7-2024

Osteopathic Manipulative Therapy: An Effective Alternative to Common Pharmacological Treatments for Low Back Pain

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OSTEOPATHIC MANIPULATIVE THERAPY: AN EFFECTIVE ALTERNATIVE TO COMMON PHARMACOLOGICAL TREATMENTS FOR LOW BACK PAIN

by

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A THESIS

submitted to Lynn University in partial fulfillment

of the requirements for the degree of

Master of Science in Biological Sciences

2024

College of Arts and Sciences

Lynn University

Abstract

Nicole Shirman: Osteopathic Manipulative Therapy: An Effective Alternative to Common Pharmacological Treatments For Low Back Pain

Osteopathic manipulative therapy (OMT) is a promising non-pharmacological treatment for low back pain, but its efficacy and mechanisms have been debated. This literature review provides a comprehensive assessment of OMT's therapeutic effects and potential mechanisms for the treatment of low back pain. Multiple randomized trials demonstrate OMT provides statistically and clinically meaningful reductions in pain intensity and disability compared to sham treatments or standard care, particularly among patients with higher baseline symptom severity. Subgroup analyses reveal older age and absence of depression enhance OMT response rates. OMT appears safe and well-tolerated, with high patient satisfaction and reduced analgesic requirements versus controls. Mechanistic studies suggest OMT may mitigate biomechanical dysfunctions, exert anti-inflammatory effects via cytokine modulation, and stimulate immunomodulatory processes. While OMT displays general efficacy, developing predictive models to optimize patient selection is a key priority in expanding its utilization. Given its benefits and non-pharmacological profile, OMT is a valuable potential tool for combating the opioid epidemic through first-line pain management. However, further research directly comparing OMT to opioids and evaluating opioid-sparing impacts is needed. Overall, this review positions OMT as an effective conservative therapy for chronic low back pain before escalating care, with a compelling role in fighting public health crises like opioid abuse as a non-invasive and non-addictive manual therapy. Strategic implementation of evidence-based OMT protocols may enhance patients' quality of life while concurrently mitigating the socioeconomic burden of low back pain.

Acknowledgments

Thank you to Dr. Jonathan Smith for his invaluable guidance and mentorship throughout this literature review. I am also deeply thankful to my parents, sister, grandparents, and my beloved cat, Oreo, for their tireless support and encouragement. Finally, I would like to thank all of the professors who have contributed to my growth this academic year.

Dedication

To my parents, thank you for always telling me to reach for the stars and giving me the means to do so.

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Osteopathic Manipulative Therapy: An Effective Alternative to Common Pharmacological Treatments For Low Back Pain

Low back pain represents a significant public health burden affecting millions worldwide. With a lifetime prevalence estimated around 80%, low back pain is the leading cause of activity limitation and work absenteeism globally (Nguyen et al., 2021). The substantial socioeconomic toll, coupled with the often chronic and debilitating nature of low back pain, underscores the urgent need for safe and effective treatment options.

Conventional management strategies for low back pain include analgesic medications, physical therapy, exercise, and patient education. However, many of these treatments demonstrate limited long-term efficacy, particularly for chronic low back pain (Schwerla et al., 2015). Pharmacological interventions like opioids are associated with risks of misuse, dependence, and adverse events such as respiratory depression (Damiescu et al., 2021). Despite guidelines recommending avoiding high opioid doses, rates of dose reduction remain low among chronic pain patients (Damiescu et al., 2021). The inadequacies of standard care and the perils of the ongoing opioid crisis highlight the necessity of exploring alternative therapeutic approaches.

Osteopathic manipulative therapy (OMT) has emerged as a promising non-pharmacological option for low back pain management. Rooted in principles of body unity, self-healing, and structure-function integration, OMT aims to alleviate musculoskeletal pain and restore optimal function through manual techniques (Licciardone et al., 2013a). Although recommended for chronic low back pain by some guidelines, a Cochrane review questioned the superiority of OMT over sham treatments (Licciardone et al., 2013a). This uncertainty, coupled with OMT's potential to reduce reliance on medications, warrants further rigorous investigation.

Several randomized controlled trials have examined OMT for low back pain, with mixed but encouraging results — while some studies showed significant benefits of OMT over control treatment, others found more modest or inconsistent effects, yet the overall trend suggests OMT has potential as an effective intervention for many patients with low back pain. Studies report small-to-moderate benefits of OMT over sham treatment in reducing low back pain-related disability and moderate-large effects in providing substantial pain relief, particularly in patients with severe chronic low back pain (Licciardone et al., 2013; Nguyen et al., 2021). OMT may also decrease opioid use and medication costs compared to usual care (Licciardone et al., 2013; Andersson et al., 1999). However, the clinical relevance and durability of these effects remain unclear.

Understanding OMT's mechanisms of action is key to determining its therapeutic potential. Research suggests OMT can reduce biomechanical dysfunctions like somatic and visceral restrictions (Licciardone et al., 2014; Tamer et al., 2017). Psoas syndrome remission in particular may underlie improvements in chronic low back pain following OMT (Licciardone et al., 2014). Anti-inflammatory effects through modulation of cytokines have also been proposed (Licciardone et al., 2012). Investigating OMT's physiological impacts is crucial for optimizing its use and patient selection.

As a non-invasive, low-risk therapy with multimodal effects, OMT is an attractive option amid the opioid crisis and escalating healthcare costs. However, substantial gaps remain in understanding its true efficacy, ideal application, and mechanisms for specific low back pain populations. This literature review aims to provide a comprehensive assessment of the therapeutic efficacy of OMT for low back pain. The review will evaluate OMT's comparative effectiveness relative to sham treatment, standard medical care, and other conventional

interventions. The potential for differential OMT treatment effects across various patient subgroups defined by factors such as symptom chronicity, pain severity, and functional status will be explored in an effort to identify opportunities for patient selection. The review will also examine the evidence surrounding potential mechanisms of action underlying OMT's therapeutic effects, including data on biochemical mechanisms, inflammatory mitigation, and neuromodulatory influences that may contribute to OMT's capacity to reduce low back pain and associated functional deficits.

By comprehensively synthesizing and critically analyzing the available research specific to OMT and low back pain, this literature review seeks to bring greater clarity to the ongoing clinical and public health discourse, with the aim of providing an evidence base to guide clinical decision making and health policy development. With growing urgency to stem the epidemic of opioid misuse and dependence, expanding access to safe, effective, and affordable non-pharmacologic pain management options like OMT is an immense opportunity to potentially transform standards of care and ease a burden of human suffering. OMT represents an effective, safe, and economical non-pharmacological treatment option for managing chronic low back pain, and should be utilized as a first-line intervention before escalating to more invasive or higher-risk treatments.

Setting the Scene

Background on Low Back Pain

The burden of back pain is a pervasive public health issue with extensive individual and societal implications. Low back pain has an exceedingly high prevalence that can be seen across all ages and demographics, representing a leading contributor to disability and socioeconomic burden worldwide (Auger et al., 2021). A global review indicates that the point prevalence of

low back pain is approximately 12%, the one-month prevalence is 23%, the one-year prevalence is 38%, and the lifetime prevalence is approximately 40% in the adult general population (Manchikanti et al., 2014).

Beyond its frequency, the impact of low back pain affects many aspects of daily living and productivity, often resulting in missed workdays, activity limitations, and substantially diminished quality of life for those afflicted. A systematic review of studies from around the world found that low back pain affected 619 million people globally in 2020, with it being the leading cause of years lived with disability both internationally and domestically in the vast majority of countries sampled (Ferreira et al., 2023). Chronic low back pain, characterized by symptoms persisting for 3 months or more, is estimated to afflict around 20.1% of the patient population, with this subgroup bearing a disproportionate share of the economic burden — healthcare costs and potential income lost due to physical limitations — and individual suffering — the pain itself — imposed by the condition (Hoy et al., 2012). This pain can be a complex response to various underlying factors, including but not limited to musculoskeletal issues, nerve compression, inflammatory processes, or psychosocial stressors, highlighting the complex nature of chronic low back pain.

Certain populations face particularly elevated risks and unique challenges with respect to low back pain. Pregnant women are one such vulnerable group, with epidemiological studies estimating that around 50% will experience pregnancy-related low back pain and associated functional impairments over the course of their pregnancy or in the postpartum period (Schwerla et al., 2015). Whether characterized as pregnancy-related low back pain, pelvic girdle pain, or lumbopelvic pain, these musculoskeletal symptoms can dramatically undermine both physical functioning and quality of life. Low back pain during pregnancy has been linked to greater risks

of labor difficulties, higher likelihoods of cesarean section, and poorer postpartum recovery trajectories (Katonis et al., 2011). Furthermore, the development of chronic low back pain is an unfortunate outcome for many women following pregnancy, often persisting well into the postpartum period and beyond.

Conventional Treatments and Their Limitations

Despite the prevalence and burden it presents, the management of low back pain remains a challenge lacking a clear consensus on optimal treatment approaches. An array of therapies are utilized in various combinations, though efficacy and safety remain topics of ongoing debate. More conservative first-line interventions typically include physical therapy techniques such as exercises, heat and cold application, manual manipulation, and back stabilization programs (Shipton, 2018). Pharmacological pain relievers including acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, and opioid analgesics have all seen widespread utilization as well. However, accumulating evidence has highlighted significant limitations and potential harms associated with some of these conventional treatments. Standard therapies like physiotherapy exercises, stabilization belts, and pain medications possess a relatively sparse evidence base demonstrating clear long-term benefits, particularly for pregnancy-related low back pain and postpartum recovery (Schwerla et al., 2015). The long-term use of pharmacological agents for chronic low back pain has come under greater scrutiny due to concerning safety profiles, with opioid analgesics being a source of heightened apprehension given the opioid abuse epidemic.

Escalating therapeutic doses of opioid medications among chronic users have been associated with an increased risk of harmful side effects, opioid abuse and dependence, as well as fatal and non-fatal overdoses (Damiescu et al., 2021). Despite many patients reporting adverse

effects and functional limitations at high opioid dosages, studies have documented alarmingly low rates of attempts by providers to reduce or discontinue these medications for chronic low back pain (Damiescu et al., 2021). This perpetuation of potentially hazardous prescribing practices reflects factors including inadequate provider education, gaps in available treatment alternatives, and the challenges involved in guiding patients away from long-term opioid use. In light of these realities, the opioid epidemic has intensified worldwide urgency for developing and expanding access to effective non-pharmacological pain management strategies.

The scope and human toll of the opioid abuse crisis are alarming and transcend geographic, socioeconomic, and demographic boundaries. In the United States alone, over 115 Americans lost their lives each day to opioid overdoses in 2016, nearly tripling the national rate since 1999 (Hagemeier, 2018). Well over 2 million Americans were estimated to have active opioid use disorders in 2016, signaling a public health emergency that has placed immense strains on medical systems and taken a heavy personal toll through disrupted lives, familial trauma, and loss of human potential (Hagemeier, 2018). While the historical factors leading to this epidemic are complex, ranging from unethical marketing practices by pharmaceutical companies to socioeconomic disparities and deficiencies in addiction treatment and recovery services, the statistics reflect the immense individual and societal costs of opioid abuse. Recent data indicates that prescription opioids were initially a main driver prior to 2014, though in more recent years, illicit opioids like heroin and synthetic fentanyl analogs have seen even sharper increases in associated overdoses and deaths (Hagemeier, 2018). With strong evidence linking higher dosages and prolonged courses of prescription opioids to greater risks of opioid use disorder and overdose fatalities, there is an urgent need to prioritize the expansion of non-

pharmacological pain management options, especially for chronic conditions such as low back pain.

Why Osteopathic Manipulative Therapy

It is in such a landscape that OMT has emerged as a promising non-invasive treatment option warranting further investigation for its potential to relieve low back pain and improve functional limitations. OMT, a core component of osteopathic medicine, encompasses a diverse array of manual techniques including soft tissue stretching, muscle energy procedures, articulation of joints, high-velocity thrusts, and other hands-on manipulations (Licciardone et al., 2016). While OMT has been recommended by some clinical guidelines for the management of chronic low back pain, a 2005 Cochrane review questioned the robustness of the evidence supporting its efficacy over sham or placebo treatments, highlighting the need for more rigorous research (Licciardone et al., 2013a). However, a growing body of clinical trials and pragmatic studies have yielded encouraging — statistically significant and clinically meaningful — results suggesting OMT's potential to alleviate low back pain and associated disability across various patient populations.

Preliminary evidence has highlighted OMT's ability to relieve musculoskeletal pain conditions like low back pain, likely through mechanisms involving reduced inflammation, biomechanical remodeling by improving structural alignment, and modulation of the neuromusculoskeletal system (Auger et al., 2021; Walkowski et al., 2014). A number of randomized controlled trials have demonstrated statistically significant reductions in low back pain intensity and functional impairment among patients receiving OMT compared to sham or placebo (Nguyen et al., 2021; Licciardone et al., 2016). Several studies have also uncovered potentially meaningful effect sizes and numbers needed to treat (NNTs) with OMT for achieving

substantial reductions in low back pain severity and restoration of functional capabilities (Licciardone et al., 2013a; Licciardone et al., 2016). NNTs are a valuable measure in clinical research, indicating the number of patients who need to receive a specific treatment for one patient to benefit compared to a control intervention. Lower NNT values suggest greater treatment efficacy, as fewer patients need to be treated to achieve one positive outcome. As such, favorite NNTs for OMT suggest that it may be an efficient and effective treatment option for low back pain. With appropriate patient selection and a short course of OMT, researchers have documented clinically important outcomes and responder rates comparable to more invasive interventions like epidural injections or surgical procedures (Burton et al., 2000).

The Opioid Crisis and Need for Nonpharmacological Treatments

Such findings take on added significance in the context of the escalating opioid crisis and the economic and clinical urgency of acting to curtail dangerous opioid prescribing practices. OMT has been proposed as a potential first-line therapy, either alone or combined with other treatments, that could delay or even completely circumvent the requirement for more high-risk pharmacological pain management regimens in certain low back pain populations (Licciardone et al., 2013a). This limitation to certain low back pain populations is an important caveat. Pain is one physiological output of many potential problems, and not all causes of low back pain might necessarily respond to OMT.

Of particular relevance from a risk management standpoint, several randomized trials found no significant differences in adverse event rates between OMT and control or placebo groups, reinforcing the perspective that OMT is a safe therapeutic option (Licciardone et al., 2013b; Licciardone et al., 2016). With opioid-related hospitalizations, fatalities, and their

associated economic toll continuing to climb, OMT presents an intriguing avenue for broader implementation as a potentially cost-effective and low-risk pain management approach.

Efficacy of Osteopathic Manipulative Therapy for Low Back Pain

The efficacy of OMT for chronic low back pain has been evaluated in several major randomized controlled trials. The OSTEOPATHIC Trial found OMT had a statistically significant and clinically relevant medium treatment effect overall in reducing chronic low back pain intensity compared to sham OMT (RR 1.41, 95% CI 1.13-1.76, p=0.002, NNT 6.9) (Licciardone et al., 2016b). Sham OMT involved hand contact, active and passive range of motion, and techniques that simulated OMT but used maneuvers such as light touch, improper patient positioning, purposely misdirected movements, and diminished force by treatment providers. Notably, a large treatment effect was observed in the substantial subgroup of patients with baseline visual analog scale (VAS) pain scores — which range from 0-100 mm, with higher scores indicating worse pain intensity — of 35 mm or greater, comprising 65% of the study population (Licciardone et al., 2016b). However, OMT was not associated with substantial improvements in back-specific functioning overall. These results must be considered in the context that patients with high pain thresholds may show less improvement with OMT due to underreporting baseline pain, while those with low thresholds might demonstrate greater perceived benefits, potentially skewing the results of the treatment effect analysis.

Subgroup analyses revealed OMT had a medium effect in improving back functioning in patients with baseline Roland-Morris Disability Questionnaire (RMDQ) scores — a 24-point scale assessing limitations in physical functioning due to low back pain, with higher scores indicating greater disability — of 7 or greater (39% of patients), and a large effect in those with baseline RMDQ of 16 or greater (5% of patients) (Licciardone et al., 2016b). These findings suggest baseline symptom severity may influence OMT's therapeutic benefits, as patients with a

baseline RMDQ of 16 or greater, a score indicating more severe pain, showed greater improvement in back functioning than those with a baseline RMDQ of 7 or greater — allowing better targeting of patients most likely to experience clinically meaningful improvements.

This premise is further supported by Licciardone et al. (2013b), who found OMT demonstrated a large effect size in relieving chronic low back pain and improving back-specific disability in patients with high baseline pain severity (≥50 mm on VAS). In this subgroup, 52% achieved substantial pain reduction (≥50%) with OMT compared to only 25% with sham OMT (RR 2.04, 95% CI 1.36-3.05, $p<0.001$) (Licciardone et al., 2013a). OMT also led to a higher rate of clinically important functional improvement per RMDQ criteria, with 34% of the OMT group achieving this compared to only 19% in the sham group (RR 1.80, 95% CI 1.08-3.01, $p=0.02$) (Licciardone et al., 2013a).

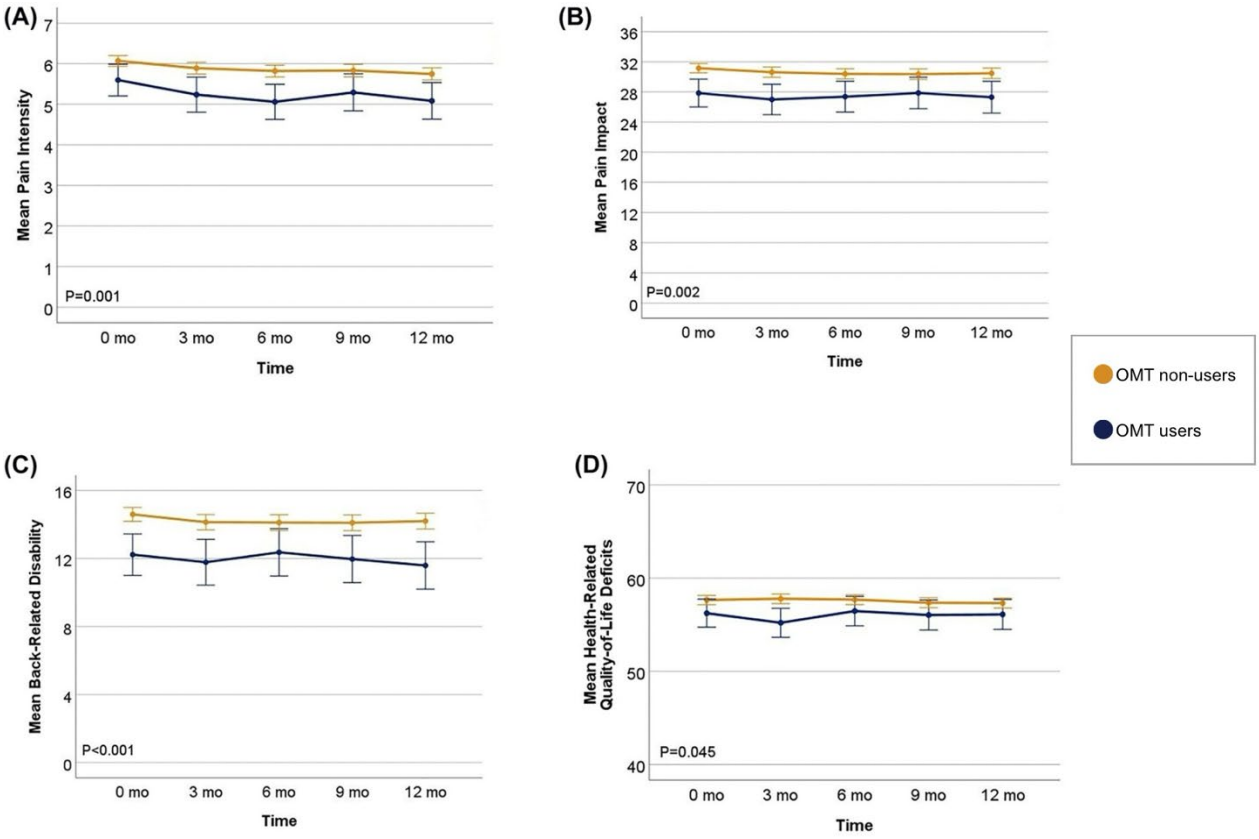
While another randomized trial by Nguyen et al. (2021) found standard OMT had a small effect in reducing low back pain-related disability at 3 and 12 months compared to sham, the authors questioned the clinical relevance of this modest benefit. Importantly, no significant differences were observed between groups in pain scores, quality of life, work absenteeism, or analgesic use over 12 months of follow-up (Nguyen et al., 2021) Thus, while the authors found a statistically significant small effect on disability, they questioned its clinical relevance as this finding was not supported by improvements in other key outcomes, suggesting the overall impact of OMT in the study was limited.

As shown by Licciardone et al. (2023), patients receiving OMT consistently reported superior outcomes compared to non-users. OMT was associated with significantly greater reductions in pain intensity scores, improvements in back-specific functional status and disability

measures, as well as enhancements in overall health-related quality of life assessments according to entirely self-reported data at quarterly follow-ups over a 12-month period (Figure 1).

Figure 1

Patient outcomes during 12 months of follow-up



Note. The use of OMT remained associated with better outcomes even after adjusting for propensity scores. (A) Pain intensity was measured with a numerical rating scale (range, 0–10). (B) Pain impact was measured utilizing pain intensity and the physical function and pain interference scales on the Patient-Reported Outcomes Measurement Information System (PROMIS; range, 8–50). (C) Physical function was measured as back-related disability with the RMDQ (range, 0–24). (D) Health-related quality of life was measured utilizing the SPADE cluster (sleep disturbance, pain interference, anxiety, depression, and low energy/fatigue) scales on the PROMIS (range, 38–77). Higher scores reflect worse outcomes on each measure. The means and p values for each outcome are based on 753 participants without OMT crossover and with complete data for all five encounters during 12 months of follow-up and are adjusted for the propensity score for reported OMT use upon entry to the cohort. Error bars represent 95% confidence intervals. Adapted from "Osteopathic manipulative treatment of patients with chronic low back pain in the United States: a retrospective cohort study" by Licciardone, J. C., Moore, S., Fix, K., Blair, L. G., & Ta, K., 2023. *Journal of Osteopathic Medicine*, *123*(5), p 259-267. (https://doi.org/10.1515/jom-2022-0212). Creative Commons 2023 by the authors. (https://creativecommons.org/licenses/by/4.0/).

A key advantage of OMT consistently demonstrated across trials is its ability to reduce medication usage for chronic low back pain. In the OSTEOPATHIC Trial, only 13% of OMT patients used prescription drugs for low back pain compared to 20% in the sham group (use ratio 0.66, 95% CI 0.43-1.00, p=0.048) (Licciardone et al., 2013b). Given the risks of long-term opioid therapy and the current public health crisis of opioid overprescribing, this effect of OMT may carry substantial clinical and economic relevance.

Low back pain also affects a significant portion of pregnant women. Several studies have evaluated OMT's role in preventing the functional decline often seen with pregnancy-related low back pain. Licciardone et al. (2010) found OMT provided important clinical benefits in lessening deterioration of back-specific function during the third trimester compared to usual obstetric care alone (effect size 0.72, 95% CI 0.31-1.14, p=0.001) or sham ultrasound treatment (effect size 0.35, 95% CI -0.06-0.76, p=0.09). Sham ultrasound treatment was delivered in the same manner as active ultrasound treatment, but at a subtherapeutic intensity. These benefits were corroborated in a supplemental analysis of patients completing at least 6 OMT sessions.

Expanding on this, Licciardone and Aryal (2013) demonstrated OMT had medium to large treatment effects in preventing progressive back-related dysfunction during late pregnancy using stringent criteria from the Cochrane Back Review Group. Patients receiving OMT were significantly less likely to experience worsening dysfunction compared to usual care alone (RR 0.4, 95% CI 0.2-0.7, p<0.0001) or sham ultrasound (RR 0.6, 95% CI 0.3-1.0, p=0.046). The numbers needed to treat (NNT) to prevent one case of progressive dysfunction were 2.5 (95% CI 1.8-4.9) versus usual care and 5.1 (95% CI 2.7-282.2) versus sham (Licciardone & Aryal, 2013).

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These findings suggest OMT may provide a valuable preventive option for mitigating the substantial burden of pregnancy-related back pain and associated functional limitations. The effects were consistent across subgroups, though the studies were limited by lack of long-term follow-up. Nonetheless, the clinical benefits and potential economic impacts of averting disability and lost productivity during pregnancy make OMT a compelling treatment option warranting further study.

The benefits of OMT extend to treating low back pain persisting after pregnancy. A randomized trial by Schwerla et al. (2015) evaluated OMT in 80 women with postpartum low back pain of at least 3 months' duration following delivery. The OMT group demonstrated improvements over 8 weeks, with a 73% reduction in pain intensity on the VAS from 7.3 to 2.0, and a 75% reduction in disability per the Oswestry Disability Index from 16.8 to 4.2. In contrast, the control group receiving no therapy showed minimal 7% pain and 9% disability improvements.

The between-group differences significantly favored OMT, with a 4.8 point greater pain reduction ($p<0.001$) and 10.6 point greater disability improvement ($p<0.001$) compared to controls at 8 weeks (Schwerla et al., 2015). Furthermore, the OMT group continued showing

progressive pain and disability improvements at 3 months' follow-up. The most commonly treated areas of somatic dysfunction were the sacrum (95% of patients), skull base (92%), and abdominal/pelvic diaphragms (82%/80%) (Schwerla et al., 2015). However, it must be noted that the lack of blinding in this study allowed participants to know whether they received the OMT intervention or not, and also for the establishment of a relationship between the patient and therapist, which may further have impacted the outcomes and data. Furthermore, due to the use of self-reporting, participants may have felt pressured to positively skew their rating.

Evidence also suggests OMT may be an effective conservative treatment option for more specific spinal pathologies like symptomatic lumbar disc herniation. A single-blind randomized trial by Burton et al. (2000) compared OMT to chemonucleolysis, an injection procedure using chymopapain enzyme to dissolve protruding disc material, in 40 patients with confirmed single-level lumbar disc herniations causing sciatica. At 12 months' follow-up, both groups achieved statistically similar improvements in leg pain, back pain, and self-reported disability scores.

However, OMT provided statistically greater reductions in back pain at 2 weeks (3.16 vs 4.00) and 6 weeks (2.68 vs 3.58), as well as disability at 2 weeks (10.15 vs 13.90), compared to chemonucleolysis injections (Burton et al., 2000). The need for additional invasive treatments was comparable, with 4 OMT patients requiring subsequent chemonucleolysis or discectomy and 4 chemonucleolysis patients needing epidural injections or manipulation under anesthesia.

A crude cost analysis revealed a substantial economic advantage for OMT, with estimated costs of £3,300 for 165 OMT sessions versus £12,000 for only 15 chemonucleolysis procedures (Burton et al., 2000). Based on these findings, the authors concluded OMT can be considered a safe and effective option for managing symptomatic lumbar disc herniations, at least in the absence of clear surgical indications. These benefits are particularly relevant for

radiculopathies which often have a self-limiting natural course, making OMT an attractive first-line option.

While the available research focuses primarily on chronic and subacute low back pain populations, findings from several studies hint at OMT's potential utility in acute low back pain as well. The observation that OMT led to faster reductions in back pain and disability over the first 2-6 weeks compared to other treatments like chemonucleolysis or standard medical care suggests it may provide more rapid symptom relief for acute episodes (Andersson et al., 1999; Burton et al., 2000).

Additionally, studies in pregnant women demonstrated OMT's ability to prevent the progressive deterioration of back-related dysfunction commonly seen during the third trimester (Licciardone & Aryal, 2013; Licciardone et al., 2010). Extrapolating this preventive effect, OMT could potentially help stem the worsening of acute low back pain and stop its transition to a chronic condition.

As a non-invasive manual therapy without medication side effects or procedural complications, OMT is a safe first-line option for acute low back pain before escalating to other interventions if symptoms do not resolve. However, research to date has not directly investigated OMT's efficacy specifically for spontaneous acute low back pain or compared it head-to-head with standard treatments in this population. Dedicated trials are needed to evaluate OMT's role in the acute care setting. Future studies should employ sham OMT protocols that mimic the hands-on approach of OMT without therapeutic intent to control for placebo effects. Additionally, researchers should stratify participants based on the etiology and nature of their acute low back pain to determine if OMT efficacy varies by injury type.

Mechanisms of Action

Osteopathic principles hold that abnormal biomechanical function, or somatic dysfunction, can contribute to pain and disability. This extends to the impact of injury and developmental defects, which are seen as potential sources of somatic dysfunction that can disrupt the body's natural balance and self-healing mechanisms. Injuries can lead to compensatory patterns of movement and posture that strain other parts of the musculoskeletal system. Similarly, developmental defects may cause structural imbalances or restrictions that affect overall bio mechanical function. According to osteopathic philosophy, these disturbances in structure and function can perpetuate pain cycles and impair the body's ability to maintain its health OMT appears to exert therapeutic effects by mitigating specific biomechanical dysfunctions.

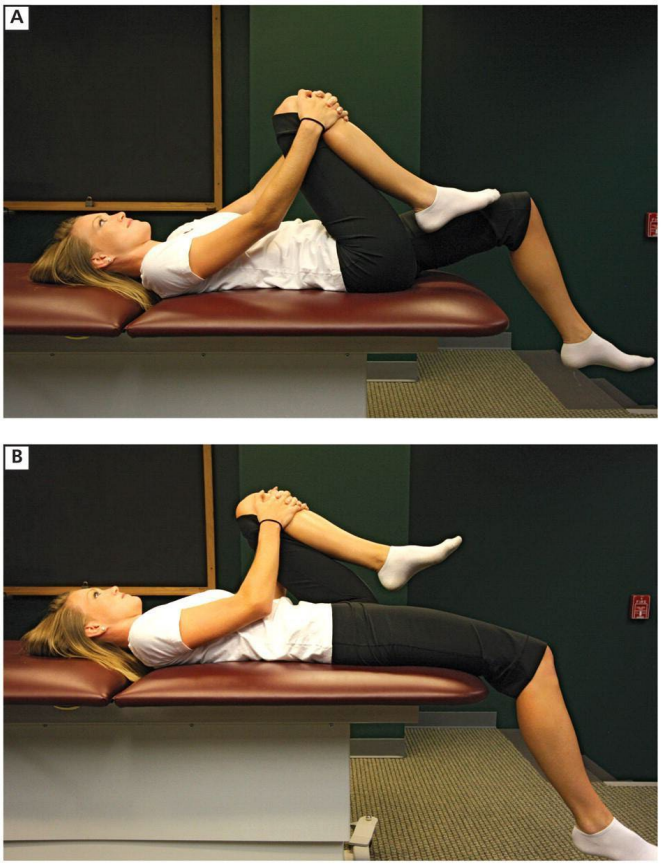
A secondary analysis from the OSTEOPATHIC Trial examined the prevalence of five key dysfunctions at baseline (non-neutral lumbar dysfunction, pubic shear, innominate shear, restricted sacral nutation, and psoas syndrome) among 230 patients with chronic low back pain who received OMT (Licciardone et al., 2014). Significant improvements were observed in all five dysfunctions following the OMT regimen. However, remission of psoas syndrome, a condition characterized by excessive psoas muscle tension and vertebral malpositioning as seen in Figure 2, stood out as the dysfunction most strongly predictive of low back pain response. Patients achieving psoas syndrome remission were over five times more likely to experience a clinically meaningful reduction in low back pain (OR 5.11, 95% CI 1.54-16.96) compared to those who did not, even after adjusting for other potential confounding factors (Licciardone et al., 2014). These findings implicate psoas syndrome as a potential key driver of chronic low back pain pathology that is relieved through OMT's biomechanical effects. However, while the odds

ratio of 5.11 suggests a potentially clinically meaningful association between psoas syndrome remission and low back pain improvement, the wide confidence interval spanning 1.54-16.94 indicates that there is considerable uncertainty around this point and the true value could be substantially lower or higher than 5.11.

While the precise mechanisms remain incompletely determined, evidence suggests OMT may modulate inflammatory pathways involved in low back pain. In a substudy of the OSTEOPATHIC Trial, higher baseline concentrations of IL-1β and IL-6 were found to correlate with greater numbers of osteopathic lesions among chronic low back pain patients (Licciardone et al., 2012). These proinflammatory cytokines have been implicated in lower back pathology and disc degeneration. Following 12 weeks of OMT, patients exhibited significantly greater reductions in TNF-α levels compared to sham manipulation, an effect that was particularly pronounced among those achieving substantial improvements in pain and back-specific functioning (Licciardone et al., 2012). As a key mediator of inflammation and nociceptor sensitization, reductions in TNF-α may be one pathway by which OMT exerts analgesic effects in chronic low back pain. However, changes in cytokine levels alone do not definitively indicate healing versus an immune response to further injury. The interpretation of these inflammatory markers in the context of OMT's effects requires further research to establish causal relationships and rule out other potential explanations for the observed changes.

Figure 2

The Thomas test for identifying patients with psoas muscle spasm



Note. In this test, patients lie supine with their legs hanging off the end of a table. They are instructed to flex their hips and knees, hugging their knees to the chest. The patient then slowly extends one leg. A positive result on the Thomas test is indicated by increased lumbar lordosis or by (A) the supine patient's inability to allow his or her leg to drop to the table when the hip and knee are extended. In a negative test result, (B) the supine patient can fully extend the leg to the table while the other leg is flexed. The Thomas test assesses tightness or spasm in the hip flexor muscles, particularly the iliopsoas group, by evaluating the patient's ability to extend their hip and leg while lying supine. From "Psoas syndrome: A frequently missed diagnosis" by Tufo, A., Desai, G. J., & Cox, W. J., 2012. *The Journal of the American Osteopathic Association*, *112*(8), p 522-528. (https://doi.org/10.7556/jaoa.2012.112.8.522). Creative Commons 2012 by the authors. (https://creativecommons.org/licenses/by/4.0/)

Evidence further suggests OMT may exert more comprehensive immunomodulatory influences. In a study of healthy volunteers, OMT induced distinct changes in circulating cytokine and chemokine levels, including early increases in MIP-1α, IL-8, MCP-1, and G-CSF

within 30-60 minutes post-treatment (Walkowski et al., 2014). OMT also triggered mobilization of a CD16+ dendritic cell subpopulation from the periphery. While the clinical implications remain speculative, these findings indicate OMT can regulate various immune parameters in a manner that could theoretically enhance immune surveillance, inflammatory resolution, or tissue repair processes — mechanisms that may contribute to OMT's benefits in certain musculoskeletal conditions (Walkowski et al., 2014). However, it is important to note that the upregulation or down regulation of inflammatory cytokines can have diverse effects depending on the specific context, tissue, and timing. The observed changes in immune markers following OMT could contribute to its benefits in certain musculoskeletal conditions, but the precise mechanisms and outcomes require further investigation. Furthermore, this must be considered in context of the relatively small sample sizes — only 19 participants in the first series of studies and 33 participants in the second series of studies — which means that small between-group differences may not have been detected and a stratified analysis of the results to include demographic differences was not able to be performed.

Other Interventions

While OMT traditionally emphasizes techniques targeting the musculoskeletal system, an emerging area of study has explored the additive benefits of incorporating visceral manipulation into treatment regimens for low back pain. A randomized trial by Tamer et al. (2017) investigated visceral osteopathic manual therapy (vOMT), which includes the use of OMT techniques applied to internal organs and visceral fascia like the diaphragm, in addition to standard OMT for patients with chronic nonspecific low back pain. Both the OMT alone and vOMT groups experienced significant improvements in pain levels and functional status following 10 treatment sessions over 2 weeks. Visceral manipulation also conferred additional

benefits in quality of life measures, leading to greater improvements in physical function, energy levels, and overall physical quality of life scores in the vOMT cohort (Tamer et al., 2017). These findings suggest that addressing potential visceral fascial limitations may aid in recovery by regulating peripheral and central pain pathways or neuromuscular responses.

However, it should be noted that this study did not appear to include a placebo or sham treatment control group, so the improvements seen cannot be definitively attributed to the visceral techniques themselves versus potential placebo effects. Additionally, the outcomes were based on self-reported pain and quality of life measures, which can be highly subjective.

The management of chronic musculoskeletal pain often involves multimodal approaches combining various rehabilitative strategies. As such, several studies have compared the efficacy of OMT to standard therapeutic exercise programs for low back pain. In one randomized, controlled trial, OMT was directly pitted against an active control regimen of stretching, stabilization, and strengthening exercises over 5 weeks in patients with chronic nonspecific low back pain (de Oliveira Meirelles et al., 2019). While both interventions were effective in reducing pain severity based on visual analog scale ratings, OMT achieved significantly greater pain reductions of 74% compared to 29% with exercise therapy. OMT was also superior in improving functional disability as measured by the Oswestry Disability Index, with the final functional disability of the osteopathic manipulation treatment group being 59% lower than baseline, which was significantly greater than the 20% reduction seen in the control group that received therapeutic exercises ($p=0.04$). Furthermore, only the OMT group experienced significant improvements in kinesiophobia — the fear of pain due to movement — and depressive symptoms (de Oliveira Meirelles et al., 2019). Improving kinesiophobia is crucial in treating low back pain because reducing fear of movement and increasing confidence in physical

activity can help alleviate apprehension and depression, which are key psychological factors that significantly influence prognosis and rate of recovery in patients. These findings highlight OMT's ability to comprehensively address the various aspects of chronic low back pain more effectively than isolated exercise-based approaches.

Response to OMT

Patterns of Clinical Response to OMT

Characterizing the trajectories of clinical response is an important step towards optimizing the utility of OMT for low back pain. Analysis from the OSTEOPATHIC Trial offers insights into the patterns observed among patients with chronic, severe low back pain treated with OMT versus sham manipulation (Licciardone & Aryal, 2014). OMT was associated with significantly higher rates of initial clinical response, defined as at least 50% reduction in pain intensity relative to baseline. 65% of OMT recipients attained this early threshold compared to just 45% receiving sham treatment. Furthermore, patients in the OMT group were over twice as likely to maintain a stable clinical response without relapse through 12 weeks of follow-up.

Among those achieving an initial response, nearly 24% of OMT patients experienced a subsequent relapse in symptoms (Licciardone & Aryal, 2014). However, this relapse rate was significantly lower than the sham group, where over half of initial responders ultimately relapsed. These patterns indicate the large OMT treatment effect was primarily driven by higher rates of stable responders who maintained clinical benefits, rather than temporary responses prone to relapse. From a clinical perspective, these data suggest potentially durable analgesic effects can be achieved through a regimen of approximately 3 OMT sessions within the first 4 weeks for patients with high baseline chronic low back pain severity (Licciardone & Aryal, 2014).

Subgroup analyses from the OSTEOPATHIC Trial have illuminated several factors associated with differential OMT effects. Notably, patients aged 50-69 years derived substantially greater benefits than younger or older counterparts, achieving over 7-fold higher recovery rates with OMT compared to sham manipulation (Licciardone et al., 2016a). This could be due to this age group being more likely to have chronic low back pain that is more amenable to manual therapy compared to younger patients with acute pain or older patients with more severe degenerative conditions, an important distinction when considering the use of OMT. Conversely, comorbid depression appeared to hinder OMT's efficacy, with significantly lower recovery rates among those with depressive symptoms because, as previously discussed, depression is a psychological factor that can amplify pain perception, decrease motivation for engaging in rehabilitative activities, and hamper the body's own healing processes.

From a sociodemographic perspective, higher educational attainment emerged as an independent predictor of low back pain improvement with OMT. Patients with a college education exhibited over a 3-fold higher likelihood of achieving a treatment response compared to those without a college degree, even after adjusting for potential confounders like age, comorbidities, and baseline symptom severity (Licciardone et al., 2014). The reasons underlying this association remain speculative but could reflect differences in health literacy, treatment expectations, or other unmeasured factors. Nevertheless, these findings highlight specific patient subgroups, such as those with higher educational attainment, who may be well-suited for OMT.

Perhaps the most clinically actionable factor in predicting OMT response has been baseline symptom severity itself. Detailed analyses have demonstrated clear relationships between higher pretreatment levels of low back pain intensity and back-specific disability with the likelihood of achieving meaningful improvements from OMT (Licciardone et al., 2016b). For

instance, patients presenting with visual analog scale pain scores of at least 35 mm or Roland Morris Disability Questionnaire scores of 7 or higher consistently experienced clinically relevant benefits that met thresholds for small to medium treatment effects with OMT.

This predictive capacity was even more pronounced at higher symptom levels, with large treatment effect sizes observed in subgroups with baseline pain intensity exceeding 50 mm or disability scores above 16 points (Licciardone et al., 2016b). By analyzing cumulative responder rates across the spectrum of baseline values, the researchers identified substantial numbers of patients likely to achieve clinically meaningful improvements in pain reduction or functional restoration based solely on pretreatment symptom burden. For example, 63% of patients with high baseline pain levels attained at least moderate improvements in pain, while nearly 40% of those with substantial functional impairment achieved considerable gains in back-specific disability following OMT (Licciardone et al., 2016b).

Safety Data and Patient Satisfaction

A critical consideration in the evaluation of any therapeutic intervention is the assessment of safety and adverse event profiles. Across the clinical trials investigating OMT for low back pain, the data indicate a favorable safety profile with minimal risk of complications or treatment-related adverse events.

In the OSTEOPATHIC Trial, there were no significant differences in overall adverse event rates between the two study arms (Licciardone et al., 2013b). While approximately 6% of participants experienced adverse events during the trial, the majority were minor musculoskeletal complaints like localized pain or stiffness. Only a single case of recurrent back spasticity was deemed potentially related to the OMT regimen. No serious adverse events were definitively attributed to OMT intervention.

This has been consistently reproduced in other OMT trials for low back pain. In a study comparing OMT to standard medical care for subacute low back pain, no major complications occurred in either treatment group over the 12-week study duration (Andersson et al., 1999). Similarly, Burton et al. (2000) reported no major safety concerns among patients undergoing OMT compared to the invasive chemonucleolysis procedure for symptomatic lumbar disc herniations. The trial by Nguyen et al. (2021) also documented such safety profiles between the OMT and sham treatment arms, with only 4 serious adverse events in the OMT group, none of which were deemed treatment-related.

This data provides evidence that OMT is a low-risk intervention for low back pain without exposing patients to excessive safety hazards. The favorable adverse event profile further reinforces the rationale for OMT as a conservative initial treatment approach prior to more invasive options.

Studies have consistently demonstrated high levels of patient satisfaction with OMT for the management of low back pain. In the OSTEOPATHIC Trial, patients randomized to the OMT treatment arm reported significantly higher satisfaction with their back care compared to those receiving sham OMT at all follow-up timepoints assessed through 12 weeks (Licciardone et al., 2013b). This favorable experience was also corroborated in Andersson et al.'s (1999) study comparing OMT to standard medical care, where over 90% of patients expressed satisfaction with their allocated treatment regardless of whether they received OMT or conventional management with medications and physical therapy modalities.

These findings likely reflect the comprehensive and integrative nature of OMT that extends beyond pharmacologic interventions. By employing diverse manual techniques to address biomechanical dysfunctions in low back pain pathology, OMT may encourage a greater

sense of individualized, holistic care more aligned to patients' unique preferences and expectations. This is especially beneficial because it fosters greater adherence to treatment plans and improves long-term health outcomes, as patients are more likely to engage with and commit to care approaches that resonate with their personal values and goals. Furthermore, the safety profile and lower treatment burden associated with OMT compared to long-term medication use or invasive procedures could further contribute to increased patient satisfaction.

Limitations and Future Directions

While the collective body of evidence supports OMT as an effective treatment for chronic low back pain, several important limitations must be considered when interpreting the findings to date. Many of the randomized trials evaluating OMT for low back pain have had relatively modest sample sizes, limiting the ability to robustly assess treatment effects in specific patient subgroups and the generalizability of results.

An additional limitation is the lack of standardization in the specific OMT techniques employed across studies. In the landmark OSTEOPATHIC Trial, an algorithmic, individualized OMT protocol was utilized based on each patient's somatic dysfunction patterns (Licciardone et al., 2016a). In contrast, other trials prescribed more uniform OMT regimens (Nguyen et al., 2021; Schwerla et al., 2015). While this heterogeneity may reflect real-world clinical practice, it prevents assessments of specific OMT technique efficacy and hampers efforts to identify mechanisms of action. Inconsistencies remain regarding OMT's immunomodulatory effects, with mixed findings related to impacts on inflammatory cytokines like IL-6 and TNF-α requiring further investigation (Licciardone et al., 2012).

Furthermore, this literature review contains numerous studies by a single lead author. This is because the field of OMT research has a relatively small pool of active researchers.

Additionally, funding for OMT research is often limited, resulting in a lack of author diversity. Consequently, the sources used in this literature review are a reflection of the context and concentration of OMT research. The limited field of research on OMT is also the reason why older studies are included in this literature review, as they provide foundational insights and specific findings that remain relevant to current understanding and practice.

To build upon the foundations laid by initial efficacy trials, several key areas warrant further research attention. Given OMT's demonstrated short-term benefits for postpartum low back pain, larger pragmatic trials with extended follow-up periods are needed to confirm OMT's longer-term impacts during this critical postpartum period. Such studies should also incorporate formal cost-effectiveness analyses to elucidate OMT's broader economic implications, building upon previous research suggesting potential cost savings from reduced medication utilization (Licciardone & Aryal, 2013).

Furthermore, continued mechanistic research is essential to determine the pathways through which OMT exerts its therapeutic effects for low back pain. While existing data implicate processes like psoas syndrome remission, biomechanical dysfunction resolution, and inflammatory cytokine modulation as potential mediators, a comprehensive understanding remains lacking (Licciardone et al., 2014). Examining OMT's impacts on pain neurophysiology, central sensitization, and peripheral immune responses is a key step to optimize treatment protocols and patient selection.

While substantial evidence supports OMT's general efficacy for chronic low back pain management, numerous gaps remain. Rigorously addressing these knowledge deficits through well-designed clinical trials, economic analyses, and mechanistic investigations will be crucial to

solidifying OMT's place in contemporary low back pain treatment and realizing its full potential for improving patient outcomes.

Conclusions

The collective evidence from multiple randomized trials consistently demonstrates that OMT provides statistically significant and clinically meaningful benefits for reducing low back pain intensity and associated disability compared to sham interventions or other conservative treatments (Table 1). Across studies by Nguyen et al. (2021), Licciardone et al. (2013b), Schwerla et al. (2015) and others, OMT emerged as superior to control conditions for improving patient-reported pain levels, back-specific functional status, and quality of life measures. Importantly, the treatment effects observed with OMT met thresholds for clinical relevance based on established criteria.

Additionally, the available data indicate that OMT represents a safe, well-tolerated intervention with consistently high patient satisfaction and acceptance. Across trials, OMT had a favorable side effect profile comparable to sham procedures, with no significant increases in adverse events (Licciardone et al., 2013b). Notably, OMT appeared to confer advantages over certain pharmacotherapies, with patients receiving OMT requiring fewer analgesic and muscle relaxant medications (Andersson et al., 1999). These attributes position OMT as a favorable option among more conservative non-pharmacological approaches.

The consistent evidence supporting OMT's efficacy for chronic low back pain, coupled with its excellent safety and tolerability profile, carries important implications for its role in contemporary treatments and protocols. The findings indicate that OMT should be considered as a therapeutic option before advancing to more invasive and costly interventions like surgery or interventional procedures for appropriate patients with subacute or chronic low back pain

(Licciardone et al., 2016b). In fact, data suggests OMT may produce equivalent long-term outcomes compared to invasive treatments like chemonucleolysis for carefully selected patients, underscoring its potential as a first-line approach (Burton et al., 2000).

Table 1

Compilation of significant results in reviewed studies

Study	Significant Result	p-value
Burton et al., 2000	OMT produced greater improvement in back pain at 2 and 6 weeks vs chemonucleolysis	< 0.05
	OMT produced greater improvement in disability at 2 weeks vs chemonucleolysis	< 0.05
de Oliveira Meirelles et al., 2019	Final low back pain lower with OMT vs control	0.001
	Final functional incapacity lower with OMT vs control	0.04
Licciardone et al., 2010	RMDQ scores deteriorated significantly less with OMT during pregnancy	0.001
Licciardone et al., 2012	TNF-α reduction greater with OMT vs sham at 12 weeks	0.03
	More patients had reduced TNF-α with OMT vs sham	0.04
	Greater TNF-α reductions with OMT in patients with clinical improvements	0.006
Licciardone et al., 2013	More patients receiving OMT achieved moderate LBP improvement vs sham	< 0.001
	More patients receiving OMT achieved substantial LBP improvement vs sham	0.002
	Patients receiving OMT less likely to use prescription drugs for LBP	0.048
Licciardone et al., 2016a	More patients met recovery criteria with OMT vs sham	0.003
Licciardone & Aryal, 2013	OMT group less likely to experience back dysfunction progression vs usual care	< 0.0001
	OMT group less likely to experience back dysfunction progression vs sham ultrasound	0.046
Nguyen et al., 2021	Mean reduction in QBPDI score at 3 months favoring standard OMT over sham	0.01
	Mean QBPDI reduction at 12 months favoring standard OMT over sham	0.01
Schwerla et al., 2015	OMT group had significantly greater reductions in pain and disability vs control	< 0.001
Walkowski et al., 2014	Decrease in plasma nitrite levels at 1 hour post-OMT vs pre-treatment	Significant
	Decrease in monocytes at 1 hour post-OMT vs pre-treatment	Significant
	Decrease in CD16+ dendritic cell subset with OMT vs sham	Significant
	Increases in MIP-1α, IL-8, MCP-1, G-CSF with OMT vs pre-treatment/sham	Significant

Note. Table showing a summary of the major significant results of the studies featured in this literature review.

To optimally implement evidence-based OMT utilization in clinical practice, continued research is needed to develop robust clinical prediction rules that accurately identify patients with the highest likelihood of response. While general predictors like higher baseline symptom burden have emerged, more detailed multivariable models accounting for demographics, comorbidities, and other factors are required (Licciardone & Aryal, 2014). Such tools would allow for precise medical approaches, ensuring OMT is efficiently allocated to patients most likely to derive maximal benefit while avoiding unnecessary treatment delays or costs.

Beyond its direct therapeutic implications, the emergence of OMT as an effective non-pharmacologic option for managing chronic low back pain may hold broader relevance within the context of the ongoing opioid abuse epidemic. Amid alarming increases in opioid overdose deaths and opioid use disorder prevalence in recent decades, there are urgent calls for safe, non-addictive alternatives for acute and chronic pain management (Damiescu et al., 2021; Hagemeier, 2018). As a manual therapy, OMT represents a valuable potential tool for combating opioid overprescribing and mitigating addiction risks.

Preliminary data suggest OMT may provide a viable opioid-sparing approach, as patients receiving OMT required fewer prescription analgesics compared to control group counterparts in several trials (Licciardone et al., 2013b). However, rigorously designed head-to-head comparisons against opioid pharmacotherapies have not been conducted. Future research directly evaluating OMT's analgesic efficacy relative to opioids in the context of acute and chronic low back pain is needed. Such studies would shed light on the real-world opioid-sparing potential of OMT and its impacts on quality of life, safety events, and other patient-centered outcomes compared to standard opioid regimens. This evidence would be invaluable for guiding OMT's

implementation as a first-line pain management strategy within the broader public health goal of curtailing the opioid crisis.

In conclusion, the majority of data from randomized trials consistently demonstrates that OMT provides safe, clinically meaningful reductions in low back pain and disability compared to sham interventions and other conservative treatments. While continued research is needed to optimize patient selection and elucidate mechanisms, the available findings support OMT's consideration for alleviating chronic low back pain before more aggressive interventions in appropriate patients. Furthermore, OMT's non-pharmacologic profile identifies it as a promising therapeutic option during urgent public health priorities such as stemming the opioid epidemic through developing non-addictive pain management approaches. Ultimately, strategic implementation of evidence-based OMT protocols stands to enhance quality of life in patients while mitigating the immense personal and socioeconomic burden imposed by low back pain.

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