Evidence-informed management of chronic low back pain with medicine-assisted manipulation

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Abstract

EDITORS’ PREFACE: The management of chronic low back pain (CLBP) has proven very challenging in North America, as evidenced by its mounting socioeconomic burden. Choosing among available nonsurgical therapies can be overwhelming for many stakeholders, including patients, health providers, policy makers, and third-party payers. Although all parties share a common goal and wish to use limited health-care resources to support interventions most likely to result in clinically meaningful improvements, there is often uncertainty about the most appropriate intervention for a particular patient. To help understand and evaluate the various commonly used nonsurgical approaches to CLBP, the North American Spine Society has sponsored this special focus issue of The Spine Journal, titled Evidence Informed Management of Chronic Low Back Pain Without Surgery. Articles in this supplement were contributed by leading spine practitioners and researchers, who were invited to summarize the best available evidence for a particular intervention and encourage to make this information accessible to nonexperts. Each of the articles contains five sections (description, theory, evidence of efficacy, harms, and summary) with common subheadings to facilitate comparison across the 24 different interventions profiled in this special focus issue, blending narrative and systematic review methodology as deemed appropriate by the authors. It is hoped that articles in this special focus issue will be informative and aid in decision making for the many stakeholders evaluating nonsurgical interventions for CLBP. © 2008 Elsevier Inc. All rights reserved.

Keywords: Chronic low back pain; Medicine-assisted manipulation (MAM); Lumbosacral; Manipulation under anesthesia

Description

Terminology

Medicine-assisted manipulation (MAM) is a broad term used to define manipulation of the spine after any type of anesthesia or analgesia, whether facilitated by injections or oral pharmaceuticals. It is often used interchangeably with the term manipulation under anesthesia (MUA), which is the most commonly used form of MAM.

History

Various forms of MAM have been used since the 1930s and several studies were published on MUA in the 1940s and 1950s when it was practiced by orthopedic surgeons and osteopathic physicians [1]. Early methods for MUA were very different than the modern practice of MAM. Complications from general anesthesia and forceful,

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long-lever, high-amplitude nonspecific manipulation procedures lead to decreased use of early MUA procedures in favor of surgery or other pain management therapies [1,2]. Once it had been largely abandoned by orthopedic surgeons in the 1960s, MUA was modified and revived in the 1990s by chiropractors and, to a lesser extent, osteopathic physicians. The resurgence of MAM was likely the result of increased interest in spinal manipulative therapy (SMT) and the advent of safer, shorter-acting anesthesia agents used for conscious sedation [1].

Subtypes

The various types of MAM that will be discussed in this review include MUA, manipulation under joint anesthesia (MUJA), and manipulation under epidural steroid injections (MUESIs). MUA refers to manipulation of the spine while the patient is under general anesthesia or conscious sedation. MUJA refers to manipulation of the spine after fluoroscopically guided intra-articular injections of anesthetic or corticosteroid agents. MUESI refers to manipulation of the spine after epidural steroid administration.

General description

Manipulation under anesthesia

The treatment procedures for MUA as practiced today are very different than those practiced by orthopedic surgeons in the 1940s and 1950s [1,2]. Performing MUA requires a multidisciplinary team that may include an anesthesiologist, a trained primary manual therapist (eg, chiropractor, osteopath), a trained secondary manual therapist, a physical therapist, and a nurse [3]. Communication and respect between team members is considered a crucial factor to success with MUA [4].

The MUA procedure generally consists of four stages: sedation, mobilization/stretching/traction, manipulation, and post-MUA care [2].

The procedure begins with an anesthesiologist who induces deep conscious sedation with intravenous propofol or midazolam and monitors the patient with a cardiac monitor, blood pressure cuff, and oximeter [1]. This form of anesthesia is considered safer than general anesthesia. The manual therapist then performs a series of mobilization, stretching, and traction procedures to the spine and lower extremities. Less force is applied during these procedures than when the patient is fully awake and use of conscious sedation preserves joint end feel, which helps the therapist determine the amount of force needed [5]. The procedure may start by passive stretching of the gluteal and hamstring muscles with repeated single straight leg raise, progressively increasing the upper range of motion. Other stretching procedures might include progressive knee to chest, followed by hip capsule stretching and mobilization in all planes of motion (eg, Fabere’s procedure). Lumbosacral traction may then be applied by repeatedly bringing both knees to the chest while stabilizing the sacrum and manually applying caudal axial distraction. The lateral abdominal and paraspinal muscles may then be stretched by bringing both knees down from the chest to each side of the body while stabilizing the upper body. Other stretching or mobilization procedures may also be applied as needed.

After the stretching and traction procedures, the patient is typically placed in a side-lying position to receive SMT with a high-velocity, short-amplitude thrust applied to a spinous process by hand, while both manual therapists stabilize the upper torso and lower extremities. In addition to the lumbosacral area, SMT may also be applied to the thoraco-lumbar or cervical area if considered necessary by the manual therapist to address the chronic low back pain (CLBP). The above procedures generally take 15 to 20 minutes. Immediate post-MUA care includes observation by a nurse until the patient recovers from the anesthesia, after which they are discharged with instructions to remain active and use heat or ice for short-term algescic control. Post-MUA care may include 4 to 8 weeks of active rehabilitation and additional manual therapy such as myofascial release techniques, mobilization, SMT, stretching, traction, and therapeutic modalities.

Some proponents of MUA recommend performing the same procedure on 3 consecutive days to achieve optimal results, but there is little evidence to support this opinion. The rationale for performing MUA on 3 consecutive days is that each procedure can be gentler because the therapist is not attempting to release all fibrous adhesions in only one session, which may require greater force. Other practitioners prefer to administer serial MUA only if the patient responds positively to the first procedure but symptoms remain that could perhaps be addressed with one to two more sessions.

Manipulation under epidural steroid injection

MUESI begins with epidural injection of a corticosteroid and local anesthetic (eg, 80 mg Depo-Medrol and 3 mL lidocaine 1%) and then proceeds similarly to the MUA procedure described above, with fewer general stretching/mobilization/traction maneuvers because muscle guarding may still be present [6].

Manipulation under joint anesthesia

MUJA begins with fluoroscopically guided intra-articular injection into zygapophyseal joints with local anesthetic [4]. If greater than 50% improvement in pain is noted, the injection is sometimes repeated with a corticosteroid. The patient may then receive SMT and stretching/mobilization procedures to the lumbosacral area. It has been proposed that six to eight sessions of SMT may be performed over 10 to 14 days after MUJA while the analgesic properties of the injection remain [7].
Practitioner, setting, and availability

The physician administering the conscious sedation for MUA should be an anesthesiologist, whereas the physician administering the epidural for MUESI or joint injection for MUJA can be an anesthesiologist, pain management physician, physiatrist, or orthopedist. The manual therapist should be extensively trained and licensed to provide SMT without anesthesia, and receive MUA certification from accredited continual medical education or continuing chiropractic education courses. Certification typically consists of 8 to 12 hours of classroom instruction, an equal amount of practical instruction, and completion of a number of procedures proctored by an experienced MUA therapist. Specific requirements for MUA certification vary by state. For example, Missouri requires 25 hours of instruction and six proctored procedures, whereas Wisconsin requires completion of a continuing chiropractic education course and 15 proctored procedures, and Texas requires 24 hours of instruction and five proctored procedures [8]. The secondary manual therapist who assists the primary manual therapist should also be certified in MUA. MUA is typically performed in an outpatient surgical center [2]. MUJA requires a fluoroscopy suite and is typically performed in an outpatient surgical/imaging center [7]. MUESI can be performed in a private practice or outpatient surgical center.

The availability of MAM is largely determined by the presence of trained manual therapists working in multidisciplinary settings with medical specialists to administer the anesthesia. The availability of this therapy is therefore difficult to generalize. For instance, there are reports that physicians and chiropractors in the smaller town of Tyler, TX have treated 1,000 patients with MUJA over a 7-year period [7]. There is one report that MUA has been performed on over 20,000 patients based on a literature review and clinician interviews in the United States and United Kingdom [5].

Reimbursement

CPT code 22505 describes manipulation of spine requiring anesthesia, any region [5]. Although there are no specific codes for MUJA or MUESI, it has been suggested that the SMT component of those procedures should not cost any more than regular SMT [7]. A single session of MUA may cost $3,000 to $6,000, the majority of which is for the anesthesia, surgical center facility fee, and radiologic procedures. Reimbursement policies regarding MUA vary widely from state to state. It was reported in 2003 that MUA was generally covered by the Texas worker’s compensation board, Texas board of insurance, and HSG administrators of Pennsylvania [8]. The same report also noted that MUA was generally not covered by BlueCross/BlueShield of Tennessee and North Carolina, nor was it covered by Aetna; it was stated at the time that there was no Medicare coverage policy on MUA [8]. MUA was covered intermittently in California by the workers’ compensation board and various private insurers when preapproval was obtained, but recent changes in legislation have cast serious doubts on the future of MUA in California [9].

Theory

Mechanism of action

The use of MUA grew from clinical observation and experience that the combined effects of anesthesia/analgesia and SMT were more beneficial than when each was administered separately [1]. The mechanism of action offered to explain these observations is that anesthesia/analgesia decreases regional pain, spasm, or muscle guarding that could interfere with effective delivery of manual therapies such as SMT, mobilization, traction, and stretching. The relaxation brought about by MUA is postulated to allow the manual therapist to more effectively break up joint and soft-tissue adhesions and reduce segmental dysfunction with less force than would otherwise be required to overcome patient resistance or apprehension [5]. It is purported that reducing such adhesions increases ligament, tendon, muscle, and articular flexibility [5]. There is no experimental research to confirm or refute these theories.

The use of anesthesia/analgesia is also thought to allow SMT to be performed on patients who cannot otherwise tolerate the procedure when fully awake because of excessive guarding or pain [2]. It has also been proposed that manual procedures performed during MUA disrupt abnormal cross-linking in collagen fibers that form after incomplete healing from injury, without precipitating the acute inflammation cascade that may result in scar tissue formation [3]. With MUESI and MUJA, the use of corticosteroid may help address the inflammatory component of CLBP while manual therapy addresses its mechanical component [6], creating a synergistic treatment effect.

Diagnostic testing required

In general, no specific diagnostic testing is required before MUA other than what is necessary to establish that the primary complaint is nonspecific mechanical CLBP. Although it has been suggested that anterior-posterior, lateral, oblique, flexion/extension, and lateral bending lumbar spine X-rays can help identify specific vertebral levels that may be corrected during the procedure [2,10] and contrast magnetic resonance imaging can help distinguish disc herniation from fibrosis [2,3], there is no evidence to confirm that these imaging studies impact the outcomes of treatment. Preanesthesia clearance must also be obtained by the anesthesiologist for MUA.

Indications and contraindications

The general indication for MUA proposed by practitioners is nonspecific mechanical CLBP that has failed to
respond to more conservative treatment options. There is
general agreement between MUA guidelines and training
materials that patients should first try 4 to 8 weeks of
SMT and other conservative care before considering MUA,
unless SMT cannot be attempted because of severe pain or
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the procedure was mostly performed by orthopedic surgeons or osteopathic physicians and differed considerably from MUA as currently taught and practiced. Nevertheless, almost all (90%) of those case series reported generally positive findings that ranged from short-term improvements in pain to long-term changes in function. The review also uncovered evidence related to other forms of MAM including four case series on MUESI for CLBP, one case series on SMT with caudal anesthesia for LBP (duration unknown), and one case series on MUJA for CLBP. All of the case series reported generally positive results. The review noted that although findings reported in most case series for MUA, MUESI, and MUJA were positive they had poor methodological quality, lacked control groups, and an incomplete understanding of the purported benefits of combining SMT with anesthesia/analgesia.

**Randomized controlled trials**

No eligible RCTs were uncovered related to MUA, MUJA, or MUESI. The RCT [19] identified in one of the SRs [8] was published in 1971 and therefore excluded.

**Observational studies**

A total of six observational studies were identified and included in this review (Table 1).

An observational study examined a prospective cohort of patients with CLBP who received 4 to 6 weeks of chiropractic care with SMT, manual therapy, and exercise [15]. Participants were eligible if they had CLBP >3 months, reduced lumbopelvic flexibility as measured by failure to bring fingertips to floor, and age range of 18 to 60 years; exclusion criteria were fracture, infection, tumor, nonmechanical cause of LBP, active rheumatoid disease, tobacco use, coagulation disorder, contraindications to anesthesia, severe coexisting disease, and workers’ compensation or litigation. Those who failed to achieve substantial improvements in pain, function, or flexibility after 4 to 6 weeks were given the option of receiving one to three sessions of MUA with conscious sedation and internal traction of the sacrocccygeal region. Of the 68 participants recruited into the study, 42 (62%) received MUA and 26 (38%) continued to receive chiropractic care and acted as a control group. Outcomes were measured at baseline, 6 weeks, 3, 6, and 12 months using the North American Spine Society composite questionnaire that included pain, disability, quality of life, patient expectations of treatment outcomes, and comorbidities. Baseline differences were noted between groups in pain and disability, and participants who eventually received MUA presented with significantly worse symptoms upon entering the study and failed to improve as much as the control groups after 4 to 6 weeks of chiropractic care. After receiving MUA, however, their improvement increased considerably and they overtook the control group behind which they had lagged after 3 months. There were no differences in outcomes between groups in subsequent follow-up at 6 or 12 months. Authors concluded that participants with CLBP presenting with greater symptoms were more likely to receive a recommendation for MUA, which appeared to offer them increased improvements over chiropractic care.

A study was conducted examining a prospective cohort of patients with CLBP presenting for care to chiropractors affiliated with surgical centers offering MUA [16]. Participants were included if they were older than 18 years, had CLBP >6 months, had clinical eligibility for MUA as established by the National Association for Manipulation Under Anesthesia Practitioners, and had received at least 4 weeks of SMT before enrolling in the study. Although all participants received a recommendation for MUA, not all were approved for the procedure by their insurance companies. Those who did (n = 38) and did not (n = 49) receive insurance approval were compared after one to four daily MUA procedures (mean, 2.7) and 4 weeks of chiropractic care (MUA group) or continued chiropractic care only (chiropractic group). MUA consisted of conscious sedation with propofol, stretching, mobilization, and SMT. Outcomes were assessed with the numerical pain rating scale and Roland Morris disability questionnaire at baseline, after their last MUA procedure, and 4 weeks later. Numerical pain rating scale scores at baseline, post-MUA, and 4 weeks later were 7.31, 4.36, and 3.66 for the MUA group and 6.78, 5.88, and 4.98 for the chiropractic group, respectively. Roland Morris disability questionnaire scores at baseline, post-MUA, and 4 weeks later were 10.9, 7.8, and 5.3 for the MUA group and 6.9, 5.6, and 4.3 for the chiropractic group, respectively. Although both groups improved, there were greater changes from baseline in both outcomes in the MUA group; it was unclear if these differences were statistically significant.

An observational cohort study reported on patients presenting for care to chiropractors with a variety of spinal complaints [11]. Eligibility criteria included consideration for MUA based on a diagnostic/treatment algorithm (eg, 2–6 weeks failed conservative care) and absence of contraindications or severe coexisting disease. Of the 200 potentially eligible participants, 177 were enrolled and 168 (95%) completed follow-up visits. Participants presented with cervicocranial, cervical, thoracic, lumbar, or pelvic complaints. Although the areas of complaint were dichotomized into cervical or lumbar for study purposes, the number of participants in each category was not reported. Outcomes were assessed by visual analog scale and range of motion before and after MUA and at 6 months post-MUA. Lumbar range of motion increased on average 83%, and lumbar visual analog scale improved from 7.27 at baseline to 4.91 post-MUA and 2.96 after 6 months. Return to work and analgesic consumption also improved, though results were not presented separately for the cervical and lumbar patients.

A case series was presented in which 10 participants with mechanical CLBP who had failed to achieve >50%
<table>
<thead>
<tr>
<th>Reference</th>
<th>Inclusion/exclusion criteria</th>
<th>Number of participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Follow-up</th>
<th>Results</th>
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<tr>
<td>[15]</td>
<td>Inc: LBP &gt;3 mo, reduced lumbopelvic ROM, age 18–60 y. Exc: fracture, infection, tumor, nonmechanical LBP, rheumatoid disease, tobacco use, coagulation disorder, contraindications to anesthesia, severe coexisting disease, workers’ compensation or litigation.</td>
<td>Enrolled: MAM: n=42; CON: n=26; 12 mo: n=63</td>
<td>MAM: 4–6 wk SMT followed by one to three treatments of modified MUA with internal traction and mobilization of the sacrococcygeal region. CON: 4–6 wk SMT followed by 4–12 wk of additional SMT.</td>
<td>Pain/disability (101-point scale based on NASS composite instrument) HRQOL (SF-36).</td>
<td>3 mo 12 mo</td>
<td>Improvement: MAM 39% CON 13%. Mean difference between groups: 4.4 (ns). Improvement: MAM 33% CON 14%. Mean difference between groups: 0.3 (ns).</td>
</tr>
<tr>
<td>[16]</td>
<td>Inc: age 18 y, LBP &gt;6 mo, clinical eligibility for MUA based on NAMUAP, received 4+ wk of SMT before enrollment.</td>
<td>Enrolled: MAM: n=38 CON: n=49</td>
<td>MAM: 1–4 MUA procedures over consecutive days followed by specific MUA rehabilitation lasting 4–6 wk. CON: SMT, passive modalities, HEP, 3×/wk, 4 wk.</td>
<td>Pain (NPRS) Disability (RMDQ).</td>
<td>4 wk after last MUA</td>
<td>Pain: MAM 50% CON 26% (p=not reported). Disability: MAM 51% CON 38% (p=not reported).</td>
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<tr>
<td>[6]</td>
<td>Inc: Mechanical LBP, failure to achieve &gt;50% improvement with conservative care (eg, medication, ESI, physical therapy, 6+ SMT sessions). Exc: Contraindication to SMT, severe coexisting disease.</td>
<td>Enrolled and 12 mo MAM: n=60</td>
<td>MUESI: ESI, flexion-distraction mobilization SMT, one to three sessions.</td>
<td>Three categories of improvement based on symptoms and continued need for care.</td>
<td>12 mo</td>
<td>20/60 (33%) significant improvement 27/60 (45%) temporary improvement 13/60 (22%) no change.</td>
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<td>[4]</td>
<td>Inc: Mechanical LBP with radiculopathy, failure to respond to prior conservative care with mobilization, SMT, exercise, and NSAIDs. Exc: Cauda equina syndrome or other severe coexisting disease.</td>
<td>Enrolled and 4–6 mo MAM: n=4</td>
<td>MUJA: 1 intra-articular injection of anesthetic and corticosteroid followed by SMT for several times over 2 wk.</td>
<td>Pain relief (unspecified).</td>
<td>4–6 mo</td>
<td>At 4 mo, nearly complete relief (n=1); at 6 mo, three pain free (n=3).</td>
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</table>

MAM=Medicine-assisted manipulation; MUA=Manipulation under anesthesia; SMT=Spinal manipulative therapy; NASS=North American Spine Society; NAMUAP=National Association for Manipulation Under Anesthesia Practitioners; NPRS=Numerical pain rating scale; RMDQ=Roland Morris Disability Questionnaire; VAS=Visual analog scale; ROM=range of motion; ESI=Epidural steroid injection; HEP=Home exercise program; HRQOL=health-related quality of life; MUESI=Manipulation under epidural steroid injection; NS=not significant. Follow-up: Time from onset of intervention, unless otherwise noted. Results: Mean change (improvement) scores from treatment initiation, unless otherwise noted.
improvement with conservative care such as medication, epidural steroid injections, physical therapy, and a minimum of six sessions of SMT received MUESI [17]. Participants were excluded if they had any contraindications to SMT or severe coexisting disease. The MUESI procedure included 10 mg oral diazepam and injection of 10 mL containing lidocaine, saline, and 15 mg betamethasone into the epidural space under fluoroscopic guidance, followed by SMT within 30 to 60 minutes of the injection. Outcomes were assessed upon completing conservative care and 30 days after the MUESI using a self-reported global improvement scale (0–100%). The mean self-reported improvement after MUESI was 25% and represented a statistically significant change from baseline (p = .0015).

A retrospective case series reported on 60 patients with mechanical LBP and radiculopathy who had failed to respond to prior conservative care with mobilization, SMT, exercise, and nonsteroidal antiinflammatory drugs (NSAIDs) and were treated with MUESI [6]. Participants were excluded if they had cauda equina syndrome or other severe coexisting disease. The epidural steroid injection was performed using 80 mg Depo-Medrol and 3 mL of 1% lidocaine, after which flexion-distraction mobilization and SMT were applied. Outcomes were assessed according to the following three categories of improvement: 1) significant (resolution of pain, no further care), 2) temporary (reduction of pain but further nonsurgical care needed), and 3) no change (required subsequent surgery). After 12-month follow-up, 20 out of 60 (33%) had significant improvement, 27 of 60 (45%) had temporary improvement, and 13 of 60 (22%) had no change.

Four cases are presented in which patients with CLBP who obtained partial, short-term relief with conservative or manual therapy but failed to improve completely received MUJA [4]. Upon successfully locating the source of their pain through challenge injections to the zygapophysial joints or sacroiliac joints under fluoroscopy, patients underwent SMT to that area several times for 2 weeks after the injection. Outcomes were assessed subjectively before and after MUJA. Results were considered encouraging as one patient had nearly complete pain relief after 4 months and three remained pain free at 6 months.

Ongoing studies

We are not aware of any ongoing studies related to MUA, MUJA, or MUESI.

Harms

Although older forms of MUA using more forceful long-lever techniques were associated with adverse events (AEs) such as cauda equina syndrome, paralysis, and fracture, more recent studies have not reported any serious AEs [1]. If malpractice insurance premiums may be used as a proxy for the safety of a procedure, it should be noted that two large chiropractic insurers provide MUA coverage at no additional charge to their members [2]. Temporary flare-ups in lumbosacral pain have been reported and are attributed to stretching of adhesions and mobilization of inflamed joints [5]. Such flare-ups are easily treated with postoperative care; serious complications are rare [5].

A review of the MAM literature reported a total of 11 AEs in 17 studies with a total of 1,525 participants [1]. These AEs included eight cases of increased lumbosacral pain, one case of myelographic evidence of herniated intervertebral disc, and two cases of respiratory distress that resolved with Valium [1]. An additional review of MUA reported no AEs in any of the published studies, indicating they are likely rare [8]. Most observational studies have reported no AEs from MUA [1, 4, 11, 16, 17]. One cohort study on both cervical and lumbar MUESI reported two wet taps and one vagal response, though it was unclear if those were related to cervical or lumbar procedures [6].

Judging from participant exclusion criteria used in previous studies on MAM, it would appear that patients with nonmechanical CLBP, active rheumatoid disease, tobacco use, severe coexisting disease, severe obesity, and involvement in workers’ compensation or litigation are less likely to respond favorably to MUA, MUJA, or MUESI [1].

Summary

As noted in previous studies, generalizing prior MUA literature is very challenging—perhaps even inappropriate—because of participant heterogeneity and differences in treatment procedures used several decades ago and those used today [1, 16]. Overall, the methodological quality of the studies uncovered related to MUA, MUESI, and MUJA is weak and evidence consists mainly of observational studies. None of the MAM procedures have been subjected to a RCT and the absence of a rigorous, comparable control group makes interpreting results difficult. However, almost all studies to date on these procedures have reported positive results, indicating that patients who undergo their procedures have a reasonable prognosis. There is currently insufficient evidence to make any recommendations concerning MUA, MUJA, or MUESI for CLBP.

As is with other manual therapies, it is challenging to conduct quality research in this area. Eligibility for MUA often includes a requirement for prior failed SMT, making SMT alone a poor control group because those proceeding to MUA would have already been identified as not responding to SMT [8]. However, a study in which participants at baseline are deemed eligible for MUA, MUJA, and MUESI, and randomly allocated to the procedure or an alternative treatment approach would provide information as to the relative outcome after two treatment approaches even if there was no blinding of participants or clinicians. An independent observer, however, is essential. The recent experience from surgery comparing outcomes in patients who have
surgery with those who do not have surgery could serve as templates for clinical trials that could be considered to determine the efficacy of MUA. There is a strong need for comparative clinical trials, large cohort studies, and experimental studies to support the theories on which these treatment approaches are based.

Despite being used for over 80 years, there is insufficient research to guide clinicians, policy makers, and especially patients’ decision whether to consider this treatment approach. At present, MAM can be considered one of the multiple treatment approaches that have been proposed for the management of CLBP whose primary justification is the mostly positive experience of clinicians, a few observational studies, and presumably satisfied patients. These procedures deserve the same consideration that is given to other treatment approaches with similarly weak levels of evidence.

References


