractic treatments.

METHODS

This study was performed between October 2000 and March 2001. Sampling occurred at 2 community-based surgical centers in northern New Jersey and at the offices of chiropractic physicians who perform the MUA procedure at these centers. These centers, identified through the NAMUAP, agreed to participate in the study.

Recruitment

Initially the sample size was estimated to include approximately 75 intervention patients and 50 nonintervention patients (N = 125). In actuality, the sample size was 87, which included all the patients receiving MUA from these 2 centers during this time, totaling 38 patients, and the non-intervention group, with patients selected from specific offices of doctors who perform the procedure, totaling 49 patients. The patients receiving MUA were selected based on clinical eligibility and insurance reimbursement precertification. The latter patients were eligible for the procedure but did not receive MUA. All patients who were eligible for the MUA procedure in the 2 surgical centers were included, and no patient refused participation. Only questionnaires were administered as part of this study. Because the study was performed on patients already selected to receive or not receive this procedure, there was no increased risk to the patient for participating.

Eligibility

The study was approved by the University of Medicine and Dentistry of New Jersey's Institutional Review Board. All patients signed informed consent before entering the study. However, because individual identifiers were collected and recorded, steps to ensure confidentiality of the information were taken. All chiropractic physicians who performed the MUA procedure at these facilities agreed to participate in this study by selecting patients for the study and ensuring that the questionnaires were completed. All patient participants met the following criteria:

1. Clinical eligibility according to the protocols set forth by the NAMUAP (Appendix 1)
2. Low back pain lasting at least 6 months (unless deemed eligible by the treating doctor)
3. No contraindications to the procedure
4. Aged 18 years or older
5. Agreed to participate in the study
6. Received at least 4 weeks of spinal manipulation

Nonintervention group participants met criteria 1 through 6 but did not obtain insurance precertification. Intervention group participants met criteria 1 through 6 and obtained precertification or pre-approval from their insurance carrier for reimbursement for the procedure and agreed to receive the procedure.

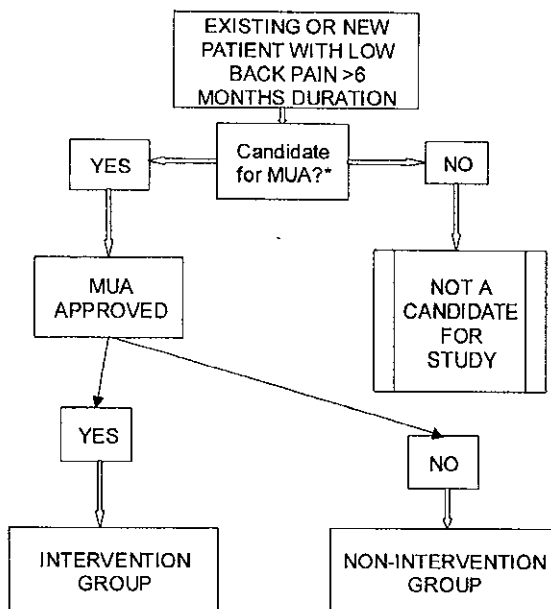


Fig 1. Flow chart for selecting study participants for manipulation under anesthesia. See National Academy of MUA Physicians indications/contraindications for MUA (Appendix 1).

Enrollment

The intervention group ($n = 38$) consisted of eligible patients who received the MUA procedure, and the nonintervention group ($n = 49$) consisted of eligible patients who did not receive the procedure. Because of the nature of this project and budget restrictions, a convenience sample was selected for this study.

Fig 1 represents the protocol doctors used to recruit patients for the study. Eligibility for MUA begins with the physician who deems a patient clinically appropriate and eligible for MUA. Once deemed clinically appropriate, reimbursement by the insurance carrier through a precertification process was obtained. If reimbursement was verified, the patient was scheduled for the procedure. Patients who met the criteria and subsequently received the procedure were assigned to the intervention group. Patients who met the criteria but who were not precertified for reimbursement were placed in the nonintervention group. No patient who was precertified chose not to receive the procedure. Patients in this category received an additional 4 weeks of chiropractic care.

Interventions

The MUA procedure is performed on an outpatient basis in the operating room of a hospital or surgical center by a specially trained and certified chiropractic physician. The patient is sedated with intravenous, short-acting anesthetics, such as propofol, by an anesthesiologist. Patients received from 1 to 4 MUA procedures consecutively over the same

number of days. This was followed by specific MUA rehabilitation therapy lasting 4 to 6 weeks.

The NAMUAP advocates 3 important principles to achieve optimal therapeutic benefits. These include careful selection of the cases, careful application of the technique, and well-planned care after the procedure. The purpose of the procedure, which consists of specific spinal manipulation and stretching of the spinal and supportive soft tissues, is to relieve chronic muscle spasm, protective guarding, and fibro-adhesions within and around the spinal articulations.¹³ Theoretically and empirically, patients who are sedated are less resistant and less apprehensive to manual procedures, allowing for deeper and more sustained techniques. Therapy after the MUA procedure consists of spinal manipulation without anesthesia, physical therapy modalities, and proprioceptive and spine stabilization exercises. This therapy is designed to further maintain the flexibility of the supporting tissues, prevent fibrous adhesions, and restore proprioceptive integrity.

Patients in the nonintervention group received traditional chiropractic treatment consisting of spinal manipulative therapy, and passive therapeutic modalities and were asked to complete home exercises. Although specific protocols were not followed in this group, only 2 practitioners treated the nonintervention group, thus increasing the likelihood of a more consistent mode of care in the nonintervention group.

Study Design

This preliminary prospective cohort study design consisted of self-reported pain and condition-specific disability assessments before the procedure, after the procedure, and at follow-up evaluation. The nonintervention group was evaluated at baseline and after 4 weeks of care. Comparison was made between the subjects receiving the MUA procedure and those not receiving the procedure, and comparisons were made in the same subjects before and after the procedure. In addition, personnel directly involved in implementing the study questionnaires were interviewed to determine the feasibility and challenges of performing this type of study.

Outcomes Assessment

Back pain treatments remain difficult to research because of its many causes and generally poor correlation of physiologic parameters to clinical parameters. Research, at least initially, must involve the measurement of symptom relief and activities of daily living, rather than relying on some extrapolation from physiologic measurements.¹⁴ In addition, MUA contains many parameters that may or may not affect the outcome. These parameters include patient selection, the practitioner's experience and ability, anesthesia, procedure followed, and protocols followed after the MUA. Ultimately, each of these parameters should be studied;

however, until MUA is performed on a large scale, studies should focus on the end-result of the treatment.

The patients who participated in the study completed a demographic questionnaire (Appendix 2), a Roland-Morris Questionnaire (RMQ) on low back pain disability (Appendix 3) before the procedure, and a Numerical Pain Scale (NPS) (Appendix 4). Participants also completed the NPS and RMQ after they received their final MUA procedure and again 4 weeks later. All responders to the final questionnaire participated in 4 weeks of the rehabilitation program, consistent with that recommended by the NAMUAP.

Patients in the nonintervention group were initially asked to complete the demographic questionnaire, the RMQ, and the NPS. They then completed the RMQ and NPS 4 weeks later. All responders to the final questionnaire in the non-intervention group completed 4 weeks of traditional chiropractic treatment.

Pain and Disability Assessment

Self-reported outcomes are a useful method for studying low back pain for several reasons. First, identifying the underlying physiologic and anatomic causes of low back pain remains difficult.¹⁵ Even when a specific cause can be identified, it may be difficult to measure objectively. Scientific data are lacking for many musculoskeletal disorders, especially those associated with chronic pain.¹⁶ In addition, other factors may affect the outcome of these patients, including secondary financial gains, work status, and psychosocial elements.

Self-reported, patient-centered outcomes were selected for this study because the complexity of chronic low back pain combined with the complexity of the MUA process would make specific objective outcomes difficult to measure. The RMQ and NPS have been shown to be valid and reliable outcome assessment tools.¹⁷⁻¹⁹

The Numeric Pain Scale is numbered from 0 to 10. The patient selects the appropriate number to rate their pain, with 10 representing excruciating pain and 0 representing no pain. This scale has been compared with the Visual Analogue Scale in terms of reliability and validity.²⁰⁻²²

The RMQ is considered a valid and reliable instrument to measure low back pain-related disability. It contains 24 questions regarding a patient's ability to perform daily activities related to quality of life. The total "yes" answers are added to determine total disability (from 0 to 24). Some authors suggest that a change of at least 4 points is required for clinically applicable change to be measured accurately.^{23,24} A score of 14 or greater represents significant disability.²⁵

It has been reported that at least 10 patients per month receive this procedure in each surgical center. Because no formal hypothesis is to be tested in this preliminary study, 60 participants are anticipated to participate in the intervention group and 40 participants are anticipated to participate in the nonintervention group.

Statistical Procedures

Self-reported outcome assessments, which included back pain severity and functional status, were analyzed. The dependent variable is the MUA procedure. The sample included patients meeting the NAMUAP eligibility to benefit potentially from MUA (Appendix 1). Those not approved for insurance reimbursement but otherwise clinically eligible were placed in the nonintervention group. Results were analyzed with descriptive statistics, one-sample Student *t* tests, paired-sample Student *t* tests, and correlations. Subjects reported their pain severity before and after the procedure. Both the intervention and nonintervention groups used the same instrument. Descriptive statistics were used to recognize trends in demographic data.

RESULTS

The sample size in this study totaled 87 subjects. The intervention group consisted of 38 patients, and the non-intervention group consisted of 49 patients.

Demographic Data

Tables 1 and 2 summarize the demographic results. All participants who initially joined the study finished the study. The average age of respondents was 39 years, and 51.7% were male. A total of 27 patients in the intervention group received 3 procedures; 9 received 2 procedures; 1 received 1 procedure; and 1 received 4 procedures. All 49 patients in the nonintervention group received 4 weeks (12 treatments) of traditional chiropractic treatment.

The intervention group was more diverse with respect to ethnicity, with 67.3% of the nonintervention group describing themselves as white compared with 42.1% in the intervention group. Most patients in both groups classified their symptom as low back pain with or without radiation to the thigh (61% in the intervention group and 51% in the non-intervention group). Nearly 74% of the intervention group described the cause of their pain as related to a disc problem, and nearly 45% of the nonintervention group classified the cause as a sprain/strain. Most (87%) of the intervention group had received at least 4 weeks of spinal manipulation (without anesthesia) before the procedure. Nearly 51% of the intervention group reported a motor vehicle collision as the cause of the symptom, whereas 14% of the nonintervention group reported a motor vehicle collision as the cause. Most personal injury policies cover the MUA procedure. Nearly half (49%) of the intervention group also reported neck pain. In this study, minimal differences were noted in the groups with respect to age, disability status, and working status.

Studying the MUA Procedure

One purpose of this study (first specific aim) was to test the feasibility of using a prospective design with self-reported questionnaires to evaluate the MUA procedure. We

Table 1. Demographic questionnaire results

Parameter	Measure	Intervention group (n = 38)	Non-intervention group (n = 49)
Age (y)	Mean	38	39
	Median	36	40
	Mode	36	40
	Range	21-66	18-64
Race	Asian/Pacific Islander	0	2.0% (1)
	Black	21.1% (8)	12.2% (6)
	Hispanic	39.5% (15)	14.3% (7)
	White	42.1% (20)	67.3% (33)
Sex	Male	47.4% (18)	55.1% (27)
	Female	52.6% (20)	44.9% (22)
Current medication	Yes	23.7% (9)	28.6% (14)
Disability compensation	Yes	15.8% (6)	12.2% (6)
Currently working	Yes	71.1% (27)	69.4% (34)

Table 2. Demographic questionnaire results

Parameter	Measure	Intervention group (n = 38)	Non-intervention group (n = 49)
Classification of pain	Low back pain with No Radiation	31.6% (12)	26.5% (13)
	Radiation to thigh	31.5% (12)	24.5% (12)
	Radiation, below knee	15.8% (6)	20.4% (10)
	Radiation, leg/weakness	10.5% (4)	18.4% (9)
	Radiation, both legs	13.2% (5)	10.2% (5)
	Duration of pain	<6 mos	7.9% (3)
6-12 mos		52.6% (20)	28.6% (14)
1-3 y		23.7% (9)	24.5% (12)
>3 y		13.2% (5)	10.2% (5)
Cause of pain	Disc syndrome	73.7% (28)	36.7% (18)
	Sprain/strain	23.7% (9)	44.9% (22)
	Muscle	26.3% (10)	36.7% (18)
	Arthritis	13.2% (5)	18.4% (9)
Prior treatments	Physical therapy	71.1% (27)	53.1% (26)
	Exercise	42.1% (16)	49.0% (24)
	Epidural steroids	36.8% (14)	8.2% (4)
	Medications	36.8% (14)	30.6% (15)
Onset	Motor vehicle	52.6% (20)	14.3% (7)
	Work injury	7.9% (3)	16.3% (8)
	Don't know	39.5% (15)	55.1% (27)
	Other trauma	2.6% (1)	10.2% (5)
Associated complaints	Neck pain	50.0% (19)	24.4% (12)
	Shoulder pain	34.2% (13)	14.3% (7)
	Headaches	18.4% (7)	26.5% (13)
	Arm pain	21.1% (8)	4.1% (2)
	Hip pain	7.9% (3)	34.7% (17)

conclude that self-reported questionnaires are easy to administer and completed with minimal difficulty. Staff members assigned to administering these questionnaires reported that the consent form was lengthy and difficult for patients to assess, especially because they had to sign procedure consents simultaneously. As with any follow-up evaluation, some difficulty was encountered obtaining the final questionnaires. Once patients were released from the surgical

center, they were released to the treating chiropractor's clinic for therapy after the MUA procedure. The treating doctor was then responsible for ensuring that the follow-up forms were completed. Our investigators reported that in some cases, the follow-up evaluation was initially forgotten. For the purpose of this study, the principal investigator reminded doctors to perform the follow-up evaluation. However, this would not likely be feasible in a large-scale

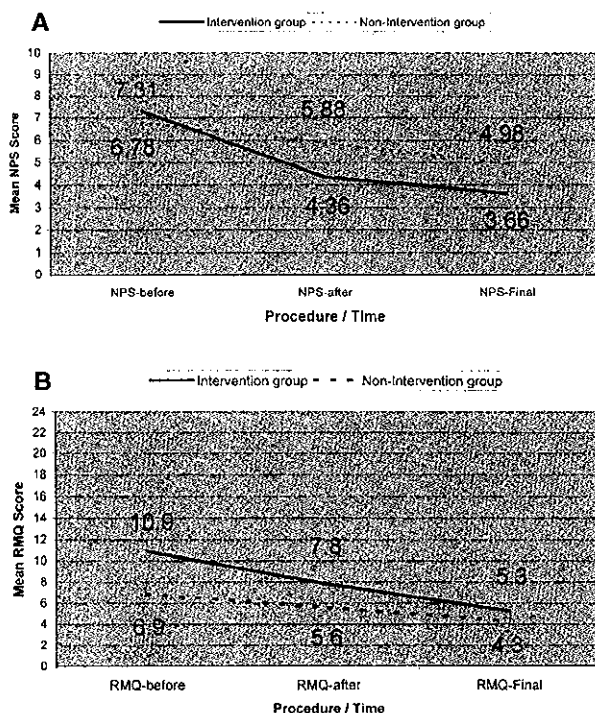


Fig 2. A, Numeric Pain Scale results. B, Roland-Morris Questionnaire results.

study. In one center, a registered nurse agreed to take on the task of administering questionnaires and conducting the follow-up evaluation with patients. If she did not receive the follow-up evaluation in a timely manner, she called the patient at home and completed the questionnaire by telephone. The strong response rate (100%), coupled with minimal difficulty reported by those administering the questionnaires, suggests that self-reported measures are a valid method to study MUA.

Assessment of Outcomes

The second objective of this study (second specific aim) was to measure self-reported changes in patients receiving the procedure and compare them with those not receiving the procedure. Improvement in pain and disability questionnaire scores was noted in both groups, although more improvement was noted in the group receiving the MUA. These findings imply the need for large-scale studies of the procedure. Results are presented in Figs 2A and 2B. One-sample Student *t* tests were used to compare NPS responses (scored from 0 to 10).¹⁸ In the intervention group, the mean response on the NPS was 7.31 at baseline, 4.36 after the final procedure, and 3.66 at follow-up evaluation, a mean improvement of nearly 50%. In the nonintervention group, the NPS score was 6.78 at baseline and 4.98 at follow-up evaluation, a mean improvement of approximately 26%. One-sample Student *t* tests were used to compare RMQ responses (scored from 0 to 24). In the intervention group,

the average RMQ score was 10.9 before the procedure, 7.8 after the final procedure, and 5.3 at follow-up evaluation, a mean improvement of approximately 51%. In the nonintervention group, RMQ scores were 6.9 at baseline and 4.3 at follow-up evaluation, a mean improvement of 38%.

Paired-sample Student *t* tests and correlations were used to compare the results of the questionnaires (Fig 3). Correlations between questionnaires were significant in both the intervention and nonintervention groups.

DISCUSSION

This preliminary study, which was performed as a graduate fieldwork project, served many purposes. Although its limitations are appreciated, the results reveal some pertinent information. As hypothesized, these results will serve as a guide to perform large-scale analytic studies on the MUA procedure.

The purpose of the first specific aim was to evaluate the process of studying the MUA procedure in patients with chronic low back pain. Evidently, the application of self-reported outcomes assessment is important when dealing with a multifaceted procedure for a complex condition. In this study, we observed that the use of self-reported measures is both reasonable and practical. When using these questionnaires in hospital or surgical center environments, designating key personnel responsible for the administration and follow-up evaluation of the questionnaires is important. These key personnel must be trained to assist the patient in responding to the questions and obtaining consent for study participation. Ultimately, the key personnel would be the treating practitioner. The use of questionnaires that can be administered by telephone make the task of follow-up evaluation easy and practical. During this study, one surgical center designated a key person (a surgical nurse) to ensure administration and follow-up evaluation. In this center, all questionnaires were easily retrieved and completed in full. In the other study center, the treating doctor was responsible for administration of the questionnaire and follow-up evaluation. Although the doctors typically had better access to the patient, the timely follow-up evaluation was not always achieved without intervention by the principal investigator. It is critical that a specific protocol of administration and follow-up be instituted. Administration and follow-up challenges can be eliminated if the treating doctors would maintain responsibility for administering the questionnaires. The treating doctor has direct contact with the patients before the procedure, immediately after the procedure, and again at follow-up evaluation, and is intimately familiar with the procedure.

Conveying to both the intervention and nonintervention patients that their participation in the study did not affect the procedures performed for them was also important. Several intervention patients reportedly questioned the experimental nature of the procedure after signing the consent. These

Correlations (intervention group)

RMQ/NPS-I	r = .460	N=38	Sig. = .003
RMQ/NPS-P	r = .780	N=38	Sig. = .000
RMQ/NPS-F	r = .849	N=38	Sig. = .000

Correlations (non-intervention group)

RMQ/NPS-I	r = .359	N=49	Sig. = .011
RMQ/NPS-F	r = .726	N=49	Sig. = .000

Fig 3. Correlation of Roland-Morris Questionnaire (RMQ) and Numeric Pain Scale (NPS) scores. I, Baseline assessment; P, assessment after the procedure; F, final assessment.

questions were virtually eliminated when proper explanation was provided at the outset. Some concern was voiced regarding the amount of paperwork required of an anxious patient. Similar problems were encountered with the non-intervention group as they questioned whether something different was going to be performed if they participated in the study. This was also alleviated by a thorough explanation of the process and study. The administration of these questionnaires, in addition to existing paperwork for the actual procedure, can be time-consuming and tedious. It is important to recruit centers and doctors who are totally committed to studying the process.

It is also apparent that future studies of MUA include follow-up questionnaires that consist of topics relating to the extent and nature of the visits after rehabilitation, change in work status, and general health status. It is important to know whether additional procedures or interventions were performed during this time.

A doctor-reported demographic questionnaire was piloted in preparation for this study to obtain more accurate information regarding diagnosis, cause, and previous treatments. Unfortunately, poor response rates forced a change to patient-generated questionnaires. Future studies should include chart reviews to ensure accuracy of the information provided and compliance with NAMUAP criteria. We recommend that an additional questionnaire, such as the Modified Oswestry low back pain and Disability Questionnaire or other previously validated instrument, be used to further support the conclusions.

Regarding the outcomes issues (second specific aim) related to this study, we noted a trend toward a more positive outcome in the MUA group. Because this was not a random sample and selection bias existed, we cannot directly attribute this effect to the MUA. However, because outcomes

improved significantly more in the intervention group, the need for further studies appears justified. Selection of a random sample of patients for a large-scale study of MUA, although difficult, is essential. Such selection will ensure equally distributed prognostic factors and minimize bias and baseline differences between the groups.³ Because the MUA procedure is not currently being performed on a large scale, difficulty in obtaining a random sample is appreciated. One way to obtain a randomly selected group of patients is to perform a nationwide study and select participants from those already approved for the procedure. This would eliminate selection bias based on the patient's insurance carrier. Because the major dependent variable would then be the procedure, one group would receive the procedure with anesthesia and the other group would receive the same procedure (and follow-up evaluation) without anesthesia. Although selection bias still exists, the 2 groups would be more similar. In addition, future studies should include longer follow-up periods. Some authors recommend a minimum of 2-year follow-up period when dealing with chronic symptoms.³

NAMUAP criteria are not the only ones being used. Personal communications with MUA practitioners across the country reveal variations among patient selection, indications, manual methods used, and route and type of anesthesia administered.

The following recommendations should be considered in future studies of the MUA procedure:

1. Only patients whose procedures and rehabilitation are performed in centers that follow consistent protocols and ensure strict compliance to the protocols should be studied
2. In addition to patient consent, doctor's consent and surgical center or hospital contracts should be ob-

tained to ensure attention to the details of the protocols

3. Self-reported outcomes instruments that are proven valid and reliable should be used. The use of more than one type of questionnaire would improve the validity, reliability, and reproducibility of the results
4. Questionnaires that can be administered by the telephone should be used
5. Questionnaires used at baseline and at the conclusion of the study should be correlated with chart reviews
6. Follow-up observation should be long-term (ultimately lasting 2 years or longer after the procedure)
7. A qualified individual (preferably a committed treating doctor or staff nurse) should be selected to administer the questionnaires and ensure follow-up evaluation
8. A random sample of subjects should be selected
9. Consult a statistician in the design, implementation, and data interpretation of the study
10. Consider the effects of the patient's culture and demographic characteristics when evaluating the outcomes

Complications of MUA

No complications in either the intervention or the nonintervention group were noted in our study. Complications of the MUA procedure may include those related to lumbar spinal manipulative therapy or the administration of anesthesia. No combined effects have been reported to our knowledge. Patients undergoing MUA must receive medical clearance for anesthesia by their primary care physician. Appropriate medical clearance and use of an anesthesiologist experienced with the MUA procedure minimizes the risk of complications. Patients that receive MUA typically receive several weeks of spinal manipulation without anesthesia before the procedure, which may act as a screening tool for potential complications. Pre-anesthesia instructions and proper monitoring of the patient during and after the procedure will help minimize the chance of adverse effects.

CONCLUSION

We conclude that large-scale studies of MUA are warranted. Because the NAMUAP constitutes the largest group of practitioners performing the procedure in a consistent manner, it is realistic to focus studies on providers following their protocol. We also recommend that self-reported outcomes be used until measurements that are more objective can accurately depict end-results of an intervention. The participation of centers interested in studying MUA, with qualified staff members is critical to success.

This study has determined that future studies would be worthwhile and has identified challenges in studying MUA. The MUA procedure warrants further analysis, and the use

of self-reported outcomes is a valid method to study the procedure.

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APPENDIX 1. INDICATIONS AND CONTRAINDICATIONS FOR MUA

Indications

- Chronic non-inflammatory arthritis;
- Chronic fibrositis;
- Chronic myositis caused by recurrent contracture or muscle splinting;
- Unresolved nerve entrapment syndrome;
- Acute exacerbation of muscle contracture;
- Adhesive capsulitis/tenosynovitis;
- Herniated disc syndrome (without sequestered fragment);
- Joint fixation syndrome;
- Failed back surgery

Contraindications

- Patients who have not undergone minimum of 4 weeks of conservative therapy including chiropractic manipulative therapy;
- Patients who have shown adverse reactions to spinal manipulation;
- Patients who have shown adverse reactions to anesthesia

APPENDIX 2. DEMOGRAPHIC QUESTIONNAIRE

Please answer each question below to the best of your ability. Feel free to ask your doctor if you need assistance with any questions.

Patient Questionnaire

1. What is your age?
2. How would you describe your race or ethnic background? (select one)
 - Asian or Pacific Islander
 - Black or African American
 - Hispanic
 - Native American or Alaskan
 - White
 - Other
3. What is your gender?
 - Male
 - Female
4. Please classify your condition into one of the following (select only one).
 - Low back pain, no radiation
 - Low back pain, pain radiates to thigh (above knee)
 - Low back pain, pain radiates to calf/foot (knee and below)
 - Low back pain, pain radiates to leg, with weakness in leg or foot
 - Low back pain, pain radiates to both legs
5. What is the duration of your problem?
 - 6 mos
 - 6 mos to 1 y
 - 1 to 3 y
 - >3 y
6. What is your diagnosis?
 - Disc problem
 - Sprain/strain
 - Muscle problem
 - Arthritis
 - Other (please describe)
7. Please describe previous treatment you have received (please check all that apply):
 - Chiropractic manipulative therapy (adjustments performed by chiropractor)
 - Physical therapy modalities (heat, muscle stimulation, ultrasound)
 - Active exercise (specific exercises for your pain)
 - Epidural or trigger point injection (injections directly into the area of pain)
 - Prescription medication for pain or inflammation (prescribed by your physician)
 - Surgery to area of complaint
8. What was the initial cause of your complaint:
 - Automobile related accident
 - Work related accident
 - Do not know
 - Other trauma (please describe briefly)
 - Related to other disease (please describe briefly)
 - Other (please describe briefly)
9. Are you currently taking pain medication for this condition?
 - No
 - Yes (please list)
10. Please select other complaints you are currently experiencing:
 - Neck pain
 - Pain between the shoulder blades
 - Headaches
 - Shoulder or arm pain
 - Hip pain
 - Other (please describe)
11. Are you currently receiving disability compensation?
 - No
 - Yes
12. Are you currently working?
 - No
 - Yes

Thank you for completing this survey.

