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Osteopathic Manual Therapy in Rural Outpatient Rehabilitation Provides Continued Improvement in Functional Status for Patients with Chronic Non-Specific Back Pain: Results of An Eleven-Year Longitudinal Study

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Abstract

Background: Osteopathic manual treatment (OMT) has been reported to have positive initial results for subjects with chronic non-specific back pain in a rural safety-net hospital. However, the effects of OMT following initial treatment have not been reported. **Objective:** To determine the effects of OMT for patients with chronic non-specific back pain in a rural safety-net hospital setting for an initial post-clinical and follow-up visit. **Methods:** A longitudinal, rolling admission, eleven-year study of cohort study with a primary complaint of chronic, non-specific back pain that had plateaued in improvement for a minimum of six months. One hundred and fifty-one subjects completed the first two study visits necessary for data collection, and fifty-nine subjects completed the follow-up visit after six months. **Results:** A two-way, mixed model, repeated measures ANOVA with pre- post1 and post2 (follow-up) treatment as the within variable and sex as the between subject variable showed a significant main effect from pre- to follow-up, ($F(1, 57) = 21.171$, $P < 0.001$, $\eta_P^2 = 0.426$), but not a significant interaction between time and sex ($F(1, 57) = 0.279$, $P < 0.598$, $\eta_P^2 = 0.002$). **Conclusions:** The results of this study support the hypothesis that OMT has a continued benefit in pain reduction and functional improvement beyond the initial treatment period. The rural, safety-net hospital setting made this study unique relative to the sample population.

Keywords

Manual Therapy, Low Back Pain, Rural

1. Introduction

It has been reported that as high as one-third of clinical visits in the United States for chronic pain conditions are to osteopathic physicians (DOs) [1]. This ratio of patients seeking care for pain from osteopathic physicians is in stark contrast to the relatively small percentage of practicing osteopathic vs. allopathic physicians. A 1999 survey reported 36,190 active osteopathic physicians in this country vs. 656,834 active allopathic physicians [2]. As of 2016, 81,115 licensed DOs practiced in the US [3], while the number of allopathic physicians had risen to 870,312. This means that DOs represent less than 10% of the practicing physicians in the US, while accounting for a disproportionate number of clinical visits for chronic pain [4].

The reasons for this disparity between the number of practicing osteopaths and patients seeking their care for chronic pain conditions have not been well studied, however, two frequently cited facets of osteopathic medicine have been suggested as possibilities.[4] Osteopathic medicine has a holistic or patient-centered philosophy, and it employs osteopathic manipulative treatment (OMT) as part of this holistic medical model [5]. According to the American Osteopathic Association (AOA), OMT can be used to ease pain, promote healing and increase overall mobility [6]. Although OMT is most-often used to treat muscle pain, the AOA states that OMT can be used to help patients with health problems ranging from sinus conditions to migraines. However, general acceptance of the efficacy of OMT will require research-based evidence.

A 2011 systematic review of clinical research into the effectiveness of OMT as a treatment option for musculoskeletal pain concluded "our review essentially shows that the effectiveness of osteopathy for MSP (musculoskeletal pain) is not well-documented (p. 289)." [7]. The research design problems discussed in this review were related to a lack of critical assessment of the methodology and validity of the included studies [8]. Among the design problems discussed were a lack of standardized OMT techniques, concurrent therapy that may be confounding, heterogeneous patient populations, disparate outcome measures, and a lack of diversity among the geographical patient populations employed. **Table 1** presents a review of several recently published studies of OMT for a variety of conditions. The common factor among these investigations is a large, urban-based patient population. While this is understandable considering research design requirements for double-blind sham group studies generally require an urban-based research team, hospital setting, and larger population of potential subjects, rural patient populations have been under-represented in the published literature. This is despite the fact that historically, osteopathic physicians have practiced in rural communities, including medically underserved areas [9].

In an earlier report, evidence was provided that OMT improves functional status for patients with chronic non-specific back pain in a *rural* safety-net hospital that served a multi-state area of small communities [10]. A safety net network was defined as consisting 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." [11]. The purpose of this study was to extend these results and determine the repeat-visit functional results of OMT on chronic back pain in a rural population. We chose to employ functional measures of clinical outcome as the focus of the rural-based osteopathic physicians was on functional return to activity. The hypothesis tested was that OMT results in an on-going increase in functional status following a 6-month plateau marked by a lack of improvement from chronic pain. A secondary objective was to determine the influence that the sex of the patients may have on this functional improvement.

2. Methods

2.1. Participants and Setting

The study was conducted at a rural safety-net rehabilitation-based hospital. Safety-net was defined earlier in this report as providers of last resort. The subjects primarily represented an underserved 5-county area of lower socio-economic status. The longitudinal design nature of this study due to the small population area necessitated an 11-year rolling admission period ranging from February 2001 to December 2011. Institutional Review Board (IRB) approval was obtained prior to the study in accordance with all international standards, and subsequently renewed annually throughout the study duration. Each subject voluntarily provided written informed consent prior to study admission. Potential subjects were identified by a rural outpatient rehabilitation physician and screened for inclusion criterion that they had self-reported chronic pain (>6 months and up to several years) that had not been resolved with their current care. Exclusion criterion included non-spinal pain, acute pain, cancer, myocardial infarction, neuromuscular diseases, alcohol and drug abuse and known psychological illness.

A total of 263 potential subjects were pre-screened during the initial clinical visit with reported non-specific spinal-region chronic pain of at least 6 months in duration between 2001 and 2011. A sample of 151 participants completed the initial 2 office visits with data collection (dropout rate 42.6%) and 59 of those subjects completed a follow-up clinical visit. The most commonly reported dropout complaint was an inability to schedule a follow-up visit, often associated with the rural nature of the population. Because the subjects were pre-screened prior to the initial clinical visit, study exclusion factors did not contribute to dropout rate.

2.2. Outcomes

The Oswestry Disability index is a common rehabilitation functional assessment tool consisting of 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 of the 10 dimensions is followed by 6 statements scored from 0 (no pain or disability) to 5 (the worst pain imaginable or complete disability). Total scores from 0 to 6 (0% to 20% of the total) are interpreted as minimal disability. Subjects reporting score of 25 and higher (81% to 100%) are assumed to be either bed-bound or exaggerating their symptoms (see **Table 1**). The Oswestry Disability Index has been reported to be a valid and reliable instrument for assessing back-specific disability and function [12].

Table 1. Initial participant demographic data.

Characteristic	Male	Female	Total
Number	57	94	151
Age (Mean ± SD)	54.51 ± 10.35	54.45 ± 12.66	

2.3. Randomization and Treatment

2.3.1. History Effects

The use of a sham treatment (control) group was not possible due to 1) the limited population from which to recruit subjects, 2) restrictions on physician time associated with the rural rehabilitation hospital, and 3) the facilities' inability to deny treatment. In the absence of a control group within the research design it was necessary to statistically evaluate if possible functional improvement status during the rolling admission could be explained by variation not due to the experiment. If improvements occurred in the absence of treatment, we would expect to find differences between groups based on when they enrolled in the study. Patients were enrolled in the study on a rolling timeline at their initial clinical screening visit.

To examine possible non-treatment natural history effects, the patients were divided into 4 groups based on the month of the initial clinical visit (0-3rd month: Jan.-March, 4th-6th month: April-June, 7th-9th month: July-Sep., and 10th-12th month: Oct.-Dec.), and possible natural history effects were examined using one-way analysis of variance (ANOVA) partial-lag design. As reported in the initial study [10], regardless of when patients enrolled in the study, they did not differ between their pre-screening and first clinical visits ($F(3, 147) = 1.87$, $P = .137$). Similar results were found for the second clinical follow-up visit ($F(3, 55) = 2.20$, $P = 0.098$). These statistical tests are for natural history effects only. This would suggest that patients with stable chronic pain levels do not begin to improve without the OMT treatment, improve along the same trajectory once receiving OMT, and that any improvement noted were due to effects of the treatment rather than natural history or random effects.

2.3.2. Treatment

The physician in charge of treatment was a licensed osteopathic physician board-certified in physical medicine and rehabilitation and interventional pain management. Osteopathic manual manipulation was applied by the study physician to the

areas of the body determined to be related to their chronic pain and individualized according to the protocol described by Andersson *et al.* [13]. Individualized OMT did not include high-velocity, low-amplitude movements. Specific OMT techniques included myofascial release, cranial/sacral manipulation, counter strain techniques, muscle energy, and visceral manipulation and others. Introduction of narcotics was excluded from the during the study period. Initial clinical visits were 60 minutes each with follow-up visits 30 minutes in duration.

2.4. Statistical Analysis

Numerical subscales of the Oswestry Disability Index were summarized as mean ± standard deviation. The Oswestry Disability Index is a non-parametric, Likert 5-point scale. However, this scale may be treated as parametric for statistical analysis [14]. A two-way, mixed model, repeated-measures ANOVA with time (pre-treatment, 1st post-visit, 2nd follow-up visit) 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 or quality of life as measured by the ODI. All statistical design and testing were determined in consultation with the RStats Institute of Missouri State University.

3. 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 2**). The mean age for the two groups was nearly identical: male, 53.1 ± 9.3 years; female 53.1 ± 11.5 years. Pre- and 2nd visit follow-up Oswestry sub scores are given in **Table 3**, while a comparison of the total ODI score across all three of the three clinical visits studied is shown in **Figure 1**. The figure shows (Mean ± SE) the total ODI score

Table 2. Oswestry Disability Index (ODI) sub scores and total.

Oswestry subscale	Pre-visit	2nd follow-up visit	Effect size*
Pain intensity	2.95 ± 0.818	2.19 ± 1.121	0.65
Personal care	1.73 ± 1.172	1.37 ± 0.998	0.3
Lifting	3.32 ± 1.238	2.95 ± 0.955	0.3
Walking	2.47 ± 1.180	1.59 ± 1.403	0.59
Sitting	2.37 ± 1.015	2.27 ± 1.031	0.1
Standing	2.90 ± 1.155	2.66 ± 1.124	0.26
Sleeping	2.29 ± 1.160	2.36 ± 1.063	−0.06
Sex Life	2.71 ± 1.733	1.69 ± 1.784	0.46
Social Life	2.78 ± 1.204	1.98 ± 1.239	0.64
Travel	2.49 ± 2.753	2.73 ± 2.753	−0.09

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

Table 3. The Oswestry disability index (ODI).

ODI score (%)	Level of disability
0 - 20	Minimal disability
21 - 40	Moderate disability
41 - 60	Severe disability
61 - 80	Cripple, pain impinges on all aspects of patient's life
81 - 100	Patients are bed-bound or exaggerating their symptoms

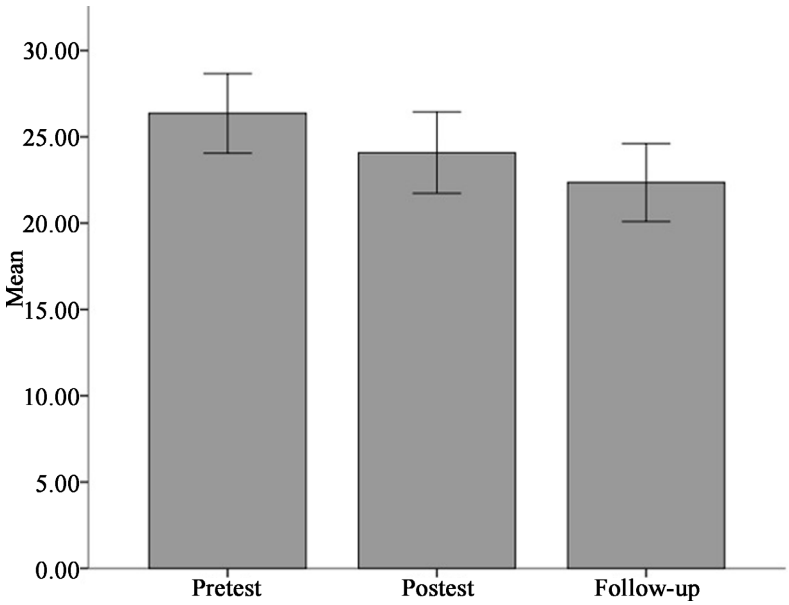

Figure 1. Total (mean ± S.D.) Oswestry Disability Index (ODI) scores for the pre-test, post-test and follow-up visits.

decreased steadily from the initial clinical visit (26.36 ± 1.149) to the first post-visit (24.09 ± 1.174), to the follow-up visit (22.36 ± 1.128).

The primary research question was whether the OMT intervention improved functional ability in this rural patient population. The secondary question was whether a sex difference existed between men and women on ODI total scores. A two-way, mixed model, repeated measures ANOVA with pre- post1 and post2 (follow-up) treatment as the within variable and sex as the between subject variable showed a significant main effect from pre- to follow-up, ($F(1, 57) = 21.171$, $P < 0.001$, $\eta_P^2 = 0.426$), but not a significant interaction between time and sex ($F(1, 57) = 0.279$, $P < 0.598$, $\eta_P^2 = 0.002$). This would imply that the intervention (OMT) was associated with an increase in functional ability as measured by the decreases in the ODI scores, while these improvements were not different between the male and female subjects.

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

ten sub-scales of functional status was 0.64 for social status and 0.63 for pain intensity. Each of these values are interpreted as a medium effect by Cohen [15].

4. Discussion

The overall goal of this investigation was to determine the effects of OMT on functional ability of rural-based patients with chronic pain. The hypothesis tested was that OMT results in increased functional status for patients with a minimum 6-month plateau in their pain and functional status. Following an individualized OMT treatment plan, a statistical increase in self-reported functional ability was found in eight of the ten ODI subscales and total ODI score. The two subscales that did not show improvement were sleeping and travel. These facets of functional status showed no improvement despite an overall statistical decrease in the subscale of pain intensity. Because this study design did not alter pre-existing over the counter medications, sleep aids could have affected this subscale. Additionally, the rural nature of the subject population often called for long travel times for office visits which may have influenced the travel subscale.

The longitudinal, rolling admission of subjects into the investigation was a potential problem due to the possibility of natural history effects not related to the treatment. Natural history effects were found to be non-significant (see Methods section), prior to data analysis. Therefore, analysis of the two post-clinical visits relative to the baseline were compared under the assumption that pretreatment scores were not affected by time of admission.

5. Limitations

This investigation had several unique elements of research design that create difficulty in attributing significant increases in functional ability directly to the treatment (OMT). The most obvious design problem is the lack of a true control (sham treatment) group. The rural safety-net nature of the hospital setting made this impossible as most patients travelled long distances and reported an inability to make repeat visits without receiving treatment. The use of a true control (non-treatment) group is difficult under the best research conditions for chronic pain. As Andersson *et al.* pointed out, it is not possible to prevent patients with back pain from initiating self-care (via activity or medication) [13]. However, numerous research reports on chronic pain have stated that the recovery rate from chronic pain is slower after the initial 3 weeks [16] [17]. We used as an admission criteria chronic pain that had plateaued in improvement for a minimum of six months. Andersson *et al* reported that 80% - 90% of patients with back pain recover within 12 weeks, but after this period recovery is slow and uncertain [18]. In fact, fewer than half of those not recovered from pain after six months return to work, and after 2 years absent from work, the return-to-work rate is nearly zero [19].

The lack of significant demographic information regarding the subjects in this study and the absolute ratings of pain may cause difficulty for clinicians attempting

to discern the use of this data in their practice. This limitation was imposed on the investigators by the nature of the data the rural hospital made available and future studies that provide more detailed information of this type would certainly strengthen the readers' ability to make conclusions regarding the efficacy of this treatment in their practice. As noted in the Methods section, mediations were not altered by the study physician, however, a detailed list of these medications for the study participants would certainly also strengthen the design of this study.

The significant increases found in dimensions of functional ability of our sample, including pain intensity are not part of the documented natural recovery from chronic pain. The majority of spinal-related pain reports have focused on the acute recovery phase representing the first 2 to 4 weeks [20] [21]. Most patients will demonstrate a natural recovery from their pain during the acute phase without the use of OMT, but studies have reported the benefit of OMT during this phase, primarily in the rate of recovery [22] [23]. Thus, the improvements shown in this investigation for chronic pain, given the rural nature of the patient population, represent an unexpected clinical outcome for an under-represented sample following osteopathic treatment.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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