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RANDOMIZED TRIAL

Acupuncture for Chronic Low Back Pain

A Multicenter, Randomized, Patient-Assessor Blind, Sham-Controlled Clinical Trial

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Study Design. Multicenter, randomized, patient-assessor blind, sham-controlled clinical trial.

Objective. To investigate the efficacy of acupuncture treatment with individualized setting for reduction of bothersomeness in participants with chronic low back pain (cLBP).

Summary of Background Data. Low back pain is one of the main reasons of disability among adults of working age. Acupuncture is known as an effective treatment of cLBP, but it remains unclear whether acupuncture is superior to placebo.

Methods One hundred thirty adults aged 18 to 65 years with nonspecific LBP lasting for at least last 3 months prior to the trial participated in the study from 3 Korean medical hospitals. Participants received individualized real acupuncture treatments or sham acupuncture treatments for more than 6 weeks (twice a week) from Korean Medicine doctors. Primary outcome was change of visual analogue scale (VAS) score for bothersomeness of cLBP. Secondary outcomes included VAS score for pain intensity and questionnaires including Oswestry Disability Index, general health status (Short Form-36), and Beck Depression Inventory (BDI).

Results There were no baseline differences observed between the 2 groups, except in the Oswestry Disability Index. One hundred sixteen participants finished the treatments and 3- and 6-month follow-ups, with 14 subjects dropping out. Significant difference in VAS score for bothersomeness and pain intensity score of cLBP has been found between the 2 groups ($P < 0.05$) at the primary end point (8 wk). In addition, those 2 scores improved continuously until 3-month follow-up ($P = 0.011$, $P = 0.005$, respectively). Oswestry Disability Index, the Beck Depression Inventory, and Short Form-36 scores were also improved in both groups without group difference.

Conclusion. This randomized sham-controlled trial suggests that acupuncture treatment shows better effect on the reduction of the bothersomeness and pain intensity than sham control in participants with cLBP.

Key words: acupuncture, chronic low back pain, clinical trial, visual analogue scale. **Spine 2013;38:549–557**

Low back pain (LBP) is a common public health issue, and it is one of the main causes of disability among adults of working age.[1] About two-thirds of adults experience LBP sometime in their lives.[2] LBP is classified as chronic when it persists longer than 3 months, and chronic low back pain (cLBP) is frequently associated with the nonspecific LBP.[3] Identifying one definite cause of nonspecific cLBP and treating this cause properly is usually difficult, because of the individual, psychological, and workplace-associated contributing factors.[4]

Patients with LBP are often dissatisfied with conventional forms of medical care that include medication, physical therapy, and exercise.[5] Acupuncture is one of the most often used interventions for the treatments of LBP as a complementary and alternative medical therapy,[6] specifically in China, Taiwan, and Korea, where acupuncture has a much longer tradition.

So far, some meta-analyses of randomized-controlled clinical trials (RCTs) of acupuncture have supported its efficacy.[7,8] Acupuncture has been proven as an effective supplement to other forms of conventional medical therapy for nonspecific cLBP.[9] The recent Cochrane Back Review Group supported the evidence that acupuncture can be a useful complementary treatment to other forms of conventional therapy for cLBP.[7,10] However, it remains controversial whether real acupuncture

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is superior to placebo.[11] Some studies have demonstrated that both real acupuncture and sham acupuncture are effective treatments of cLBP, and other studies have suggested that real acupuncture is not more effective than sham acupuncture.[12–14] Therefore, acupuncture's effectiveness may involve a placebo effect.[8,13,14] However, the results of one study have suggested that there were some advantages of acupuncture compared with sham acupuncture.[15]

These inconclusive results reflect the low methodological quality, small sample size, and other factors such as inherent difficulties in the use of controls (*e.g.*, placebo and sham acupuncture). One of the most important problems is adopting proper controls. So far, the controls used most often have been no treatment,[16] sham interventions,[12,13,15–17] and other interventions that include massage, conventional therapy, transcutaneous electrical nerve stimulation, and spinal manipulation.[18,19] Sham intervention has been tried with minimal acupuncture at nonacupuncture points[13,20–22] and nonpenetrating sham acupuncture.[15] In this study, nonpenetrating sham acupuncture at nonacupuncture points was used to apply the most appropriate placebo treatment. One study reported the use of similar sham acupuncture, but it was applied to the most painful spot and the result was assessed only once after the treatment.[12]

In this trial, we investigated the efficacy of acupuncture for cLBP by adhering to revised STandards for Reporting Interventions for Clinical Trials of Acupuncture recommendations and Consolidated Standards of Reporting Trials-guideline[23] as a way of overcoming the previous shortcoming of methodology.

MATERIALS AND METHODS

Study Design

A multicenter, parallel, randomized, sham-controlled clinical trial was conducted in 3 hospitals in Korea from October 2008 to June 2010. It was approved by the institutional review board. After screening, participants were randomized into 2 groups (real acupuncture and sham acupuncture) by central allocation. Randomized participants completed a questionnaire that solicited information regarding age, sex, marital status, occupation, education, and medical history. The blinding credibility of the treatments was evaluated at the end of the treatment.

Study Participants

Patients aged 18 to 65 years who have nonspecific cLBP were considered on the basis of a battery of eligibility criteria. Inclusion criteria were cLBP lasting for at least the last 3 months, 10-cm visual analogue scale (VAS) for bothersomeness of LBP exceeding 5, and nonspecific, uncomplicated LBP that was intact on neurological examination. Exclusion criteria were sciatic pain (*i.e.*, if a patient reported typical radiating pain in the leg as well as one or more neurological indications of nerve root tension or neurological deficit[24]); pain mainly below the knee; serious spinal disorders including malignancy, vertebral fracture, spinal infection, inflammatory spondylitis and cauda equine compression; history of previous spinal surgery or scheduled surgery to address a chronic disease that could interfere with treatment effects (*e.g.*, cardiovascular disease, diabetic neuropathy, fibromyalgia, rheumatoid arthritis, dementia, and epilepsy); acupuncture treatment of LBP during the previous month; conditions that could compromise the safety of acupuncture (*e.g.*, clotting disorders, taking anticoagulant agent, pregnancy, and seizure disorders); severe psychiatric or psychological disorder; and history of use of corticosteroids, narcotics, muscle relaxants, or herbal medicine to treat LBP.

Recruitment and Randomization Procedures

Participants were recruited through advertisements in local newspapers, the hospital's monthly magazine, the hospital's Web site, and bulletin boards. Participants were asked to answer questions and were diagnosed to determine eligibility. If recruited participants were eligible and agreed with the procedures of this trial, written informed consent was obtained. The patients were randomized per center and allocated to 1 of the 2 groups using a block randomization by computer generation. The random code was generated by the medical statistician and was kept by a clinician who did not contact patients. To ensure balance within the 2 groups, stratified block randomization was used. The exact procedures of this clinical trial have been published.[25]

Education of Acupuncture Practitioners

Licensed Korean Medicine Doctors (KMDs) with at least 3 years experience who specialized in Korean Rehabilitation Medicine (experts in acupuncture for LBP) typically took the educational courses to adhere to the study protocol. In those courses, KMDs practiced how to use sham acupuncture device to maintain blinding of the participants, and shared the methods of acupuncture treatment mentioned in the protocol.

Treatments of Acupuncture and Sham Acupuncture

Both groups received 12 acupuncture sessions (approximately 2 times a week for 6 wk). In the first visit, participants were given an exercise manual for patients with LBP and instructed about the manual-specified appropriate posture and exercises for LBP. The patients were requested to do the exercises everyday, and to try to maintain the correct posture. However, the amount of exercise that was actually done depended on their individual spontaneity. Participants were asked to complete more than 80% of the 12 possible treatments. Participants were notified that they would be dropped from the study if they received any additional therapy, such as analgesics or physical treatments, before the primary end point of 8 weeks.

Interventions

Real Acupuncture for Treatment Group

To make the real acupuncture treatment reflect an ordinary clinical practice condition, participants received individualized acupuncture treatment. That treatment was accomplished by selecting a group of acupuncture points that participating KMDs predefined. Acupuncture points were chosen according to the 3 types of meridian patterns

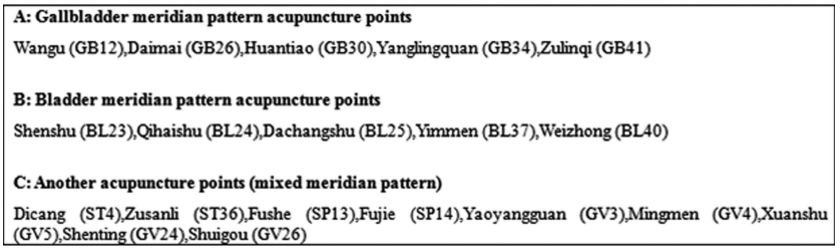

Figure 1. Three types of meridian patterns.

identification (Figure 1). Other acupuncture points could be used according to the diagnosis. Treatment was given using sterile, disposable stainless steel needles (40 × 0.25 mm; Dongbang Acupuncture, Kyunggi-do, Korea) with the same tube used for the sham acupuncture device. The needles were inserted perpendicular to a depth of 5 to 20 mm depending on the acupuncture point, which was followed by manual stimulation by bidirectional rotation to induce *Deqi* sensation. *Deqi* was defined as a dull, localized, and aching sensation, which signaled the attainment of *qi*.[26] After the *Deqi* sensation was achieved, the needles were left in place for 15 to 20 minutes.

Sham Acupuncture for Control Group

The treatment was carried out using the same technique and protocol as real acupuncture, except for the use of a semi-blunt needle on nonacupuncture points without penetration. Nonpenetrating sham needles (Acuprime, Exeter, UK)[27] were used. They have been shown to be a credible sham acupuncture by Korean patients.[28] Eight predefined points at the lower back unrelated to traditional acupuncture points were used: 1 cm below *Weiyang* (BL39, which is acupuncture point 39 of Bladder meridian), 1 cm lateral to *Ganshu* (BL18), 1 cm lateral to *Pishu* (BL20), and 2 cm above the *Huantiao* (GB30), all bilaterally.

Outcome Measures

Primary Outcome Measure

The primary outcome measure was VAS for bothersomeness of LBP. To understand the impact of cLBP on the patients' life, VAS for bothersomeness was chosen instead of pain intensity. The patients were asked to mark, on a 10 cm VAS (0, absence of bothersomeness; 10, the worst bothersomeness imaginable), the average degree of bothersomeness due to LBP experienced within the most recent 1 week from the day of the assessment. This measurement has substantial validity.[20] Bothersomeness of LBP was measured at weeks 0, 6, 8, 12, and 24. The primary end point was the 8-week follow-up (*i.e.*, 2 wk after finishing all of the treatments).

Secondary Outcome Measures

VAS for pain intensity is a simple method evaluating the subjective intensity of pain. Pain intensity was measured in the same way as VAS for bothersomeness. Validity of its reliability has been demonstrated.[29,30] The Oswestry Disability Index (ODI)[31] was used to measure back pain–related dysfunction. The ODI consists of 11 questions about daily activities related with LBP; however, we used the Korean version of ODI[32] that excluded the sex life item. The reason for the exclusion was to avoid risk of bias because most Koreans are reluctant to answer the question because they follow the Confucian tradition. Health-related quality of life was measured using the well-validated Short Form-36.[33] A higher score is indicative of a better general health status. In our study, the validated Korean version of Short Form-36[21] was used. The Korean version of the Beck Depression Inventory (BDI)[22] is a 21-item self-administered questionnaire. It provides a quantitative measure of depression symptoms. Validated Korean version of credibility test first proposed by Vincent and Lewith[34] was used to assess the expectation for acupuncture treatments at the beginning of the research.

Safety

To monitor safety of acupuncture, participants were asked about adverse events at each visit. If any serious adverse event occurred, details of the event were announced to the particular institutional review board and direct actions were supplied to those involved.

Statistical Analyses

To determine appropriate sample size, the VAS mean difference between the 2 groups was assumed to be 1.5 and standard deviation to be 2.73 cm with significance level(α) = 0.05 and power($1-ß$) = 0.80. For the equal allocation for the 2 groups, total sample size considering dropout rate of 20% was calculated as 130 subjects, which means that at least 104 subjects would finally be required after drop outs. We performed the Shapiro-Wilk normality test to determine whether or not the sample values followed a normal distribution and finally assumed normality according to the test result. For all statistical analysis, SPSS 14.0 (SPSS Inc., Chicago, IL) was used. Significance level was set at $P < 0.05$. Per protocol (PP) analysis included all participants randomized and followed up until the last follow-up point.

Description of Baseline Characteristic and Homogeneity Test of 2 Groups

For the description of baseline characteristics, mean with standard deviation (SD) for continuous data and frequency with percentage for dichotomous data were described. Also for the homogeneity test of baseline characteristics between 2 groups, 2-sample *t* tests for continuous data and χ^2 test for dichotomous data were performed.

Efficacy

Two-sample *t* tests were used for outcome measurements at baseline and 8 weeks for the comparison between 2 groups. Also, 95% confidence interval was added for all analysis. A mixed-model approach of repeated-measures 2-factor analysis was used to analyze the difference and mean change in baseline, 6-, 8-, 12-, 24-week VAS score, difference and mean change between groups, interaction between groups, and periods.

RESULTS

Study Recruitment and Follow-up

Figure 2 illustrates the flow of participants through the trial. A total of 142 participants responded to the recruitment materials and 130 (91.6%) were eligible. The main reasons for ineligibility were less than 3 months of LBP, sciatica, and previous acupuncture within 1 month, and inability to attend treatment visits. Twelve patients dropped out during the treatment and 1 patient was eliminated after finishing all the treatments because of pregnancy. Measurements were obtained for 90% of the sample at 2 months (n = 117), for 89% at 3 months (n = 116), and for 89% at 6 months (n = 116). Analyses included 116 participants for the primary and secondary outcome at 2, 3, and 6 months.

Baseline Characteristics

Table 1 shows the baseline characteristics and outcome measurements. There was no relevant difference between the groups in so far as the potentially prognostic factors ($P > 0.05$) and no significant difference between the groups in the scores ($P > 0.05$) related with cLBP, except for ODI ($P < 0.05$). To evaluate the effect of psychological factors on the improvement of symptoms, the expectation and BDI scores of participants were calculated. Credibility test score denoted the patients' positive expectation. There was no significant difference in expectation or BDI scores ($P > 0.05$).

EFFICACY

Primary Outcome Measure

Mean VAS for bothersomeness scores for the real acupuncture groups decreased by 3.36 points, compared with 2.27 points for participants receiving sham acupuncture at the primary end point. The difference was significant by 2-sample *t* tests ($P < 0.05$). Significant interaction between "periods" and "groups" was noticed by repeated-measures 2-factor analysis ($P < 0.05$) (Table 3).

Secondary Outcome Measures

All of the secondary outcomes of both groups were improved during the entire trial ($P < 0.01$), and the improvements of the real acupuncture group were greater than the sham acupuncture. However, real acupuncture was significantly more effective only in the VAS for bothersomeness and pain intensity at the primary end point and all during the follow-up time points ($P < 0.05$) (Table 2, Figure 3).

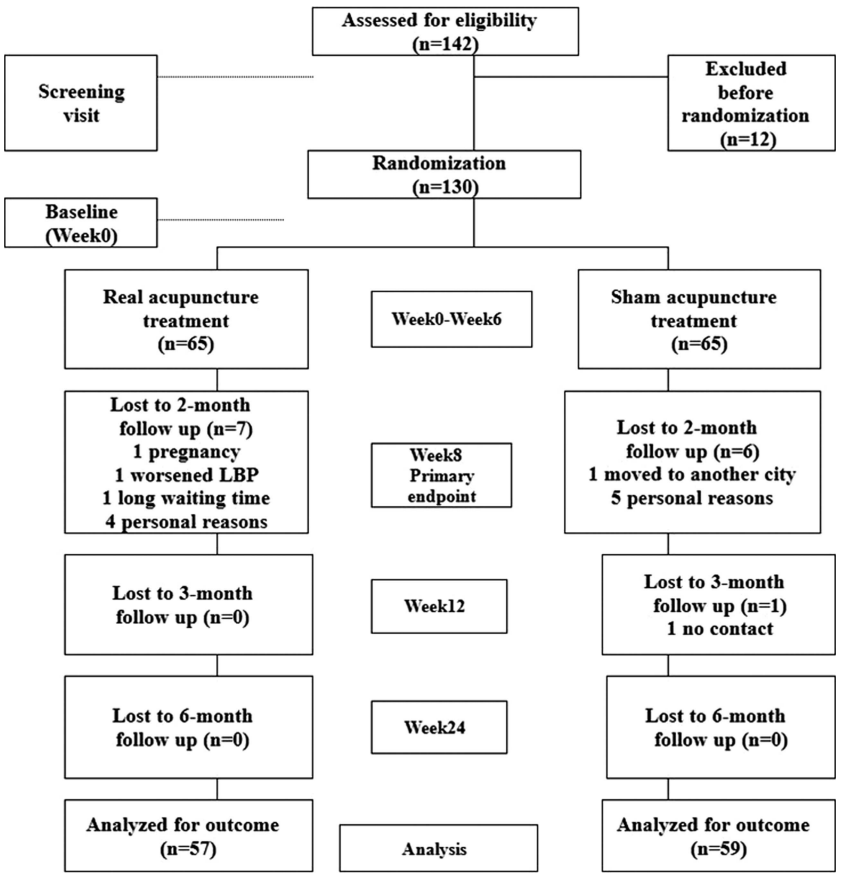

Figure 2. Consolidated Standards of Reporting Trials flow of this trial.

TABLE 1. Baseline Characteristics and Outcome Measurements of the Participants With cLBP

	Mean (SD) or n (%)			
	Real Acupuncture (n = 57)	Sham Acupuncture (n = 59)	Total (n = 116)	$t(P)$ or $\chi^2(P)$
Age (yr)	42.39 ± 14.62	41.75 ± 13.57	42.06 ± 14.04	0.807*
BMI (kg/m^2)	23.86 ± 3.35	24.19 ± 3.70	24.03 ± 3.52	0.620*
Sex				
Male	10 (17.5)	8 (13.6)	18 (15.5)	0.553
Female	47 (82.5)	51 (86.4)	98 (84.5)	
Marital status				
Unmarried	13 (22.8)	19 (32.2)	32 (27.6)	0.258
Married	44 (77.2)	40 (67.8)	84 (72.4)	
Education				
Graduated	25 (43.9)	32 (54.2)	57 (49.1)	0.264
Others	32 (56.1)	27 (45.8)	59 (50.9)	
Smoking status				
Smoking	4 (7)	4 (6.8)	8 (6.9)	0.960
Nonsmoking	53 (93)	55 (93.2)	108 (93.1)	
PMS				
PMS	9 (15.8)	6 (10.2)	15 (12.9)	0.395
Non-PMS	38 (66.7)	46 (78)	84 (72.4)	
Male	10 (17.5)	7 (11.9)	17 (14.7)	
VAS for bothersomeness	6.44 ± 1.50	6.32 ± 1.14	6.38 ± 1.32	0.615*
VAS for pain intensity	6.52 ± 1.41	6.37 ± 1.18	6.45 ± 1.30	0.545*
ODI	28.23 ± 10.54	24.17 ± 10.5	26.17 ± 10.69	0.040*
SF-36	107.72 ± 18.93	110.41 ± 15.91	109.09 ± 17.44	0.409*
BDI	11.33 ± 5.51	11.75 ± 8.10	11.54 ± 6.92	0.748*
Expectation†	20.08 ± 2.59	19.66 ± 2.72	19.81 ± 2.57	0.369*

**Result of 2-sample t tests.*

†Credibility test.

SD indicates standard deviation; BMI, body mass index; VAS, visual analogue scale; ODI, Oswestry Disability Index; BDI, Beck Depression Inventory; cLBP, chronic low back pain; SF, Short Form.

Adverse Events

Sixteen participants reported 27 minor to moderate adverse events that they considered as symptoms possibly related to treatment (Table 4). None of them were persisting for more than 1 week, and no serious adverse events were reported.

DISCUSSION

The purpose of this study was to clarify the efficacy of acupuncture compared with sham acupuncture in the management of cLBP with rigorous methodology. Although the main results showed that there was a positive improvement in both groups, the significant superiority of real acupuncture compared with sham acupuncture with no additional treatment has been clearly demonstrated for the reduction of symptoms.

Sham acupuncture method usually consists of minimal acupuncture and nonpenetrating acupuncture. Minimal acupuncture penetrates skin very slightly. Nonpenetrating sham acupuncture uses semiblunt needle being in contact with skin. In this study, sham acupuncture without penetrating was used. Minimal needling acupuncture is usually thought to be, but there is also stimulation by penetration. It is possible that superficial penetration could potentially analgesic stimulation. According to Harris *et al*,[35] the neurotransmitter system mediates the analgesic placebo effects related with acupuncture

TABLE 2. VAS for Bothersomeness and Pain Intensity of cLBP

VAS for	Acupuncture	Baseline	End of Treatments	Primary End Point	3-mo Follow-up	6-mo Follow-up	*P*†
Bothersomeness	Real	6.44 ± 1.50	3.05 ± 2.49	3.08 ± 2.44	2.83 ± 2.34	2.85 ± 2.44	0.011§
	Sham	6.32 ± 1.14	4.26 ± 1.80	4.05 ± 1.84	3.99 ± 2.06	3.63 ± 2.37	
	*P**	0.024‡					
Pain intensity	Real	6.52 ± 1.41	2.96 ± 2.39	3.00 ± 2.41	2.78 ± 2.32	2.79 ± 2.44	0.005§
	Sham	6.37 ± 1.18	4.28 ± 1.83	4.10 ± 1.85	4.06 ± 2.19	3.52 ± 2.53	
	*P**			0.008§			

**Significance by 2-sample t test at the primary end point (week 8).*

†Significance by repeated-measures 2-factor ANOVA, between groups.

There was significant interaction between "period" and "group" ($P < 0.01$).

‡$P < 0.05$

§$P < 0.01$

cLBP indicates chronic low back pain; ANOVA, analysis of variance.

therapy. However, despite the neurotransmitter system evoked by real acupuncture in the short term and the long term, there were no short-term and long-term effects in nonpenetrating sham acupuncture group. Those findings could suggest that there may be divergent neurotransmitter pathways mediating the analgesic effects of acupuncture by penetration. Therefore, nonpenetrating sham acupuncture may be the most proper method as a placebo in an acupuncture trial.

In this trial, every treatment was meted out with eliciting *Deqi*. Elicitation of *Deqi* is one of the major factors in acupuncture treatment.[26] However, the trials so far did not lead to *Deqi* during acupuncture treatment.

TABLE 3. Proportion of Outcome Measurements Improvement (Mean ± SD)

	Acupuncture	ΔVAS for Bothersomeness	ΔVAS for Pain Intensity	ΔODI	ΔSF-36	ΔBDI
End of treatments	Real	0.54 ± 0.34	0.53 ± 0.38	0.42 ± 0.25	0.06 ± 0.16	0.42 ± 0.48
	Sham	0.32 ± 0.28	0.33 ± 0.28	0.25 ± 0.43	−0.02 ± 0.12	0.18 ± 0.62
	P	**0.000‡**	**0.001‡**	**0.01†**	**0.007‡**	**0.023†**
Primary end point	Real	0.53 ± 0.34	0.53 ± 0.39	0.42 ± 0.39	0.20 ± 0.23	0.39 ± 0.56
	Sham	0.35 ± 0.30	0.35 ± 0.29	0.29 ± 0.44	0.16 ± 0.13	0.26 ± 0.83
	P	**0.003‡**	**0.007‡**	0.096	**0.006‡**	0.341
3-mo follow-up	Real	0.56 ± 0.36	0.57 ± 0.36	0.43 ± 0.33	0.21 ± 0.22	0.48 ± 0.48
	Sham	0.35 ± 0.34	0.35 ± 0.37	0.28 ± 0.50	0.11 ± 0.14	0.30 ± 0.62
	P	**0.002‡**	**0.002‡**	0.051	**0.005‡**	0.096
6-mo follow-up	Real	0.56 ± 0.38	0.56 ± 0.41	0.44 ± 0.38	0.20 ± 0.23	0.44 ± 0.58
	Sham	0.41 ± 0.39	0.44 ± 0.41	0.24 ± 1.10	0.14 ± 0.15	0.36 ± 0.66
	P	**0.044†**	0.118	0.202	0.093	0.486

Every proportion was calculated by the formula given in the following text.

ΔVAS for bothersomeness (at the end of treatments) = absolute value of [VAS for bothersomeness (baseline) − VAS for bothersomeness (end of treatments)] / VAS for bothersomeness (baseline) significances by 2-sample t test.

†$P < 0.05$, ‡$P < 0.01$.

VAS, visual analogue scale; ODI, Oswestry Disability Index; SF, Short Form; BDI, Beck Depression Inventory.

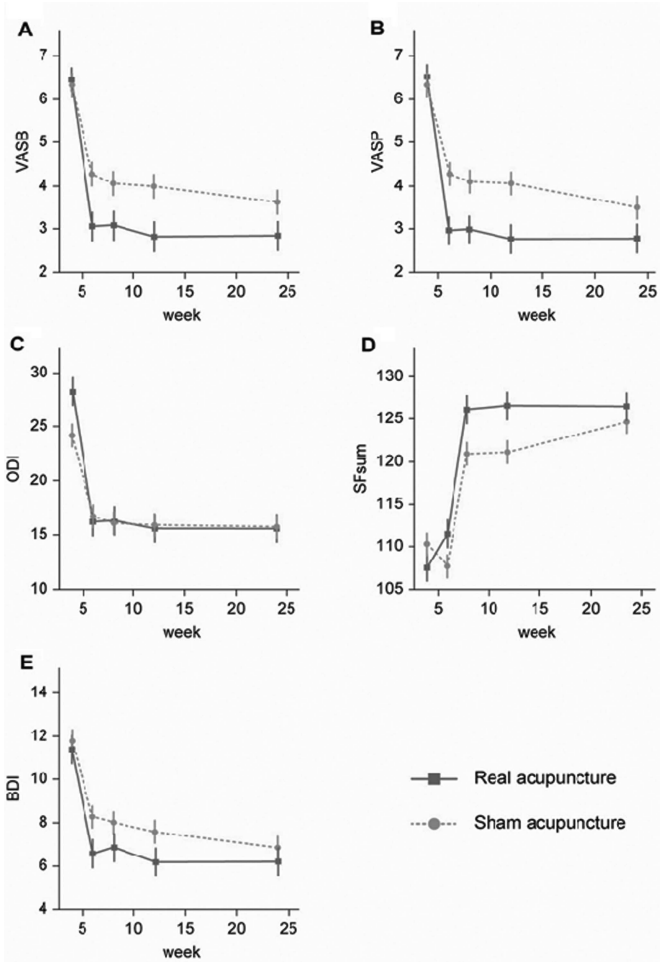

Figure 3. Mean VAS scores for bothersomeness scores of cLBP. (**A**) VAS scores for pain intensity; (**B**) ODI scores; (**C**) SF-36 scores; (**D**) BDI scores; and (**E**) 95% confidence intervals for treatment group and time (wk). There were significant improvements only in the VAS scores for bothersomeness ($P < 0.05$) and pain intensity ($P < 0.01$) of cLBP in real acupuncture group, compared with the sham acupuncture group by repeated-measures ANOVA (Table 2). VAS indicates visual analogue scale; cLBP, chronic low back pain; ODI, Oswestry Disability Index; SF, Short Form; BDI, Beck Depression Inventory; ANOVA, analysis of variance.

Because patients received real individualized acupuncture treatment that is geared to the symptoms and condition of each patient by KMDs, patients in the real acupuncture group could benefit more than the sham acupuncture group. According to the revised STandards for Reporting Interventions for Clinical Trials of Acupuncture,[23] characteristics of the practitioners including qualifications or affiliation and years in acupuncture practice could be relevant to the trial.

If the efficacy of real acupuncture could be clarified, how can we explain the mechanism of the sham acupuncture that was manifest as improvement without any other treatments? The purpose of sham *versus* real acupuncture is to distinguish the physiological effect of acupuncture from the psychological placebo effects. Acupuncture is complicated to evaluate because it is difficult to isolate the characteristic or specific effects of the technique from the nonspecific ones.[36] We calculated the positive expectation of patients with a credibility test questionnaire and we assessed depression with the BDI questionnaire to elucidate the psychological effects. As a result, there was no significant difference between the groups at the baseline, but both of those groups expressed optimism that acupuncture would be helpful for their cLBP in the credibility test. It is possible to assume that this expectation worked as one of factors in the beneficial mechanism of sham acupuncture. But, as seen in Table 5, the blinding of this research was maintained, the expectation mechanism could work in both groups. Correlation between higher baseline depression score and higher pain scores at the end of treatment using sham acupuncture has been reported.[37] However, the relatively low BDI score of participants in this research make it difficult to affirm that effect of psychosomatic pain of participants be a significant variable. But, according to a report from Korea,[38] patients with cLBP have difficulty in expressing emotions such as anger, depression, and sensitivity. And the longer the pain persisted, the less the awareness of their depression. Therefore, more specific methodologies are required to use BDI score as a primary factor assessing cLBP. According to the previous study, in addition to the needling itself, several aspects of acupuncture could contribute to its effectiveness, including the individualized treatment,[39] the practitioner's skills at developing good

TABLE 4. Adverse Events (Number of Reported Cases, Multiple Answers)

Symptoms	Real Acupuncture (n)	Sham Acupuncture (n)
Temporarily worsened LBP	4	8
Pain at acupunctured site	2	2
Bruise of acupunctured site	1	0
Pain, numbness, or other bothersomeness in leg (including knee)	1	5
Systemic bothersomeness (feeling sluggish or having body ache)	…	1
Shoulder pain	2	…
Pain or bothersomeness in foot	0	1
Total	10	17

LBP indcates low back pain.

TABLE 5. Blinding Index (End of the Treatments)

Type of Acupuncture Received	Type of Acupuncture Participants Stated They Had Received, n (%)			
	Real Acupuncture	Sham Acupuncture	Don't Know	Total
Real acupuncture group	14 (24.56)	9 (15.79)	34 (59.65)	57
Sham acupuncture group	19 (32.20)	6 (10.17)	34 (57.63)	59
Sum	33	15	68	116

Real acupuncture group; 0.07 (95% CI: −0.10, 0.24), blinded.

Sham acupuncture group; −0.23 (95% CI: −0.39, −0.08), blinded.

CI indicates confidence interval.

therapeutic relationships,[40] process benefits such as protected time and attention from the practitioner,[41] and the widely reported relaxing experience of the treatment itself.[42] There was still stimulation by touching skin in sham acupuncture, one functional magnetic resonance imaging experimental research reported that superficial and deep acupuncture needling are associated with imaging patterns that have no significant differences.[43] The finding supports the results that there are equivalent therapeutic outcomes of real and sham acupuncture that are claimed by acupuncture researches for cLBP using superficial acupuncture needling as a placebo. Otherwise, it is possible that both groups were advised to do exercise during the research period have influenced the result that there are equivalent therapeutic effects between real and sham acupuncture. Among them, because relationship or attention is a kind of psychological support, depression or positive expectation or any other factors related with psychological aspects could be a parameter affecting the patient's condition in this study.

Acupuncture is a relatively safe treatment of cLBP. Substantial adverse events were not severe and resolved in a short period. Most intriguingly of all, there were similar adverse events between the 2 groups.

To our knowledge, this is the first RCT for nonspecific cLBP performed with nonpenetrating sham acupuncture. It was performed as an RCT, but it could not be a practitioner blind trial because of distinct characteristics of acupuncture. Thus, this study was conducted as a patient-assessor blinded study. This could be another bias because practitioners (8 KMDs delivered the treatment) have the knowledge of real acupuncture group.

In conclusion, this study contributes evidence of acupuncture intervention compared with nonpenetrating sham acupuncture for the treatment of nonspecific cLBP.

➢ Key Points

- ❑ There is evidence that individualized acupuncture treatment reduces bothersomeness of cLBP better than sham acupuncture.
- ❑ There is evidence that individualized acupuncture treatment reduces pain intensity of cLBP better than sham acupuncture.
- ❑ No significant effect was observed on disability, depression, or general health by individualized acupuncture treatment compared with sham acupuncture.
- ❑ There was no significant adverse event by acupuncture treatment.

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