Neuromusculoskeletal Medicine (OMT) Original Article

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The short- and long-term effect of osteopathic manipulative treatment on pain, and psychosocial factors in adults with chronic low back pain

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Abstract

Context: Chronic low back pain (CLBP) has long plagued mankind, but little progress has been made in finding a rational and effective treatment, let alone a common cause. This study is an attempt to fill that void by measuring short- and long-term effects of osteopathic manipulative treatment (OMT), including psychosocial and pain reduction in CLBP patients.
Objectives: The objectives of this study were to investigate the effectiveness of neuromusculoskeletal medicine/osteopathic manipulative medicine (OMM) in treating CLBP, with a focus on biopsychosocial (pain sensitivity questionnaire [PSQ]) and pain control in chronic conditions.
Methods: The study involved a large, single cohort observational design of 101 patients. The inclusion criteria for selecting patients targeted those with "nonspecific" CLBP. The National Institutes of Health (NIH) Minimum Dataset for Chronic Low Back Pain (NMD) was the measurement tool and was administered at consent (baseline), 2, 4, and 8 weeks and at 6 and 12 months. Time trends were analyzed as overall mean. Pairwise differences were compared between time points. Mixed-effects models were utilized to test the association of time with pain and biopsychosocial scores.
Results: Pain and PSQ scores decreased over the study timeline. The most significant change for both pain and biopsychosocial scores occurred at 6 months compared to baseline, with a further reduction at 12 months.
Conclusions: OMT has been demonstrated to significantly reduce pain and psychosocial factors related to CLBP in both the short and long term.

Keywords: chronic low back pain; osteopathic manipulative treatment; pain management

Chronic low back pain (CLBP) is a common ailment affecting a substantial number of individuals worldwide, with approximately 70–85 % of all people experiencing some kind of back pain in their life [1]. It is the second most frequent reason for visits to the physician [2], the fifth-ranking cause of admission to the hospital [3] and the third most common cause of surgical procedures [2, 3]. The impact of CLBP extends beyond the physical body, often leading to emotional distress, decreased productivity, and increased healthcare utilization [4, 5]. With the significant prevalence of CLBP pain, there should be new techniques to transform the way CLBP is diagnosed and treated. Managing CLBP presents a significant challenge for patients and healthcare providers. Osteopathic manipulative medicine (OMM) is a specialized branch of medicine that focuses on evaluating, diagnosing, and treating musculoskeletal dysfunctions utilizing a hands-on approach [6]

The research on OMM for CLBP has found promising results for long-term pain relief. Multiple studies have found that osteopathic manipulative treatment (OMT) provides significant and clinically meaningful improvements in pain that persist for at least 3–12 months. In two previous studies by Licciardone et al – in 2013 with 455 patients and in 2016 with 345 patients – it was found that 6 to 8 sessions of OMT over 8–12 weeks produced substantial and sustained reductions in pain intensity [7, 8]. Patients receiving OMT were twice as likely to experience

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major improvements in pain at 3 months [7]. In a study of 445 patients that was published in 2020 by Licciardone and Gatchel [9], OMT also decreased the need for pain medication over the long term. The previously mentioned study of 455 patients by Licciardone et al. [7] also found that OMT combined with usual medical care relieved pain better than usual care alone at 3–6 months. Licciardone's studies also suggest that OMT's effects on pain and functioning translate to meaningful benefits in quality of life and work disability [7, 9].

We hypothesize that as pain decreases from OMM treatment, biopsychosocial factors will improve in both the short and long term.

Methods

This study was deemed to be a nonexempt expedited human subject research study and was Institutional Review Board approved (MSU IRB Legacy17-958). The study was funded by the American Osteopathic Association (grant no. 21005845). The study consisted of a single cohort, observational approach documenting the effective use of OMT to treat CLBP by reducing pain and increasing quality of life in both the short term and long term.

Data source

A total of 101 patients were consented over 6 months (September 2021 to March 2022) and followed for 1 year from date of consent (September 2022 to March 2023).

Patients were identified from the AthenaHealthNet Electronic Health Records (EHR) of new patients seeking CLBP treatment and recruited by convenience at their first visit to the MSUCOM OMM clinic. Once the provider qualified the patient, they were consented by the Research Coordinator (i.e., not the practitioner) to avoid bias. The paper consent form was reviewed with and provided to the patient, and any questions regarding the consent and research were answered. Patients were not compensated for their participation.

The inclusion criteria consisted of ambulatory patients 18–85 years old with CLBP lasting longer than 3 months. The exclusion criteria included patients with spinal or neurological disorders, spinal fractures within the past year, severe osteoporosis, scoliosis, or osteoarthritis in the spine or hip joints. The patients must not have a history or diagnosis of retroperitoneal tumors or lymphadenopathy, or a diagnosis of lumbar spine radiculopathy verified by imaging, negative electromyography/nerve conduction velocity (EMG/NCV) testing as well as matching symptoms. A patient was also rejected if he or she had a spinal surgery completed within the past year. Rhizotomies, epidural injections, and spinal cord stimulator implants were acceptable if completed at least 3 months prior to the beginning of the study and if they were not the apparent source of increased pain following the procedure as identified by the patient. Scoliosis was accepted if it was considered mild, defined as cases with a Cobb angle less than 20°. Generally speaking, patients meeting these criteria are termed to have "nonspecific" CLBP.

Outcome measures

The instruments to measure pain, function, and biopsychosocial factors were the National Institutes of Health (NIH) Minimum Dataset for Chronic Low Back Pain (NMD) [10]. The dataset evolved from the NIH Task Force on CLBP and is a 40-item checkbox questionnaire developed to increase the use of standardized measurements and a definition for CLBP (Supplementary Material). The research task force (RTF) impact score was calculated from the NMD. The RTF score was tabulated from adding up the numbers assigned to answers from selected questions, including the answers from a visual analog scale, pain interference on day-to-day activities, and responses on the ability to do day-to-day activities. The score determines the level of impact that CLBP has on daily function, with a range between 8 (lowest possible pain score) and 50 (highest possible pain score). The biopsychosocial score (pain sensitivity questionnaire [PSQ]) was calculated from the NMD set including scores from psychological questions and sleep disturbance. The score determines the level of impact on psychological factors like depression, feeling of worthlessness, anxiety, and sleep disturbance, with a range from 10 (minimal psychological affects) to 44 (most psychological effects). The survey also has patients record whether they have ever utilized any other treatments such as exercise therapy, injections, opioids, or psychological counseling.

The pain instrument was given in person by the research coordinator at the first patient visit after initial treatment (baseline) and sent electronically via research electronic data capture (REDcap) at 2, 4, and 8 weeks and at 6 and 12 months after initial treatment. This sampling frequency was selected to ensure that changes in both the short term and long term are documented. Study data were collected and managed utilizing REDCap electronic data capture tools hosted at Michigan State University [11, 12]. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing: (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources.

Description of treatment

Treatment protocols for this study were not standardized, and each patient was treated as the practitioner saw fit based on the principles found in the Foundations of Osteopathic Medicine, 4th Edition [13]. All providers participating in this study were AOA Board (ABONMM)-certified practitioners in Neuromusculoskeletal Medicine/OMM. Their practice experience (since completion of residency) ranges from 4 to 28 years, with an average of 12 years. Although each practitioner may have approached the patient in a slightly different manner from the other practitioners, they always followed the established osteopathic practices and principles of the profession [13]. There are also two residents who participated in this study; as they treated each patient, the residents were supervised by one or more of the providers.

Power analysis

A power analysis was conducted in G*power version 3.1 software [14] to observe a drop in pain utilizing a paired t test for a Cohen's d z-score effect size of 0.322 at 80 % power and 5 % level of significance, and it required a sample size of 61 total patients.

Statistical analysis

To determine whether patients receiving OMT experienced improvements in pain symptoms and biopsychosocial factors over time, a repeated-measures multivariate longitudinal regression model [15] was utilized to model the association between pain symptoms and biopsychosocial factors over time.

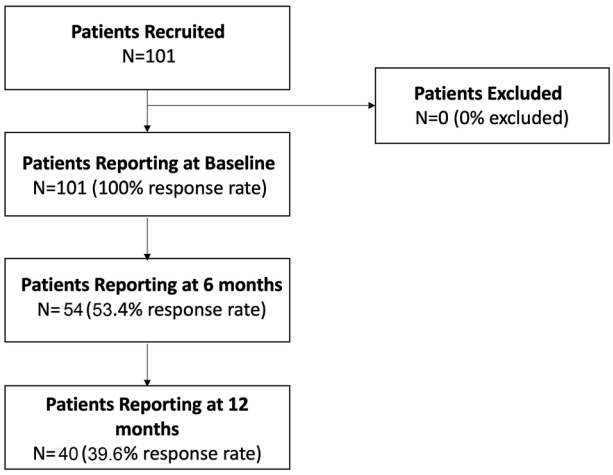

Figure 1: The workflow diagram. A total of 101 patients were recruited at the patient's convenience, and none of the patients were excluded. The number of patients responding to the surveys decreased over time.

Table 1: The average RTF impact scores. (A) The time trends of the mean pain scores from baseline to 12 months. (B) Comparisons between the time points.

A.	
Time point	**Estimated marginal mean (95% CI)**
Baseline	24.7 (22.9, 26.4)
2 weeks	22.8 (20.9, 24.7)
4 weeks	21.5 (19.6, 23.4)
8 weeks	21.3 (19.3, 23.2)
6 months	18.9 (16.9, 21.0)
12 months	18.7 (16.5, 21.0)

B.		
Comparison	**Estimate (SE)**	**p-Value**
4 weeks vs. baseline	3.23 (0.84)	0.001
6 months vs. baseline	5.76 (0.93)	<0.001
12 vs. 6 months	0.21 (1.13)	0.85

RTF, research task force; CI, confidence interval; SE, standard error.

Time trends of pain symptoms and biopsychosocial factors were analyzed as overall mean and by decile of the level at baseline. Pairwise differences or measurements were compared between time points and baseline to identify the time when there was a significant improvement. Mixed-effects models were utilized to test the association of time (from baseline to 12 months) with pain scores and biopsychosocial factors. Comparisons were estimated for comparing 4 weeks and 6 months to baseline and 6–12 months to baseline.

Results

As seen in Figure 1, a total of 101 patients were enrolled in the study, and all of the patients reported at baseline, with no patients being excluded. At 6 months after treatment, 54 patients reported, and then at 12 months after treatment, only 40 patients responded to surveys. The age range of the patients was 18–82 years of age, with a mean age of 49.0 (standard deviation [17.4]). There were more females (75, 74.3 %) than males (26, 25.7 %) in the sample. Their mean ages were not different statistically, with the mean age for females being 49.0 (standard deviation [SD] 16.3) and the mean age for the males also being 49.0 (SD 20.5). The interquartile range was 47 for females and 45 for males, and 47 combined.

RTF pain impact scores

As displayed in Table 1A, the baseline RTF impact score assessment had an estimated marginal mean impact score of 24.7. Within the initial 2 weeks, this score decreased to 22.8. At the 4-week mark, the RTF score was 21.5. At 8 weeks, the score was 21.3. At 6 months, the RTF impact score was 18.9, and at the 12-month mark, it was 18.7 (Figure 2).

Comparisons were made between time points (Table 1B). The difference between 4 weeks and baseline was statistically significant (3.23, p=0.001), while there was no additional change between 6 months and 12 months (0.21, p=0.850).

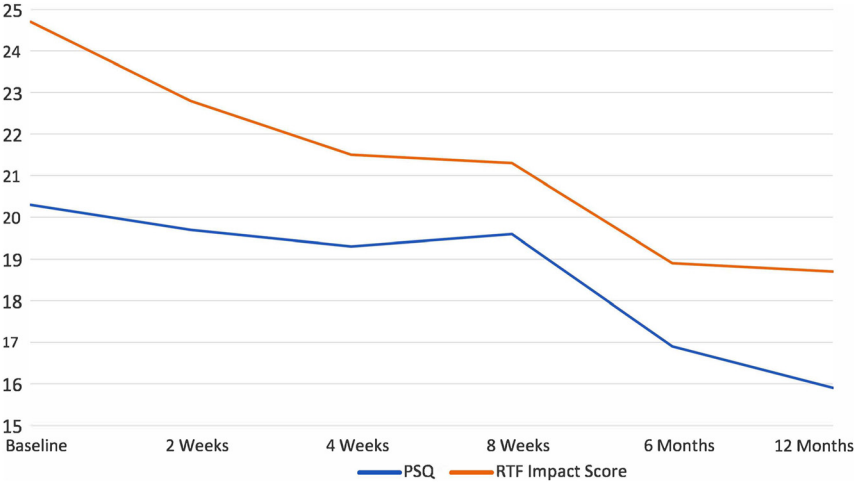

Figure 2: Time trends of mean RTF impact pain scores (orange) and mean biopsychosocial scores (PSQ, blue). A significant decrease occurs at 6 months vs. baseline in both the pain score and biopsychosocial score.

Table 2: Average biopsychosocial (PSQ) scores. (A) Time trends of mean PSQ scores from baseline to 12 months. (B) Comparisons between time points.

A.	
Time point	**Estimated marginal mean (95% CI)**
Baseline	20.3 (19.4, 21.3)
2 weeks	19.7 (18.6, 20.8)
4 weeks	19.3 (18.2, 20.4)
8 weeks	19.6 (18.5, 20.8)
6 months	16.9 (15.7, 18.1)
12 months	15.9 (14.6, 17.3)

B.		
Comparison	**Estimate (SE)**	**p-Value**
4 weeks vs. baseline	1.03 (0.70)	0.14
6 months vs. baseline	3.44 (0.73)	<0.0001
12 vs. 6 months	0.93 (0.86)	0.28

PSQ, pain sensitivity questionnaire; CI, confidence interval; SE, standard error.

Biopsychological scores (PSQ)

As presented in Table 2, the baseline assessment of the PSQ scores had an estimated marginal mean of 20.3. Within the initial 2 weeks, the score was 19.7. The 4-week assessment was 19.3. At 8 weeks, the score was 19.6. At the 6-month mark, the PSQ score was 16.9, and at 12 months, it was 15.9 (Figure 2).

Comparisons were made between time points (Table 2B). The difference between 4 weeks and baseline was not statistically significant (1.03, p=0.141), while there was a statistically significant reduction (3.44, p<0.001) between 6 months and baseline. The additional change between 12 months and 6 months was not statistically significant (0.93, p=0.281).

Discussion

This study provides information on the impact of OMT on patients' pain management and quality of life. The study population's dropout rate over time highlights the challenges of maintaining patient engagement in longitudinal research. Despite the reduction in participants from baseline to 12 months, the data show a comprehensive view of the treatment's effects on pain and biopsychosocial scores. The median age of the participants (47 years) indicates a diverse age range. The predominance of female participants (74.3 %) may reflect the higher prevalence of musculoskeletal issues in this group or the tendency for females to seek help for their pain compared to males.

The RTF impact score displayed a progressive reduction over 12 months with OMT. This pattern reflects the positive impact of OMT on pain management, with significant decreases observed from baseline to 4 weeks and 6 months. This reduction, particularly within the initial 2 and 4 weeks after treatment, indicate an early alleviation of pain. The sustained improvement in impact scores at 12 months highlights the treatment's ability to enhance patients' quality of life beyond the short-term effects.

PSQ scores mirrored the positive trends observed in pain and impact scores, indicating a decrease in psychological effects over time. A gradual reduction in PSQ scores showcases an increase in the quality and well-being of patients after OMM treatment. The most significant change occurred at 6 months compared to baseline, with an even further reduction at 12 months, indicating that as pain scores decreased, so did the quality of life of the patients.

Providers recorded a set of somatic dysfunctions (pain generators) associated with each patient during each of the recording periods to help identify the underlying mechanisms of CLBP. Because the amount or the use of analgesics could not be controlled or well documented, this aspect of the study was dropped.

Limitations

The dropout rate over the year of the trial could have resulted in possibly the loss of higher-quality participants, incomplete results, and an impaired interpretation of the data resulting in data loss and poor data quality. When asked why the patient did not complete a timeline survey, many patients stated that they felt better or were no longer attending the OMM clinic, so they did not know they needed to continue with the surveys. Other reasons were due to psychosocial issues such as depression or anxiety. A better explanation at the onset of the trial, along with continued communication about response importance, may have allowed for better retention. A financial incentive may have also helped them to realize how their participation benefits them. The survey allowed for self-reporting of other treatments but only if the participant has ever had a different treatment modality that was not specific to the year of OMT. A future study would need to include other treatment modalities such as exercise therapy, analgesic usage, injections, or psychological counseling sought during the year of the study, in order to better understand whether the OMT was indeed effective. The survey data was self-reported, with no system to validate self-reported outcomes. Participants could exaggerate or underreport their pain levels, or not recall the levels as they were in the previous time points, and thus report them in a different manner.

Conclusions

OMT has been demonstrated to significantly reduce pain and psychosocial factors related to CLBP in both the short and long term. The significant reduction in pain, lasting effects over time, and an increase in positive biopsychosocial effects has important positive implications in utilizing OMT in the treatment of CLBP.

Research ethics: The local institution review board deemed the study to be a nonexempt expedited human subject research study and was Institutional Review Board approved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Informed consent: Informed consent was obtained from all individuals included in this study.

Author contributions: The authors have accepted responsibility for the entire content of this manuscript and approved its submission.

Competing interests: None declared.

Research funding: None declared.

Data availability: The raw data can be obtained on request from the corresponding author.

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