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Clinical Study

Short-term effectiveness of spinal manipulative therapy versus functional technique in patients with chronic nonspecific low back pain: a pragmatic randomized controlled trial

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Abstract

BACKGROUND CONTEXT: Chronic low back pain (LBP) is a prevalent condition associated with pain, disability, decreased quality of life, and fear of movement. To date, no studies have compared the effectiveness of spinal manipulation and functional technique for the management of this population.

PURPOSE: This study aimed to compare the effectiveness of spinal manipulation and functional technique on pain, disability, kinesiophobia, and quality of life in patients with chronic LBP.

STUDY DESIGN/SETTING: A single-blind pragmatic randomized controlled trial conducted in a university research clinic was carried out.

PATIENT SAMPLE: Sixty-two patients (62% female, age: 45±7) with chronic LBP comprised the patient sample.

OUTCOME MEASURES: Data on disability (Roland-Morris Disability Questionnaire [RMQ], Oswestry Low Back Pain Disability Index [ODI]), pain intensity (Numerical Pain Rate Scale [NPRS]), fear of movement (Tampa Scale of Kinesiophobia [TSK]), quality of life (Short Form-36 [SF-36] quality of life questionnaire), isometric resistance of abdominal muscles (McQuade test), and spinal mobility in flexion (finger-to-floor distance) were collected at baseline immediately after the intervention phase and at 1 month postintervention by an assessor blinded to group allocation of the patients.

METHODS: Patients were randomly assigned to the spinal manipulative therapy group or the functional technique group and received three once-weekly sessions.

FDA device/drug status: Not applicable.

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RESULTS: In comparison to patients receiving functional technique, those receiving spinal manipulation experienced statistically, although not clinically, significant greater reductions in terms of RMQ (standardized mean difference in score changes between groups at post-treatment: 0.1; at 1 month: 0.1) and ODI (post-treatment: 2.9; at 1 month: 1.4). Linear longitudinal analysis showed a significant improvement in both groups over time for RMQ (manipulative: F=68.51, p<.001; functional: F=28.58, p<.001) and ODI (manipulative: F=104.66, p<.001; functional: F=32.15, p=.001). However, significant treatment-by-time interactions were not detected for pain intensity (p=.488), TSK (p=.552), any domains of the SF-36 quality of life questionnaire (p≤.164), McQuade test (p=.512), and finger-to-floor distance (p=.194). Differences between and within groups were not clinically meaningful in any of the reported measures.

CONCLUSIONS: In comparison to functional technique, spinal manipulative therapy showed greater reduction in disability in patients with chronic LBP, but not in terms of pain, fear of movement, quality of life, isometric resistance of trunk flexors, or spinal mobility. However, differences in disability were not clinically meaningful; therefore, spinal manipulative therapy did not result in any clinically important short-term benefits over functional technique therapy. In addition, as neither group met the threshold for minimum clinically important difference following treatment, neither treatment resulted in a clinically meaningful benefit. © 2016 Elsevier Inc. All rights reserved.

Keywords:

Chronic pain; Low back pain; Manipulation; Quality of life; Randomized controlled trial; Disability evaluation

Introduction

Chronic low back pain (LBP) represents a significant health-care problem that results in substantial costs to society [1]. It is a prevalent condition that leads to increased disability and decreased quality of life [2]. In fact, the 1-year prevalence for LBP ranges from 22% to 65% [3]. The management of LBP constitutes an economic burden as it represents the highest compensation costs for workers in the United States [4]. Several studies suggest that LBP is characterized by central sensitization [5,6]. Subjects with chronic LBP have hypersensitivity to pain which may be indicative of a centrally mediated mechanism and neuroplastic changes [7].

Some authors have proposed that interventions such as spinal manipulative therapy may alter central sensitization [8,9] and may be effective for the treatment of individuals with chronic LBP [10,11]. In fact, spinal manipulation may inhibit neuroplastic changes in pain perception at the dorsal horn of the spinal cord [8,12]. However, although a number of studies have investigated the mechanical, physiological, and neurological effects produced by lumbar spine manipulations, there is considerable controversy regarding the efficacy of spinal manipulation for patients with chronic LBP because some reviews conclude that it has positive effects [13,14] whereas others do not [15,16].

Other authors have proposed the application of massage and soft tissue interventions for the management of chronic LBP [17,18]. A previous Cochrane systematic review concluded that massage can be beneficial in the management of LBP [19]. However, there is a scarcity of studies investigating other soft tissue interventions, such as soft tissue myofascial release, for managing patients with LBP [20].

The purpose of the current randomized clinical trial was to compare the effectiveness of spinal manipulation versus a functional technique on pain, disability, kinesiophobia, and quality of life in individuals with chronic LBP.

Methods

Participants

A single-blind parallel groups pragmatic randomized controlled trial was conducted on patients with chronic LBP, who were recruited from patients referred for physical therapy at a clinical unit of the Health Science School of the University of Almeria (Spain). Chronic nonspecific LBP was defined as tension, soreness and/or stiffness localized below the costal margin persisting for ≥3 months, for which it was not possible to identify a specific disease or clear pathologic cause of the pain. Several structures in the back, including the joints, discs, and connective tissues, may contribute to symptoms. To be eligible, patients had to meet the following inclusion criteria: (1) LBP for 3 months or more; (2) age between 25 and 55 years; (3) a score of 4 points or more on the Roland-Morris Disability Questionnaire (RMQ); (4) not currently receiving physical therapy; and (5) the inability to achieve lumbar muscle flexion-relaxation in trunk flexion. Exclusion criteria included (1) the presence of lumbar stenosis; (2) any clinical signs of radiculopathy; (3) a diagnosis of spondylolisthesis; (4) a diagnosis of fibromyalgia; (5) treatment with corticosteroid or oral medication within the past 2 weeks; (6) a history of spinal surgery; (7) disease of the central or peripheral nervous system. The protocol was approved by the local human research committee of the University of Almeria and registered with clinicaltrials.gov (NCT01796496). After registration was completed, some changes were made to the eligibility criteria: (1) the age range of the participants was extended to between 18 and 65 because of limitations in the recruitment of the sample size; (2) two exclusion criteria were added: contraindication to spinal manipulative therapy and having previously undergone spinal manipulative therapy. These last criteria were included because of the need to apply the manipulative treatment safely and because previous experiences (positive or negative) with these approaches could

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