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Original article

Outcomes of osteopathic manual treatment for chronic low back pain according to baseline pain severity: Results from the OSTEOPATHIC Trial☆

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ABSTRACT

Purpose: To assess response to osteopathic manual treatment (OMT) according to baseline severity of chronic low back pain (LBP).
Methods: The OSTEOPATHIC Trial used a randomized, double-blind, sham-controlled, 2 × 2 factorial design to study OMT for chronic LBP. A total of 269 (59%) patients reported low baseline pain severity (LBPS) (<50 mm/100 mm), whereas 186 (41%) patients reported high baseline pain severity (HBPS) (≥50 mm/100 mm). Six OMT sessions were provided over eight weeks and outcomes were assessed at week 12. The primary outcome was substantial LBP improvement (≥50% pain reduction). The Roland–Morris Disability Questionnaire (RMDQ) and eight other secondary outcomes were also studied. Response ratios (RRs) and 95% confidence intervals (CIs) were used in conjunction with Cochrane Back Review Group criteria to determine OMT effects.
Results: There was a large effect size for OMT in providing substantial LBP improvement in patients with HBPS (RR, 2.04; 95% CI, 1.36–3.05; $P < 0.001$). This was accompanied by clinically important improvement in back-specific functioning on the RMDQ (RR, 1.80; 95% CI, 1.08–3.01; $P = 0.02$). Both RRs were significantly greater than those observed in patients with LBPS. Osteopathic manual treatment was consistently associated with benefits in all other secondary outcomes in patients with HBPS, although the statistical significance and clinical relevance of results varied.
Conclusions: The large effect size for OMT in providing substantial pain reduction in patients with chronic LBP of high severity was associated with clinically important improvement in back-specific functioning. Thus, OMT may be an attractive option in such patients before proceeding to more invasive and costly treatments.

1. Introduction

The Global Burden of Disease Study 2010 reported a low back pain (LBP) prevalence of 632 million persons, making it the leading cause of years lived with disability (Vos et al., 2013). In the United States, LBP is the most common reason for adults to use complementary and alternative medicine (CAM) (Barnes et al., 2008), including utilization of manual therapy practitioners. Practice guidelines have recommended spinal manipulation for chronic or persistent LBP (Chou et al., 2007, National Institute for Health and Clinical Excellence, 2009) and, specifically, osteopathic manual treatment (OMT) (Clinical Guideline Subcommittee on Low Back Pain, 2010). Nevertheless, a Cochrane Collaboration review subsequently concluded that spinal manipulation is not more effective than sham interventions for short-term relief of chronic LBP (Rubinstein et al., 2011). Recently, however, the OSTEOPAThic Health outcomes In Chronic low back pain (OSTEOPATHIC) Trial demonstrated statistically significant and clinically relevant LBP improvement over 12 weeks with OMT when compared with sham OMT (Licciardone et al., 2013). Notably, OMT was associated with substantial LBP improvement, decreased use of prescription medication for LBP, and greater patient satisfaction with back care in the OSTEOPATHIC Trial. The present study now aims to determine if response to OMT differs significantly according to baseline

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severity of chronic low back pain by comparing patient subgroups within the OSTEOPATHIC Trial.

2. Methods

2.1. Study overview

The OSTEOPATHIC Trial was approved by the Institutional Review Board at the University of North Texas Health Science Center and registered with ClinicalTrials.gov (NCT00315120). Its methodology has been previously described (Licciardone et al., 2008; Licciardone et al., 2013). The trial used a randomized, double-blind, sham-controlled, 2 × 2 factorial design (Fig. 1) to study OMT (factor 1) and ultrasound therapy (factor 2) over 12 weeks in patients with nonspecific chronic LBP. Therein, OMT was shown to be safe, well accepted by patients, and associated with statistically significant and clinically relevant reduction in LBP (Licciardone et al., 2013). Consequently, the present study focused on comparing OMT vs. sham OMT in patient subgroups with low baseline pain severity (LBPS) and high baseline pain severity (HBPS). Ultrasound therapy was not studied herein because the OSTEOPATHIC Trial failed to demonstrate its efficacy.

2.2. Enrollment and randomization

Patients were recruited throughout Dallas–Fort Worth from August 2006 to September 2010 through newspaper advertisements, community agencies, and medical clinics, including those affiliated with the group practice of the University of North Texas Health Science Center, exclusive of clinics that provided OMT specialty services. The eligibility criteria were developed to include patients with nonspecific chronic LBP and to exclude patients who recently used manual therapy for LBP. Essentially, patients were those 21–69 years of age who self-reported low back pain on most days during the past three months, but who were without any of the following: "red flag" conditions; history of recent low back surgery, receipt of worker's compensation benefits, or ongoing litigation involving back problems; medical conditions that might impede OMT (or ultrasound therapy) protocol implementation; corticosteroid use in the past month; or clinical evidence of lumbar radiculopathy, as determined by the presence of ankle dorsiflexion weakness, great toe extensor weakness, impaired ankle reflexes, loss of light touch sensation in the medial, dorsal, and lateral aspects of the foot, or shooting posterior leg pain or foot pain upon ipsilateral or contralateral straight leg raising (Bigos et al., 1994). Patients who had received manual therapy in the past three months, or more than three times in the past year, were also excluded. Patients were randomly allocated to either OMT or sham OMT by a computer-based process. These assignments were conveyed to treatment providers via opaque sealed envelopes. Randomization was not stratified according to baseline pain severity. Patients and outcome assessors were not informed of treatment group assignments.

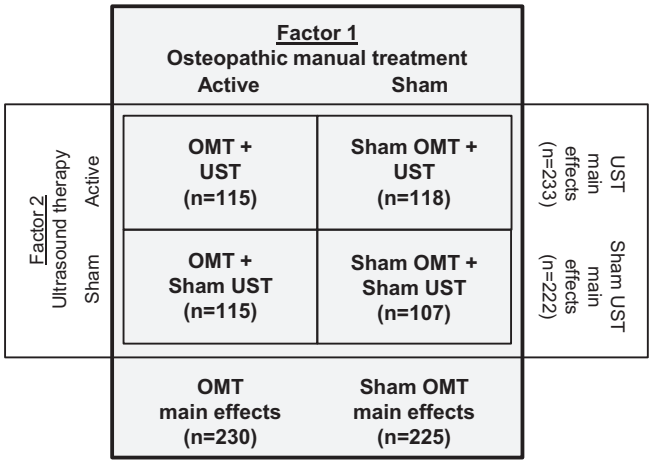

Fig. 1. Overview of the OSTEOPATHIC Trial's 2 × 2 factorial design. OMT denotes osteopathic manual treatment; UST, ultrasound therapy. As indicated by the shaded box, the present study focuses on OMT (factor 1) because it was found to be efficacious in reducing low back pain in the OSTEOPATHIC Trial, whereas UST (factor 2) was not efficacious.

2.3. Patient subgroups

Low back pain was measured with a 100-mm visual analog scale (VAS) at baseline, before each treatment session, and at week 12. We dichotomized patients into two subgroups defined as having LBPS (VAS < 50 mm/100 mm) or HBPS (VAS ≥ 50 mm/100 mm) for three reasons. First, dichotomization yielded relatively larger subgroups than would have been obtained with other polychotomous categorizations (e.g., trichotomization as "mild", "moderate", or "severe"). Second, it was intuitively appealing to simply bisect the 100-mm VAS. Third, the 50-mm cutpoint would facilitate extrapolation of our LBP results to numerical and other rating scales used in research settings or clinical practice.

2.4. Treatment protocols

Treatment fidelity methods (Bellg et al., 2004) were used to train 15 treatment providers to deliver the OMT and sham OMT protocols. Both protocols consisted of 15-min treatment sessions at weeks 0–2, 4, 6, and 8, delivered by the same provider to a given patient unless there was a scheduling conflict. Osteopathic manual treatment included high-velocity, low-amplitude thrusts; moderate-velocity, moderate amplitude thrusts; soft tissue stretching, kneading, and pressure; myofascial stretching and release; positional treatment of myofascial tender points; and muscle energy techniques. These techniques were aimed primarily at the lumbosacral, iliac, and pubic regions. Other osteopathic techniques were allowed only if the treatment provider judged a designated technique to be contraindicated or ineffective for a given patient. The sham OMT protocol was based on that developed in the North Texas Clinical Trial (Licciardone et al., 2003) and subsequently determined to provide a robust response in comparison with other placebo treatments for pain (Hrobjartsson and Gotzsche, 2001). The sham methods included hand contact, active and passive range of motion, and techniques that simulated OMT, but that utilized such maneuvers as light touch, improper patient positioning, purposely misdirected movements, and diminished treatment provider force. Patients were allowed to receive their usual LBP care and other co-treatments during the study with the exception of manual therapies.

2.5. Outcomes

2.5.1. Substantial low back pain improvement

Substantial LBP improvement was based on the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) consensus statement recommendations (Dworkin et al., 2008). We used the relative threshold of ≥50% pain reduction to determine substantial improvement at week 12, rather than the absolute threshold of ≥40 mm pain reduction, to minimize floor effects in assessing OMT efficacy in patients with LBPS. This threshold is highly sensitive and specific in predicting global