Osteopathic Manipulation Improves Functional Status in Patients With Non-Specific Chronic Back Pain in a Rural Outpatient Setting

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ORIGINAL RESEARCH

Abstract

Context

Osteopathic manipulative treatment (OMT) is a widely used methodology for the clinical treatment of spine-related pain. Recent reports have been especially positive regarding the use of OMT for chronic back pain. However, published reports have been focused on populations available within large university-based institutions, with rural-based hospitals and their clientele unrepresented within the professional literature.

Objective

The objective of this multi-year study was to examine the effects of OMT on spine-related chronic pain and its effects on dimensions of functional ability in a rural setting served by a safety-net hospital.

Methods

In this study, 151 participants with chronic (>6 months) spine-related pain (mean age 54.58 ± 11.88 years) completed at least 2 office visits. The Oswestry Disability Index (ODI) was used to assess 10 dimensions (pain intensity, personal care, lifting, walking, sitting, sleeping, standing, sex life, social life, and travel) and a total score of functional ability related to back pain.

Results

A 2-way mixed-model, repeated-measures analysis of variance (ANOVA) with time (pre- and post-office visit) as the within-participants factor and with sex as the between-participants factor resulted in a significant main effect from pretest to posttest, ($F(1,149) = 67.12$, $P < .001$, $\eta^2_p = .311$), but not a significant interaction between time and gender, ($F(1,149) = .426$, $P = .515$, $\eta^2_p = .003$).

Conclusions

The results of this study support the hypothesis that OMT improved measures of functional ability related to pain intensity, unrelated to sex. The rural nature of the clinical setting provided a unique population for this study.

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Key words

Chronic pain, rural, OMT, Oswestry Disability Index

Introduction

A reported one-third of clinical visits in the United States for chronic pain conditions are to osteopathic physicians,[1] prompting medical researchers to increase the focus on the efficacy of osteopathic manipulative treatment (OMT) as a treatment for a variety of chronic pain conditions. Published reports[2,3] have provided positive support for the use of OMT as a modality for the relief of chronic pain, primarily low back pain. This is evidenced by the largest single-site efficacy trial of spinal manipulation conducted for low back pain, completed in 2011 and enrolling 455 participants.[1] Research from the Osteopathic Research Center at the University

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of North Texas Health Science Center Texas College of Osteopathic Medicine in Fort Worth now serves as the basis for the American Osteopathic Association's only clinical practice guideline, addressing the use of OMT for use in the treatment of low back pain. [4]

The use of OMT to treat chronic pain (defined as pain of a continuous duration of at least 6 months) takes on an added dimension due to its higher rate of use in rural areas. Rural-based treatment facilities have reported a higher incidence of chronic back pain than in urban areas,[5] while urban hospitals have reported a higher frequency of treatment visits for their chronic pain than rural hospitals.[6] Hoffman et al found that self-reported incidences of chronic pain differ by geography, with 65.6% in their sample being from rural areas and 50% from urban areas.[7] It has been suggested that one factor that may lead to these geographic differences in chronic pain reporting may be access to health care,[8] and thus, studies of treatment efficacy should not generalize across these populations.[9]

The purpose of this study was to determine the effects of OMT on spinal-region chronic pain in a rural population. To measure functional aspects of everyday life related to chronic pain, the Oswestry Disability Index (ODI) was used to determine changes in a variety of life activities affected by chronic pain. The hypothesis tested was that OMT results in increased functional status following a 6-month plateau of no improvement in recovery from chronic pain. A secondary objective was to determine if the sex of participants may play a role in increased functional status of patients with chronic back pain following OMT.

Methods

Participants and Setting

The study was conducted at a rural safety-net hospital. A safety-net network consists of "…hospitals and other providers that organize and deliver a significant level of health care and other health-related services as providers of last resort."[10] Participants represented an underserved 5-county area of primarily lower socio-economic status. Inclusion in this study was on a voluntary basis during an 11-year period, ranging from February 2001 to December 2011. Institutional review board approval was obtained prior to the study, and it was renewed annually during the study duration. Potential participants as identified by a rural outpatient physician met the criterion that they had self-reported chronic pain (>6 months and up to several years) that had not been resolved with their current medical care. Patients with non-spinal pain or acute pain were excluded. Patients with serious medical conditions such as cancer, myocardial infarction, neuromuscular diseases, alcohol and drug abuse and known psychological illness also were excluded from this trial.

A total of 263 potential participants were pre-screened during the initial clinical visit with non-specific spinal-region chronic pain of at least 6 months in duration between 2001 and 2011. From this sample, 151 participants completed 2 office visits with data collection (dropout rate 42.6%). The most common reason for dropout was an inability to schedule a follow-up visit with the patient. Since the patients were pre-screened before the initial clinical visit, dropout was not due to any of the exclusion factors, but either a lack of willingness to continue the study, or unknown external factors.

Outcomes

The Oswestry Disability Index is a self-completed questionnaire measuring 10 dimensions of quality of life: pain intensity, lifting, ability to care for oneself, ability to walk, ability to sit, ability to stand, social life, sexual function, sleep quality, and ability to travel. Each dimension is followed by 6 statements scored from 0 (no pain or disability) to 5 (the worst pain imaginable or complete disability). Scores from 0 to 6 (0%-20% of the total) are interpreted as minimal disability. Participants reporting scores of 25 and higher (81%-100%) are assumed to be either bed-bound or exaggerating their symptoms. The ODI has been shown to be a valid and reliable instrument for assessing back-specific disability and function.[11]

Randomization and Treatment

History Effects

Use of a control group was not possible due to restrictions on physician time and facilities and the inability to deny treatment. In the absence of a control group, it was important to evaluate whether possible improvements noted over time could be explained by variation not due to the experiment. If improvements would have occurred in the absence of treatment, we would expect to find differences between groups based upon when they enrolled in the study. Patients were enrolled in the study at their initial clinical visits, a rolling timeline during the first year of the study.

Patients were divided into 4 groups based on the timing of the initial clinical visit (0-3 months; 4-6 months; 7-9 months; and 10-12 months), and possible natural history effects were examined using one-way analysis of variance (ANOVA) partial-lag design. Regardless of when patients enrolled in the study, they did not differ at their baseline ($F(3,147) = 1.87$, $P = .137$) or second clinical visit ($F(3, 55) = 2.20$, $P = .098$). Examination of the corresponding line plots *(see Figure)* showed that the 4 starting groups differed in the same pattern across the 2 clinical visits and that they improved in the same pattern. These findings suggest that patients with stable chronic pain levels do not begin to improve without treat-

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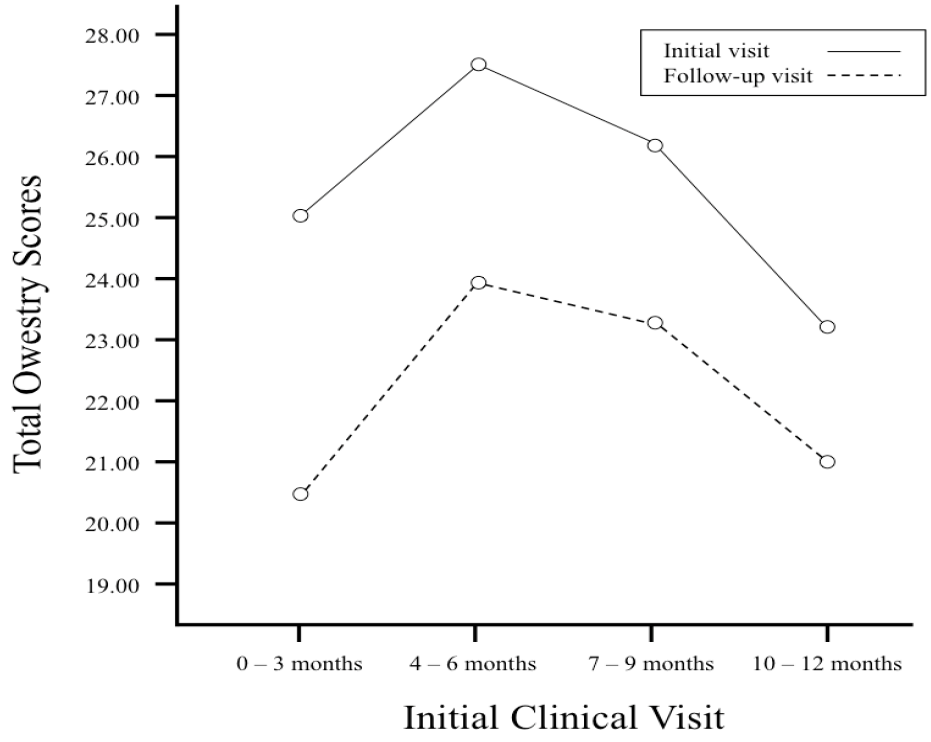
Figure. *Total average Oswestry scores for initial (solid line) and follow-up (dotted line) visits across four rolling admission times.*



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ment, improve along the same trajectory once treated, and that any improvements noted were due to the effects of the treatment not to history effects or random variation.

Treatment

The study physician was a licensed osteopathic physician, board-certified in physical medicine and rehabilitation and interventional pain management. OMT was applied to the body areas the physician determined to be related to the chronic pain, and thus was individualized similar to the protocol described by Andersson et al.[12] Treatments included no high-velocity, low-amplitude movements. Osteopathic manipulation techniques included myofascial release, cranial/sacral manipulation, counterstrain techniques, muscle energy, and visceral manipulation among others. The one exclusion to treatment was the introduction of narcotics during the study period. Initial clinical visits were 60 minutes each with 1 follow-up visit per participant of 30 minutes.

There were a number of OMT techniques employed depending on the underlying cause of the chronic pain diagnosed. These methods included cranial manipulation, myofascial release, counterstrain, and muscle energy techniques.

Statistical Analysis

All numerical subscales of the Oswestry Disability Index were summarized as means ± standard deviation. Although the ODI is measured in a Likert, non-parametric scale, due to the 5-point nature of each subscale, the data was able to be treated as parametric.[13] A two-way, mixed-model, repeated-measures ANOVA with time (pre-treatment and post-treatment) as the within-participants factor and sex (male and female) as the between-participants factor was used to determine overall effects of OMT on indicators of quality of life as determined by the ODI. All statistical design and testing was determined in consultation with the RStats Institute of Missouri State University.

Results

A total of 151 participants, 57 men and 94 women aged 28 to 87 years, were enrolled between 2001 and 2011 in the rural sample *(see Table 1)*. The mean age for the 2 groups was nearly identical: male, 53.1 ± 9.3 years; female, 53.1 ± 11.5 years. Pre- and post-treatment Oswestry sub scores are given in *Table 2*. The male group reported slightly higher total ODI scores at the initial visit (26.23 ± 7.21 vs. 25.28 ± 8.36) *(see Table 3)*.

The first research question asked whether the intervention improved functional ability, and a secondary research question asked whether a sex difference existed between men and women on total ODI scores. A two-way, mixed-model, repeated-measures ANOVA with pre- and post-treatment as the within variable and sex as the between-participants variable showed a significant main effect from pretest to posttest, ($F(1,149) = 67.12$, $P < .001$, $\eta^2_p = .311$), but not a significant interaction between time and sex, ($F(1,149) = .426$, $P = .515$, $\eta^2_p = .003$). These findings indicated that while the intervention was associated with an increase in functional ability as measured by decreases in ODI scores, patterns of change did not differ between male and female participants, functionally ruling out a sex difference in total ODI scores.

Cohen's *d*, defined as the difference between the means divided by the standard deviation, was calculated for pre- and post-treatment score differences to aid in the interpretation of each sub-scale of the ODI. The largest effect size was for the total of the 5 dimensions of

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Table 1. *Participant demographic data.*

	Male	Female	Total
Quantity	57	94	151
Age (M ± SD)	54.51 ± 10.35	54.45 ± 12.66	

Table 2. *Oswestry Disability Index sub scores and totals*

	Pre	Post	Effect size*
Pain intensity	2.84 ± 0.90	2.67 ± 0.89	0.15
Personal care	1.70 ± 1.17	1.43 ± 0.95	0.26
Lifting	3.28 ± 1.12	2.97 ± 1.11	0.28
Walking	2.25 ± 1.28	1.91 ± 1.32	0.29
Sitting	2.44 ± 1.02	2.10 ± 1.03	0.33
Standing	2.97 ± 1.23	2.60 ± 1.06	0.36
Sleeping	2.40 ± 1.07	2.15 ± 1.12	0.24
Sex life	2.42 ± 1.78	1.93 ± 1.72	0.30
Social life	2.67 ± 1.27	2.33 ± 1.32	0.29
Travel	2.46 ± 1.15	2.33 ± 1.60	0.08
TOTAL	25.63 ± 7.93	22.29 ± 8.11	0.68

**Effect size is reported as Cohn's d, defined as the difference between the means divided by the standard deviation.*

Table 3. *Oswestry Disability Index scores by sex.*

	Male		Female	
	Pre	**Post**	**Pre**	**Post**
Pain intensity	2.89 ± 0.90	2.74 ± 0.77	2.81 ± 0.91	2.63 ± 0.96
Personal care	1.70 ± 1.15	1.40 ± 0.86	1.69 ± 1.19	1.45 ± 1.00
Lifting	3.16 ± 1.08	2.81 ± 1.212	3.35 ± 1.13	3.07 ± 1.06
Walking	2.18 ± 1.27	1.81 ± 1.34	2.30 ± 1.29	1.98 ± 1.30
Sitting	2.42 ± 0.80	2.18 ± 0.97	2.45 ± 1.13	2.05 ± 1.07
Standing	3.00 ± 1.23	2.47 ± 1.00	2.96 ± 1.24	2.67 ± 1.09
Sleeping	2.35 ± 1.03	2.23 ± 1.07	2.43 ± 1.09	2.11 ± 1.16
Sex life	2.81 ± 1.71	2.11 ± 1.71	2.18 ± 1.80	1.83 ± 1.72
Social life	2.81 ± 1.20	2.33 ± 1.20	2.59 ± 1.31	2.33 ± 1.39
Travel	2.58 ± 0.98	2.30 ± 1.03	2.38 ± 1.24	2.35 ± 1.86
TOTAL	26.23 ± 7.21	22.51 ± 7.71	25.28 ± 8.36	22.11 ± 8.38

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functional status (0.68), which was interpreted as a medium effect by Cohen.[14]

Discussion

The purpose of this study was to determine the effects of osteopathic manipulative treatment on spinal-region chronic pain in a rural population. The hypothesis tested was that OMT results in increased functional status following a 6-month plateau of no improvement in recovery from chronic pain. Following OMT, a statistical increase in self-reported functional ability was found in patients who had experienced at least 6 months of chronic back pain. No statistical differences were found between the sexes in their functional improvement.

The study design allowed for testing history effects, or natural recovery effects, prior to the first clinical visit that may have existed due to the rolling admission to the study. Natural history effects were found to be non-significant (see Methods section), prior to first data collection. Therefore, the rolling admission into the study made no difference, and pretreatment scores were not affected by time prior to initial visit.

Attributing increases in functional status with chronic pain to OMT is complicated due to the lack of the use of a placebo or non-treatment group. Andersson et al pointed out that it is not possible to prevent patients with back pain from initiating self-care (using activity or medication), making the use of a true non-treatment group difficult to control.[12] Thus, the statistical increases in functional status found following OMT in this study cannot be directly attributed to the clinical treatment. However, numerous studies have reported that recovery rate from chronic pain is slower after the initial 3 weeks than before.[15,16] In addition, most studies of spinal-region pain have focused on the acute-phase, the first 2 to 4 weeks.[17,18] Most patients will have a natural recovery from their pain during this time period without the use of manual therapy, but studies have documented the benefit of OMT during this period, primarily in the rate of recovery.[19,20] Thus, reduced pain levels and increases in functional status during the chronic pain stage, especially following a documented plateau in pain levels, is not expected during the natural course of recovery.

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Study Limitations

The primary limitation of this study design, as previously discussed, was the lack of a true control group. In this study, each patient served as their own control by demonstrating a lack of pain intensity recovery over a 6-month period despite conventional medical treatment.

A second limitation often cited in research literature is the lack of cost of medical treatment documentation. It has been reported that the frequency of medical visits is greater when patients are receiving OMT as opposed to standard allopathic care.[21,22] An increase in medical visits could introduce its own placebo effect, but this is not relevant to this study as the number of visits were identical. Documenting medical costs, however, may provide additional evidence of the benefits associated with OMT.

Conclusion

Osteopathic manipulation is used to treat a variety of medical conditions including back-related pain. This study reported that the use of these techniques applied to a rural population of patients resulted in significant improvement in functional status in a variety of activities despite a previous plateau in both level of pain and functional status.

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