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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

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an intramuscular injection of diclofenac sodium (75 mg; KUKJE Pharmaceutical, SeongNam, Korea) in the gluteal region. Both groups were informed of the favorable prognosis of aLBP and were advised to remain active, if possible, within the range of nonaggravation of pre-existing symptoms.

2.5. Outcome measurements

Assessing doctors were blinded to group assignment and did not participate in the acupuncture treatment. Sex, age, height, weight, blood pressure, and medical history were included in the baseline demographic assessment. The initial evaluation of primary and secondary endpoints was carried out at baseline and 30 minutes after baseline because, based on the investigators' previous observations, we know that the pain relief and improvement in motion due to MSAT appears immediately after treatment, and the maximum plasma concentration for diclofenac occurs approximately 10 to 20 minutes after intramuscular injection [29]. Thus, 30 minutes after baseline was the primary time point. We also performed additional follow-up evaluations at 2, 4, and 24 weeks. Also, at the 24-week follow-up, we checked as to whether any patients had received inpatient treatment or surgical procedures at other institutions in association with the current aLBP incidence, and, if so, the length of their hospitalization. Radiology specialists who were blinded to group allocation assessed the lumbar X-rays and MRIs. The lumbar MRI readings were categorized into 4 groups: no protrusion or extrusion; protrusion with no extrusion; extrusion; and both protrusion and extrusion in the lumbar discs. The primary outcome referred to the intensity of aLBP evaluated through NRS by the trained assessor. Although the NRS is a subjective evaluation indicator, it is widely used because of its simplicity. Using the NRS, the patient chooses 1 number, ranging from 0 to 10, that best expresses their current level of pain (0 being no pain, and 10 being the most excruciating pain that the subject has ever experienced) [9,35]. As the severity of pain can differ at rest and during activity, patients were asked to indicate the intensity of pain that they felt as they tried to move. The NRS for aLBP was assessed at baseline and at 30 minutes after and 2, 4, and 24 weeks after treatment. Secondary result outcomes included functional status using the accredited Korean version of the ODI questionnaire [8]. It was recorded at baseline and at 30 minutes after and 2, 4, and 24 weeks after treatment. We also evaluated the patient global impression of change (PGIC) [9], which enables patients to subjectively assess their improvement at 30 minutes and at 24 weeks after treatment. We also checked the patients' lumbar range of motion (ROM) and degree of straight leg raising (SLR) to determine the change in movement between baseline and 30 minutes after treatment. The measurement of ROM is reliable ($r = 0.94$) and valid ($r = 0.97$) [32] but not very responsive (effect size = 0.1–0.6) [15]. Also, the measurement of SLR is reliable (intraclass correlation coefficient = 0.95) [7], the sensitivity is 0.8 (72%–97%), and the specificity is 0.4 (11%–66%) [28], but it is not very responsive (effect size = 0.2). As the responsiveness of ROM and SLR measurement is not high, we decided to use it only as a secondary outcome measure. When assessing the NRS for leg pain, we asked the patients to indicate the intensity of pain that they felt in each leg as they tried to move, and we recorded the NRS of the leg with the higher score at baseline. The NRS for leg pain was checked at baseline and at 30 minutes after and 2, 4, and 24 weeks after treatment. Any adverse events were monitored and reported as secondary outcomes. No changes were made to the prespecified trial outcome measures [33] after the trial commenced.

2.6. Randomization and allocation concealment

Randomization was conducted by a statistics specialist who had no contact with the participants. Random numbers with block randomization were generated using the SAS version 9.1.3 statistical package (SAS Institute, Cary, NC), and a block size of 6 was used to allocate the 2 groups (1:1 ratio). A statistics specialist generated the random allocation sequence. Korean medicine doctors who had received prior training enrolled participants and conducted the data collection sessions, and the randomized numbers were kept in sealed envelopes by a researcher who had no direct contact with the study participants. Random allocation was conducted by opening an envelope as the researcher was informed of a participant's registration at each clinical trial center. Before the randomization allocation, participants were informed that they would be assigned to 1 of the 2 groups. Random allocation was performed if a participant was eligible and had signed the informed consent form. The subject identification codes were recorded on the case report forms (CRFs) and randomization table.

2.7. Blinding

Assessor-blinding was achieved by blinding the assessor performing outcome assessment and CRF data entry to the random allocation, as blinding of participants or practitioners was impossible because of the nature of the treatment. Statistical analysis was performed by an independent statistician who was blinded to the identification of each treatment group.

2.8. Statistical analysis

Continuous variable data was expressed as mean ± standard deviation (SD) and compared using the independent t test. Categorical variables were expressed as numbers or percentages and compared using the χ^2 test or Fisher exact test, as appropriate. Moreover, if the normality assumption was violated, the Mann–Whitney U test would be used. For the comparison of NRS, ODI, ROM, and SLR between the 2 groups, an independent t test was used, followed by calculation of effect size (Cohen's d) with a 95% confidence interval. The results were considered to be statistically significant when P was <0.05. All adverse events reported during the study were included on the CRFs, and the incidence of adverse events was calculated. The percentage of subjects with adverse events, the percentage that received inpatient care in association with the current aLBP incidence, and the length of hospital stay in each group was calculated and compared using the χ^2 test or Fisher exact test. By the principle of intention-to-treat analysis, the last observed value (non-missing value) was used to fill in missing values at a later point in the study. All statistical analyses were performed using SAS version 9.1.3 software.

3. Results

In all, 93 consecutive patients with aLBP were screened, and of these patients 58 were enrolled (Fig. 1). A total of 29 were randomized to each group, and all patients completed treatment with no drop-outs or adverse events. All 58 patients were evaluated at the 30-minute follow-up. The patients were re-evaluated at 2, 4, and 24 weeks after treatment by telephone interview. The follow-up rate was different for each evaluation. A total of 24 patients in the MSAT group and 27 in the injection group answered the entire follow-up questionnaire at 24 weeks. However, we were able to investigate the length of hospital stays, number of hospital visits, or surgery in greater numbers of patients (Table 3).

3.1. Demographic data

There were no statistically significant differences between the 2 groups in the baseline demographic and clinical features (Table 1).

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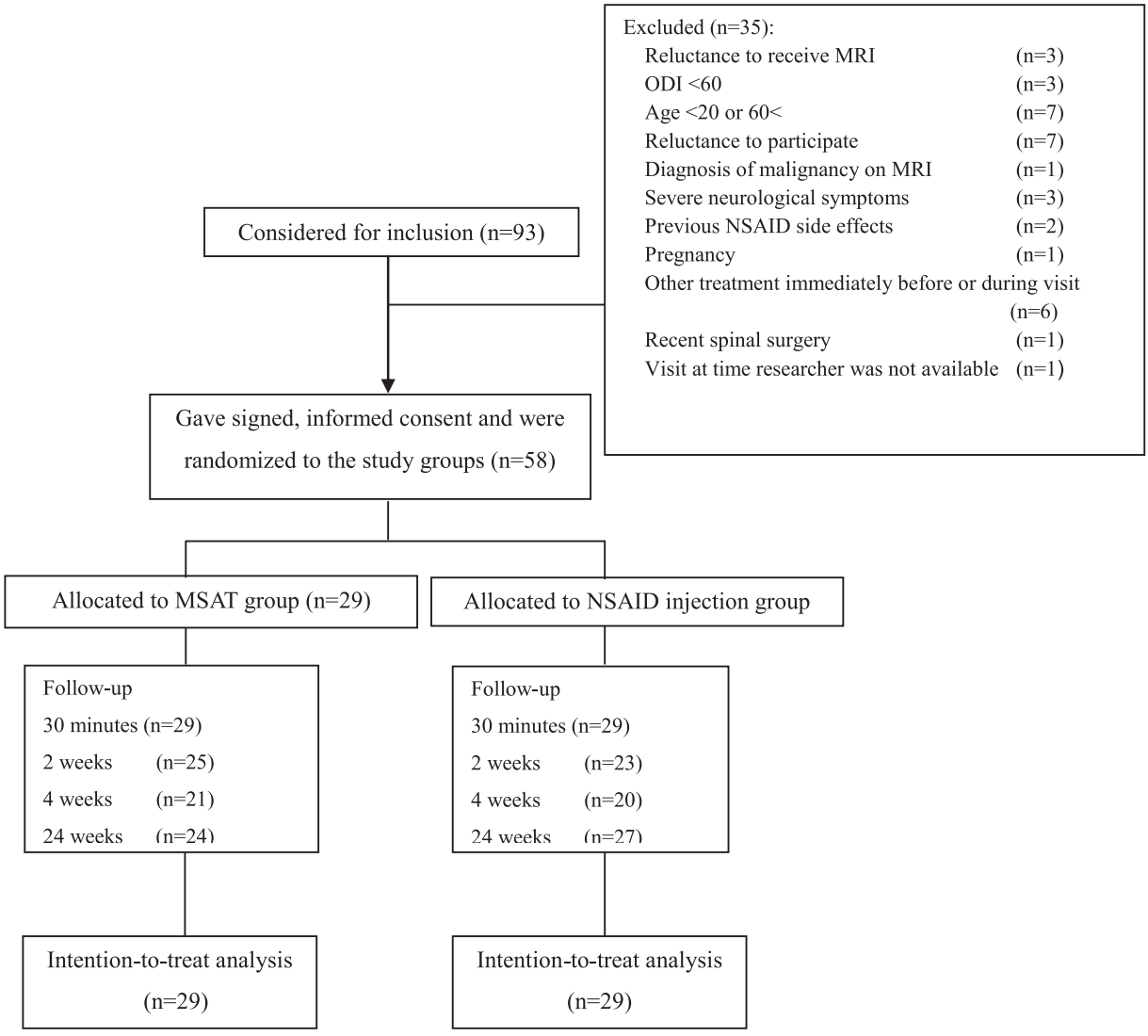

Fig. 1. Recruitment and follow-up of study participants.

The duration period was defined as the duration days of current pain at baseline visit regardless of prior LBP incidents. There was no significant difference between the 2 groups in the mean NRS of low back pain and leg pain, ODI, ROM, and SLR at baseline. The NRS of low back pain, which was the primary outcome measure, of the MSAT group was superior to that of the injection group at 30 minutes. This difference was maintained at 2 and 4 weeks, but the difference gradually decreased, with no significant difference at 24 weeks. Whereas the NRS of leg pain in the MSAT group showed a significant decrease at 30 minutes after treatment, the injection group did not. Both groups presented with a significant decrease at 2 and 4 weeks, and at 24 weeks the injection group showed a greater reduction in pain. There was a significant decrease in the ODI score of the MSAT group at 30 minutes after treatment, whereas there was not in the injection group. The MSAT group showed a more significant difference than the injection group at 30 minutes and at 2 and 4 weeks, but not at 24 weeks. Furthermore, the MSAT group showed a significant difference in SLR at 30 minutes (Table 2).

In PGIC, the MSAT group showed a higher level of satisfaction (1.90 ± 0.67) than the injection group (3.62 ± 0.62) ($P < .0001$) at 30 minutes. However, at the 24-week follow-up there was no significant difference between the 2 groups. Only 3 patients in the MSAT group and none in the injection group could be assessed for the ROM of lumbar flexion and extension at baseline, and the rest could not because of patients' refusal of measurement due to severe pain and/or disability. The lumbar ROM of 27 patients in the MSAT group could be measured, and the mean lumbar flexion and extension measurement were 22.07 ± 25.48 and 7.41 ± 7.02, respectively. The lumbar ROM could be measured in only 1 patient in the injection group, and the rest refused.

3.2. Post hoc outcome measures

All participants consulted with different physicians from those who conducted previous treatment regarding inpatient/outpatient treatment plans after the initial MSAT or injection treatment. Inpatients received an integrative package (consisting of herbal medicine, Chuna manipulation, bee venom pharmaco-acupuncture, and acupuncture) [24] an average of 5 sessions a week, and outpatients once or twice a week (Table 3). Although the physicians who were not involved in data collection or group allocation were not informed of the purpose of this trial, they were still not blinded to the patients' previous treatments.

We investigated whether the participants received inpatient care in association with the current aLBP incidence, and found that

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Table 1
Demographic and clinical features of the participants at baseline.

Variables	Total N (%)	Group		*P* value
		MSAT (n = 29)	Injection (n = 29)	
Sex				
Male	34 (59)	19 (66)	15 (52)	.2862
Female	24 (41)	10 (34)	14 (48)	
Age, y (mean ± SD)	38.31 ± 7.97	37.93 ± 7.37	38.69 ± 8.64	.7204
BMI, kg/m^2 (mean ± SD)	23.91 ± 3.64	24.18 ± 3.37	23.63 ± 3.93	.5729
Duration, days (mean ± SD)	1.76 ± 1.97	1.41 ± 1.45	2.10 ± 235	.1854
MRI findings				
Bulging	4 (7)	3 (10)	1 (3)	.3638
Protrusion	33 (57)	18 (62)	15 (52)	
Extrusion	8 (14)	2 (7)	6 (21)	
Protrusion and extrusion	13 (22)	6 (21)	7 (24)	

BMI, body mass index; MRI, magnetic resonance imaging.
Data are n (%) or mean ± SD. Continuous variables were calculated by 2-sample *t* test, and categorical variables were calculated by the χ^2 test.

Table 2
Difference in primary and secondary results of motion style acupuncture treatment (MSAT) group and nonsteroidal anti-inflammatory drug injection group between each evaluation and baseline (change from baseline to follow-up time point).

Variable	Baseline	Change from baseline to follow-up time point			
		30 Minutes	2 Weeks	4 Weeks	24 Weeks
NRS- LBP					
MSAT	8.33 ± 1.91	3.83 ± 2.05*	5.83 ± 2.61*	6.41 ± 2.45*	6.64 ± 2.47*
Injection	8.12 ± 1.63	0.71 ± 1.06*	4.17 ± 3.05*	4.91 ± 2.94*	6.84 ± 1.9*
Difference (95% CI)		3.12 (2.26, 3.98)	1.66 (0.16, 3.15)	1.5 (0.08, 2.92)	−0.21 (−1.37, 0.95)
P value	.6598	<.0001	.0305	.0393	.7221
NRS, leg pain					
MSAT	2.31 ± 3	1.22 ± 1.88*	1.57 ± 2.7*	1.59 ± 2.78*	1.64 ± 2.46*
Injection	4.1 ± 4.11	0.26 ± 0.7	1.83 ± 2.66*	2.33 ± 3.06*	3.48 ± 3.62*
Difference (95% CI)		0.97 (0.22, 1.71)	−0.26 (−1.67, 1.15)	−0.74 (−2.28, 0.8)	−1.85 (−3.47, −0.22)
P value	.0628	.0137	.7149	.3386	.0276
ODI					
MSAT	85.72 ± 10.46	33.37 ± 14.91*	56.41 ± 24.86*	62.72 ± 21.88*	73.23 ± 20.24*
Injection	88.34 ± 7.71	0.41 ± 6.64	36.34 ± 29.1*	45.84 ± 29.58*	80.83 ± 13.58*
Difference (95% CI)		32.95 (26.88, 39.03)	20.07 (5.83, 34.31)	16.88 (3.19, 30.57)	−7.6 (−16.67, 1.47)
P value	.2820	<.0001	.0066	.0166	.0995
SLR					
MSAT	41.9 ± 26.61	15.00 ± 20.27			
Injection	37.76 ± 25.79	1.38 ± 14.75			
Difference (95% CI)		13.62 (4.3, 22.95)			
P value	.5500	.005			

Data are mean ± standard deviation. Outcome results at baseline and post treatment at 30 minutes and at 2, 4, 24 weeks were compared between the 2 groups with independent-sample *t* test.
NRS, numerical rating scale; ODI, Oswestry Disability Index; SLR, straight leg raising; CI, confidence interval.
* <.005

the MSAT group showed a significantly lower hospitalization rate than the injection group. Although the length of hospital stay in the MSAT group was shorter than the injection group, the difference did not reach statistical significance. Although we could not confirm the surgical status of 6 patients at 24 weeks, 1 patient in the injection group who completed the 24-week follow-up reported having received surgery because of the current LBP.

4. Discussion

Our study has shown that MSAT was more effective for pain and function in aLBP patients with severe disability in the short term and up to 4 weeks than was conventional NSAID injection. These results suggest that MSAT has superior effects on pain and functional status as shown by the NRS of LBP, NRS of leg pain, ODI scores, lumbar ROM, and range of SLR over those of the NSAID injection control.

Statistically significant results may differ from clinically significant results and it was reported by Ostelo and de Vet that a reduction in NRS of $\geqslant$3.5 and improvement in ODI scores of $\geqslant$10 are clinically significant in LBP patients [23]. In the MSAT group, the NRS of LBP decreased 3.83 ± 2.05, and the ODI 33.37 ± 14.91, which are clinically significant levels of pain reduction and functional recovery. These results were also reflected in the admittance rate of patients. Whereas 93% of the NSAID group patients opted for hospitalization because of little improvement in functional disability (0.41 ± 6.64), 66% of the MSAT group chose to receive hospitalization with greater improvement in function (33.37 ± 14.91). The difference in the admittance rate of patients between groups was statistically significant. Although the duration of hospital stay was shorter in the MSAT group, the statistics did not reach statistical significance.

The main shortcoming of this study is that we were unable to blind the patient and physician simultaneously. The divergence be-

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Table 3
Medical service use and period during the 24-week follow-up (in association with the current aLBP incidence).

	Total	MSAT (n = 29)	Injection (n = 29)	*P* value
Type				
Inpatient, n (%)	46	19 (66)	27 (93)	.021
Outpatient, n (%)	12	10 (34)	2 (7)	
Hospital stay, n (days, mean ± SD)	46 (15.74 ± 10.95)	19 (12.58 ± 8.24)	27 (17.96 ± 12.17)	.101
Surgery*				
No, n (%)	51 (98)	24 (100)	27 (96)	1.0000
Yes, n (%)	1 (2)	0	1 (4)	

Continuous variables were calculated by 2-sample t test, and categorical variables were calculated by χ^2 test.
* Variable had 6 missing values.

tween the 2 treatment group methods was too substantial to blind the patient and physician both. Although the assessors were blinded, whereas the majority of patients in the MSAT group regained mobility after treatment, the patients in the injection group still tended to show difficulty in movement, which made the group allocation of the patient rather obvious to physicians familiar with MSAT through clinical experience or the previous pilot study. Therefore, to increase objectivity, the questionnaire measurements such as NRS, ODI, and PGIC, which can be made on paper, were fully explained to the patients at baseline, and then identical forms were used at baseline and the 30 minute follow-up. Also, in the telephone follow-ups, assessors blinded to previous treatment conducted the questionnaires. However, the fact that the successfulness of the blinding attempts was not assessed could be a major limitation of this study.

Because the setting was a Korean medicine hospital, and because patients visit for the specific purpose of receiving Korean medicine, there is a fair possibility that patients would be more favorably inclined toward acupuncture, and that this propensity may have affected the results. Also, whereas patients in the MSAT group received treatment and support from the practitioners for 20 minutes, patients in the NSAID group had only a brief encounter with the practitioners at time of injection, which may have influenced the overall level of psychological stability and satisfaction.

The fact that the patients' expectations, pretreatment preferences, or credibility questionnaires were not assessed could be a further limitation of this study, especially in light of previous research results that have reported the large placebo effect of acupuncture [11]. Nevertheless, the placebo effect can also be considered an active part of the total therapeutic effect. Even if the placebo effect of MSAT is greater than other conventional treatments, if the total therapeutic effects of MSAT are superior, MSAT could still be considered a clinically advantageous and valid treatment. Furthermore, the more objective "hard" outcome measures, such as hospitalization rates and length of hospital stay, reinforce the argument that the remarkable therapeutic effects of MSAT measured with the more subjective outcome measures such as NRS or ODI, which are more prone to being affected by placebo effects, are an intrinsic attribute. These exceptional results could not be explained in their entirety simply as a placebo effect.

Another limitation of this study is related to the time-based effect of diclofenac. Although it is known that the maximum plasma concentration of diclofenac is 10 to 20 minutes after intramuscular injection and that the effectiveness is maintained from 30 minutes to more than 4 hours [17,29], whether 30 minutes after treatment is the most appropriate time frame to observe the reduction in pain for both interventions is open to debate. In both groups, we did not restrict the selection of treatment after the initial treatment session, because of ethical reasons, which implies that the results after the first follow-up at 30 minutes are not clean and therefore are difficult to generalize.

A systematic review analyzed 35 RCTs on LBP covering 2861 patients from 1966 to 2003, but reported insufficient evidence to make any recommendations about acupuncture or dry-needling for aLBP. Of the analyzed RCTs, 1 clinical trial by Wu [42] et al. in 150 patients with aLBP stands out as the only trial combining acupuncture with movement. After applying acupuncture at Extra 29 (EX-UE7), which is an acupuncture point located on the hand, a strong *Deqi* sensation was obtained by combining acupuncture with lumbar spine movement until symptoms were relieved. The results showed that this manual technique was less effective than traditional acupuncture at acupoint SI 3. However, the treatment method was different from MSAT, and this study also has the limitation of low methodological quality, with a score of 3 out of 10 in the Methodological Quality Assessment by the review authors. The other trials analyzed used meridian or trigger point stimulation techniques in acupuncture or dry needling.

Recently, more studies are focusing on the practicality of acupuncture for aLBP. One recent rigorous RCT by Vas et al. allocated 275 acupuncture-naive patients with nonspecific aLBP into 4 groups. One group received conventional treatment only (patients were advised and were prescribed paracetamol or NSAIDs in accordance with clinical guidelines), and the other 3 groups received acupuncture, sham acupuncture, and placebo acupuncture, respectively, in addition to conventional treatment. The 3 groups receiving acupuncture reported greater reduction in disability scores and intake of conventional drugs than did the conventional treatment group [39].

The mechanisms underlying the immediate effects in pain reduction and steady recovery of function in MSAT are, as yet, unclear. However, based on previous research, it may be suggested that acupuncture analgesia and a cognitive shift in perception of pain are involved. The strong stimulation of distal acupuncture points in MSAT may enhance the effects of pain relief by triggering "diffuse noxious inhibitory controls" and increasing secretion of endorphins by stimulating internal activity of the central nervous system [40]. If patients feel less pain and gain more mobility with encouragement and MSAT treatment, the treatment could create a positive cycle leading to heightened therapeutic effects. Patients with severe LBP may have a negative interpretation of pain, which in turn may induce physiological, cognitive, and fear avoidance responses [31,36]. Fear and negative cognition toward pain may result in evasion of movement that leads to disability and pain, forming a negative pain cycle [1,13,34]. These unwanted consequences could possibly be averted with MSAT, thus enabling patients to follow the general advice of avoiding bed rest and remaining active as suggested in guidelines for aLBP [14,16].

As the participants in our trial were screened from among patients experiencing difficulty walking or those dependent on wheelchairs or stretchers because of severe aLBP without severe neurological symptoms or deficit, we cautiously but hopefully

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anticipate immediate pain relief and swifter functional recovery of nonspecific aLBP patients in typical clinical settings also. All of the participants' lumbar MRI findings revealed disc protrusions and/or disc extrusions, with an exception of 4 (6.90%) participants. According to a systematic review, the false-positive detection of lumbar disc herniation by MRI in LBP or sciatica patients is estimated to be high at 23% (95% confidence interval = 12%–39%), but the MRI readings of the aLBP patients that participated in our study demonstrated a very high sensitivity. Therefore MSAT has applications not only for nonspecific LBP patients but also for herniated disc patients with aLBP and/or leg pain. Although Korean and Asian patients typically have more exposure to and less aversion to acupuncture, the participants in our trial, except for 1 patient, were unaccustomed to the concept of active movement during acupuncture. The fact that no patients from the MSAT group dropped out during the treatment session can be taken as an indication that movement during acupuncture at certain points does not act as an aggravating factor or cause significant adverse effects and/or exacerbation of fear.

4.1. *Conclusion*

It is concluded that this study showed highly positive effects on pain and function through the collaborative treatment of acupuncture and motion style in aLBP patients. The results make a contribution to the prior knowledge of the effects of acupuncture on aLBP. We expect that additional studies comparing MSAT with traditional acupuncture and investigations of post-MSAT MRI follow-up results of patients experiencing severe disability because of acute disc herniation will shed more light on this area.

Conflict of interest statement

The authors report no conflict of interest.

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