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Effects of motion style acupuncture treatment in acute low back pain patients with severe disability: A multicenter, randomized, controlled, comparative effectiveness trial

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ABSTRACT

Reviews of the efficacy of acupuncture as a treatment for acute low back pain (aLBP) have shown that there is insufficient evidence for its effect and that more research is needed. Motion style acupuncture treatment (MSAT) is novel in that it requires a part of the patient's body to move passively or actively while acupuncture needles are retained. A multicenter, randomized, comparative effectiveness trial was conducted to evaluate the effects of MSAT in aLBP with severe disability. A total of 58 aLBP patients with severe functional disability (defined per Oswestry Disability Index [ODI] $\geqslant$60%) were recruited and assigned randomly to receive 1 session of either conventional diclofenac injection (n = 29) or MSAT (n = 29). The primary outcome measured improvement in LBP using the 10-point numerical rating scale of LBP, and the secondary outcome assessed disability using the Oswestry Disability Index at 30 minutes and at 2, 4, and 24 weeks after treatment. Analyses were by intention to treat. The numerical rating scale of the MSAT group decreased 3.12 (95% confidence interval = 2.26, 3.98; $P < .0001$) more than that of the injection group and the Oswestry Disability Index of the MSAT group decreased 32.95% (95% confidence interval = 26.88, 39.03; $P < .0001$) more than that of the injection group, respectively. The difference between the 2 groups maintained statistical significance at 2 and 4 weeks after treatment. These results suggest that MSAT has positive effects on immediate pain relief and the functional recovery of aLBP patients with severe disability.

1. Introduction

Although the natural history of back pain has been considered favorable, with most cases of acute low back pain (aLBP) resolving within weeks [34], a recent systematic review of the prognosis of aLBP showed that this view of spontaneous healing is inaccurate. Pain and disability are typically ongoing, and recurrences are common [5]. Up to 70% of patients who initially improve experience repeated fluctuating pain episodes [26]. It was reported that back pain patients classified as dysfunctional have more pain-specific fear and avoidance. This disposition may be a factor in the transition from acute to chronic LBP [1]. Thus, effective treatments for aLBP patients are needed to prevent the persistence of pain and disability beyond the acute phase.

Recent systematic reviews of randomized clinical trials have concluded that various types of nonsteroidal anti-inflammatory drugs (NSAIDs) are effective for short-term symptomatic relief in the early management of aLBP [19,38]. In the Cochrane review on the role of NSAIDs, the effectiveness of NSAIDs was shown to be more significant than placebo in relieving aLBP [38]. Although oral NSAIDs are widely used as a drug of first choice for low back pain, because of slow onset of action and modest analgesic potency, the effects are rather limited in acute cases. Hence, in severe cases of aLBP, parenteral administration of NSAIDs is preferred for its rapid onset of action and strong analgesic properties [4,25,30,37]. Diclofenac is the most commonly prescribed NSAID and its efficacy for relieving aLBP is well established [3,22], making it the standard NSAID in treatment of such particular indications [22,43]. In a randomized trial reported by Babej-Dölle et al., 2

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groups of 82 patients with aLBP were each intramuscularly administered 3 ml of diclofenac-sodium (75 g) or 5 mL of isotonic saline as a placebo. When the pooled effect size for the decrease in visual analogue scale (VAS) of low back pain was estimated at 30 minutes after baseline, the standardized mean difference (SMD) of diclofenac compared to placebo was 0.38 [2].

Acupuncture has been extensively used to treat back pain, but there has been continued controversy about its efficacy. A systematic review concluded that acupuncture was found to be effective for pain relief and functional recovery in chronic LBP in the short term but not for aLBP [11]. Even LBP treatment guidelines recommend acupuncture only for chronic back pain [6,37]. Motion style acupuncture treatment (MSAT) is a relatively novel acupuncture method that has been recently used increasingly often in South Korea [18]. It is similar to traditional acupuncture in that needles are inserted at specific acupuncture points, but is unique in that it requires passive or active movement of the patient's body while acupuncture needles are retained.

To our knowledge, there are no previous trials that have studied the effect of a treatment modality that combines acupuncture with exercise in a manner comparable to MSAT for aLBP patients, nor are there alternative clinical treatment guidelines for aLBP patients who are unable to adhere to the general "remain active" recommendations because of pain. This study was designed to examine the effects of MSAT on aLBP patients with severe disabilities.

2. Methods

2.1. Study design

This study was a multicenter, randomized, conventional diclofenac injection–controlled, assessor-blinded, 2–parallel arm clinical trial. It was conducted from April 2011 to April 2012, and patients were recruited from April 2011 to October 2011. The patients were randomly allocated to either MSAT group or active control group in a ratio of 1:1. The experimental group received 1 session of MSAT, and the active control group received 1 intramuscular injection of NSAIDs. We observed the outcome variables 5 times: before treatment, and 30 minutes and 2, 4, and 24 weeks after treatment.

This study protocol received approval from the Institutional Review Boards of Jaseng Hospital of Korean Medicine, and was registered at ClinicalTrial.gov (NCT01315561). A full description of the protocol was previously published [33]. Participants were not offered economic incentives, but the treatment was free of charge as compensation for participation. We did not restrict the patients' option of treatment during the follow-up period. The study is reported according to the Consolidated Standards of Reporting Trials (CONSORT) [10] and STRICTA [21] guidelines.

2.2. Participants

The participants included in this study were recruited from 2 hospitals: Jaseng Hospitals of Korean Medicine located in Seoul and Bucheon. Study researchers screened the eligibility of aLBP patients experiencing discomfort walking and requiring such assistance as wheelchairs or stretchers. If eligible, all patients underwent plain radiography and magnetic resonance imaging (MRI) of the lumbar spine. Eligible participants were those between 20 and 60 years with aLBP of <4 weeks' duration, with or without radiating pain to the limb with an Oswestry Disability Index (ODI) value $\geqslant$60% as an indicator of severe disability. Exclusion criteria were as follows: serious disease that could cause LBP (eg, cancer, vertebral fracture, spinal infection); chronic disease that could interfere with the effect of the treatment or the interpretation of treatment results (eg, cardiovascular disease, diabetic neuropathy, fibromyalgia); progressive neurological deficit or severe neurological symptoms; conditions inappropriate or unsafe for acupuncture (eg, hemorrhagic disease, blood coagulation disorders); current intake of corticosteroids, immunosuppressant drugs, psychiatric medicine; experience of gastrointestinal side effects after taking NSAIDs or current treatment for gastrointestinal disease; pregnancy; and reluctance to accept the treatment regimens or examinations (eg, X-ray, MRI) of this study.

All eligible participants were given verbal and written information about the study and the 2 treatment alternatives. Each participant voluntarily signed an informed consent form before participating in the study.

2.3. Sample size

The sample size was estimated using the mean difference in numerical rating scale (NRS) for LBP between the experimental and control groups. Based on previous pilot studies, we set the effect size (Cohen's d) at 0.8. Although the difference between the 2 groups in their mean NRS change scores was 2.3, we conservatively set it as 2. The standard deviation of change of the NRS scores pooled from the 2 groups was calculated as 2.5. When a 2-tailed test with a test power of 80% and significance level of 5% was applied [20], the number required for each group was 26 subjects. For a successful study, a total of 58 subjects, with a 10% dropout rate factored in, were required. Interim analysis was not to be performed, or patient recruitment to be discontinued, unless the principal investigator decided that there was an unacceptable risk of serious adverse events in the groups.

2.4. Study interventions

MSAT was conducted by Korean medicine doctors who had >5 years of clinical experience. The doctors conducting MSAT were required to complete 3 workshop sessions before participating in the study, to ensure that MSAT was conducted in the standardized form as stated in the protocol [33]. (For more information see additional files 1 and 2 of the protocol [33], which contain the origin and a detailed explanation of MSAT.)

We briefly introduced the method of MSAT as follows: Two assistants stand on both sides of the patient with their arms around the patient's waist while gently holding 1 of the patient's hands. In this position, the practitioner inserts disposable acupuncture needles (40 mm $\times$ 0.25 mm; Dong-bang Acupuncture, Seong-Nam, Korea) to a depth of 10 to 15 mm at the subject's Pungbu (GV16) and on both sides of Haenggan (LR2) and Gokji (LI11). These acupuncture points were selected according to traditional Chinese medicine theory (*qi* circulation) [12,27] and previous clinical experience. The location of each acupuncture point was determined using guidelines published by the World Health Organization Standard Acupuncture Point Locations in the Western Pacific Region [41]. No specific manipulation was used in this process, and "Deqi" sensation was not sought, but practitioners occasionally manually stimulated the needle inserted in GV16. With the needles still retained at the acupoints, the patient is asked to walk with assistance. The more the subject's walking ability improves and the pain is alleviated, the less the amount of support to be provided, and the assistants are asked, 1 by 1, to gradually stop supporting the subject. When the patient gains the ability to walk without any support, all the needles are removed and the patient is asked to continue walking for another 1 to 2 minutes. The practitioner also provided verbal encouragement to the patient, as needed, to relieve the patient's apprehension and fear of movement. The average procedure takes up to about 20 minutes per patient. Video supplements of the MSAT procedure are available (http://msat.jaseng.net/). In the control group, subjects received