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Acupuncture vs Sham Acupuncture for Chronic Sciatica From Herniated Disk
A Randomized Clinical Trial

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IMPORTANCE Sciatica is commonly caused by herniated lumbar disc and contributes to severe pain and prolonged disability. Although acupuncture is widely used by patients with chronic sciatica, the evidence of its efficacy is scarce.

OBJECTIVE To investigate the efficacy and safety of acupuncture compared with sham acupuncture in patients with chronic sciatica from herniated disk.

DESIGN, SETTINGS, AND PARTICIPANTS This was a multicenter 2-arm randomized clinical trial conducted in 6 tertiary-level hospitals in China of patients with chronic sciatica from herniated disk. Participants were recruited from March 25, 2021, to September 23, 2021, with a final follow-up through September 22, 2022. Data analyses were performed from December 2022 to March 2023.

INTERVENTIONS Participants were randomly assigned to receive 10 sessions of acupuncture (n = 110) or sham acupuncture (n = 110) over 4 weeks. Participants, outcome assessors, and statisticians were blinded.

MAIN OUTCOMES AND MEASURES The 2 coprimary outcomes were changes in visual analog scale (VAS) for leg pain and Oswestry Disability Index (ODI) from baseline to week 4. Secondary outcomes were adverse events.

RESULTS A total of 216 patients (mean [SD] age, 51.3 [15.2] years; 147 females [68.1%] and 69 males [31.9%]) were included in the analyses. The VAS for leg pain decreased 30.8 mm in the acupuncture group and 14.9 mm in the sham acupuncture group at week 4 (mean difference, −16.0; 95% CI, −21.3 to −10.6; $P < .001$). The ODI decreased 13.0 points in the acupuncture group and 4.9 points in the sham acupuncture group at week 4 (mean difference, −8.1; 95% CI, −11.1 to −5.1; $P < .001$). For both VAS and ODI, the between-group difference became apparent starting in week 2 (mean difference, −7.8; 95% CI, −13.0 to −2.5; $P = .004$ and −5.3; 95% CI, −8.4 to −2.3; $P = .001$, respectively) and persisted through week 52 (mean difference, −10.8; [95% CI, −16.3 to −5.2; $P < .001$; and −4.8; 95% CI, −7.8 to −1.7; $P = .003$, respectively). No serious adverse events occurred.

CONCLUSIONS AND RELEVANCE This randomized clinical trial found that in patients with chronic sciatica from herniated disk, acupuncture resulted in less pain and better function compared with sham acupuncture at week 4, and these benefits persisted through week 52. Acupuncture should be considered as a potential treatment option for patients with chronic sciatica from a herniated disk.

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Visual Abstract

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Supplemental content

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Sciatica is characterized as pain radiating along the course of the sciatic nerve and sometimes associated with low back pain.[1] Lumbar disk herniation with compression to the lumbosacral nerve root and resultant inflammation is able to interpret 85% of sciatica incidence.[2] Compared with low back pain alone, patients with sciatica are considered to have more severe pain.[3] Although most patients with sciatica will recover spontaneously or with conservative treatments,[4-6] patients are at increased risk for unfavorable outcomes and increased use of health care services if symptoms prove refractory. Among patients with chronic sciatica, 45% do not have a meaningful improvement in their condition after 1 year,[7] and 34% report chronic pain beyond 2 years.[8]

Pain medications such as paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), and opioids are commonly prescribed, while inconclusive recommendations exist in clinical guidelines considering the uncertain benefits and potential risk of adverse effects.[9,10] With few harms reported, conservative nonpharmacological treatments (eg, exercise, spinal manipulations) are more acceptable; however, the available evidence is insufficient to draw definite conclusions.[10] Although it has been suggested that both epidural steroid injection and surgery may relieve symptoms of sciatica, a proportion of patients hesitate to undergo these procedures because of concern regarding the risk of complications.[11,12] Given that the available treatments are controversial, the management of chronic sciatica is challenging.

Acupuncture has been found to have persistent analgesic effects on chronic pain.[13] A recent meta-analyses[14] suggested that acupuncture may be effective for sciatica; however, the evidence is limited and reflects a lack of high-quality investigations.[15] This multicenter randomized clinical trial was designed to evaluate the efficacy and safety of acupuncture compared with sham acupuncture in patients with chronic sciatica from herniated disk.

Key Points

Question Does acupuncture alleviate pain and improve function in patients with chronic sciatica from herniated disk?

Findings This multicenter randomized clinical trial found a statistically significant difference in the mean decrease in leg pain using the visual analog scale, from baseline to week 4 (30.8 mm with acupuncture vs 14.9 mm with sham acupuncture). The findings for function using the Oswestry Disability Index were similar (13.0 vs 4.9 points).

Meaning Acupuncture alleviates pain and improves function among patients with chronic sciatica from herniated disk and should be considered as a potential treatment option.

Methods

The trial protocol[16] was approved by the institutional review board of the Beijing University of Chinese Medicine and is available in Supplement 1. Written informed consent was obtained from participants before randomization. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.[17]

Study Design

This was a multicenter, parallel-group, randomized, sham-controlled trial that was conducted at 6 tertiary hospitals in China. Participants were consecutively recruited through advertisements on posters and WeChat (a social media networking tool) between March and September 2021. Participants were subsequently assessed by a spine specialist to ensure that diagnoses criteria were met based on a clinical visit and image review (magnetic resonance imaging or computed tomography) according to the guidelines of North American Spine Society.[10]

Study Participants

Patients were eligible if they were aged 18 years or older, had unilateral sciatica from herniated disk for more than 3 months, and had moderate or severe leg pain intensity (≥40 mm on the 100-mm visual analog scale [VAS]).[18] Patients were excluded if they had severe spinal disease or severe progressive neurological symptoms; cardiovascular, liver, kidney, or hematopoietic system disease; a mental health disorder or other severe coexisting disease; were pregnant, lactating, or planning to conceive; had undergone lumbar disc surgery; were taking medication that has a therapeutic effect on sciatica (rescreening was offered to interested patients after 5 half-lives of drug discontinuation); had received acupuncture for sciatica in the past year; or were planning to receive surgery or interventional treatment.

From March 2021 to September 2021, we screened 359 patients, of which 220 patients were randomized. Two patients were excluded from each study group (3 were patients of 2 included hospitals [duplicates]; and 1 did not meet inclusion criteria) (**Figure 1**).

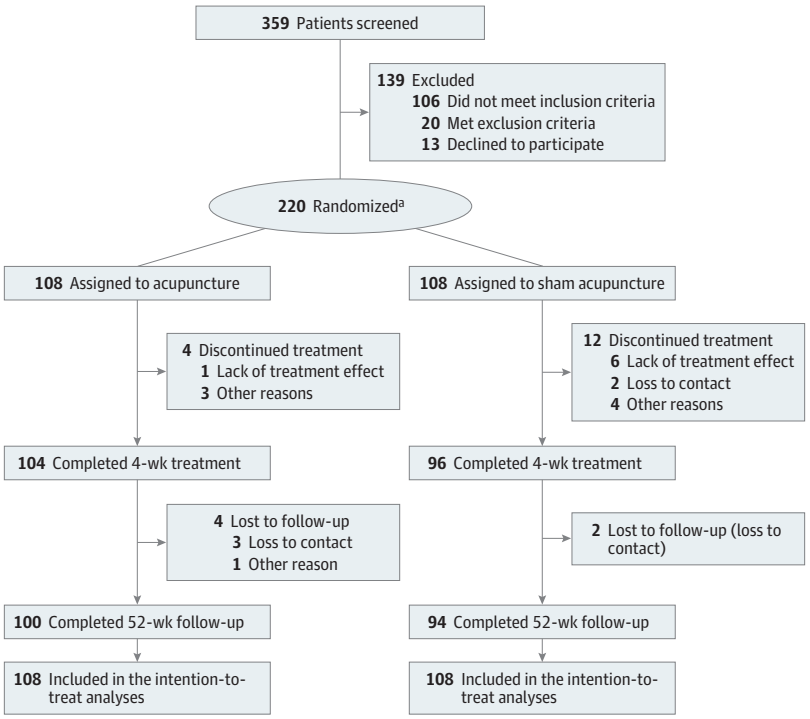
Randomization and Masking

Eligible participants were randomly assigned to either the acupuncture or the sham acupuncture group in a 1 to 1 ratio. The blocked randomization sequence was generated and stratified within the enrollment hospitals with a random block size of 4 or 6. The sequence was embedded into the REDCap system.[19] The clinical research coordinator inputted the patient information on a tablet computer and received a random number. Patients, outcome assessors, and statisticians were masked. Given the nature of acupuncture manipulation, acupuncturists in this trial were not blinded.

Intervention

The semistandardized treatment scheme was aligned with our recent expert consensus.[20] Both acupuncture and sham acupuncture were performed by licensed acupuncturists with at least 3 years of experience (eTable 1 in Supplement 2). Standardized operating procedures were provided for acupuncturists and the content of training included locations of acupoints and nonacupoints, choice of needle size based on acupoints and nonacupoints, manipulation of needles, and standardized communication with patients.

Figure 1. CONSORT Participant Flow Diagram



[a]Three patients (2 in the acupuncture group and 1 in the sham acupuncture group) were randomly assigned twice (duplicates). The fourth patient in the sham acupuncture group was determined to not meet the inclusion criteria.

Ten acupuncture or sham sessions were delivered over 4 weeks, with treatment frequency decreasing from 3 sessions per week for the first 2 weeks to 2 sessions per week for the remaining weeks.

Location of acupoints followed the World Health Organization's *Standard Acupuncture Locations*.[21] Obligatory acupoints for the acupuncture group were bilateral *dachangshu* (BL25) and *guanyuanshu* (BL26) in the lower back; for those with radiating pain in the lateral of the lower extremity, *huantiao* (GB30), *fengshi* (GB31), *xiyangguan* (GB33), *yanglingquan* (GB34), and *xuanzhong* (GB39) on the affected side; those with radiating pain in the posterior of the lower extremity, *zhibian* (BL36), *chengfu* (BL40), *weizhong* (BL54), *chengshan* (BL57), and *kunlun* (BL60) on the affected side; and for those with radiating pain in both lateral and posterior of the lower extremity, 5 acupoints were chosen by the acupuncturists from the 10 acupoints listed (eFigure; eTable 2 in Supplement 2).

For the acupuncture group, acupuncturists used disposable stainless steel needles of varying sizes depending on the acupoint and adhesive foam pads (diameter and depth, 10.0 × 5.0 mm) placed on the skin at acupoints (Suzhou Hwato Medical Instrument). For *GB30* and *BL36*, needles (0.3 × 75.0 mm) were inserted to a depth of approximately 40 to 50 mm, and for *BL25* and *BL26*, to approximately 30 to 40 mm. *De qi* sensation (soreness, numbness, distension, or heaviness) was achieved by up to 10 seconds of twirling, lifting, and thrusting manipulations, and was expected to radiate down to the affected leg. For other acupoints, needles (0.3 × 40.0 mm) were inserted to reach *de qi* sensation locally. Needles were retained in place for 30 minutes.

For the sham group, acupuncturists used nonacupoints away from the meridians, which are considered to have no effect; this is common practice for sham controls in acupuncture research.[22] Seven nonacupoints were preset for sham acupuncture (eFigure; eTable 3 in Supplement 2). The same adhesive foam pads were placed and blunt-tipped needles[23] (0.3 × 25.0 mm; Suzhou Hwato Medical Instrument) were inserted into the pads; these needles did not penetrate the skin but stayed upright over the skin. To promote blinding, the fifth nonacupoint was performed with a conventional needle inserted to 25 to 40 mm. No manipulation was performed with no attempt to induce the *de qi* sensation. Duration and frequency of the treatment were identical to those of the acupuncture group.

If needed, an NSAID (celecoxib) was administered as rescue medicine (eMethods in Supplement 2). The patients were advised not to use treatment other than celecoxib for sciatica during the trial. Any use of painkillers was ascertained at each 4-week follow-up after randomization.

Outcome Measures

Efficacy measures were recorded at baseline and weeks 2, 4, 8, 26, and 52 after randomization. The measurement instruments used were visual analog scale (VAS) for leg pain, VAS for back pain, Oswestry Disability Index (ODI),[24] and Sciatica Frequency and Bothersomeness Index (SFBI).[25] Quality of life was measured at baseline and weeks 4, 8, 26, and 52 by the 36-item Short Form Health Survey (SF-36).[26] A 7-point Likert self-rating scale with options from completely recovered to vastly worse was used to evaluate the patient's global

Table 1. Demographics and Baseline Characteristics of Study Participants

Characteristic	No. (%)		
	Total	Acupuncture	Sham acupuncture
Participants, No.	216	108	108
Female	147 (68.1)	77 (71.3)	70 (64.8)
Male	69 (31.9)	31 (28.7)	38 (35.2)
Age, mean (SD), y	51.3 (15.2)	51.61 (14.9)	50.9 (15.5)
BMI	23.8 (21.8 to 25.8)	24.0 (21.8 to 26.1)	23.6 (21.8 to 25.8)
Duration of disease, y	3.0 (1.3 to 10.0)	3.0 (1.3 to 8.0)	3.5 (1.3 to 10.0)
Radicular pain treatment history			
NSAIDs	16 (7.4)	7 (6.5)	9 (8.3)
Steroids	1 (0.5)	1 (0.9)	0
Lumbar traction	5 (2.3)	1 (0.9)	4 (3.7)
Neurotrophic drug[a]	8 (3.7)	4 (3.7)	4 (3.7)
Acupuncture	58 (26.9)	27 (25.0)	31 (28.7)
Tuina	22 (10.2)	11 (10.2)	11 (10.2)
Chinese herbal medicine	20 (9.3)	9 (8.3)	11 (10.2)
Other physiotherapy	14 (6.5)	6 (5.6)	8 (7.4)
Body side			
Left	114 (52.8)	57 (52.8)	57 (52.8)
Right	102 (47.2)	51 (47.2)	51 (47.2)
Site[b]			
L3-L4 disk	71 (32.9)	35 (32.4)	36 (33.3)
L4-L5 disk	169 (78.2)	78 (72.2)	91 (84.3)
L5-S1 disk	151 (69.9)	78 (72.2)	73 (67.6)
History of acupuncture	81 (37.5)	39 (36.1)	42 (38.9)
Leg pain VAS score[c]	59.6 (12.5)	60.0 (12.7)	59.3 (12.4)
ODI[d]	34.4 (13.7)	32.6 (12.3)	36.2 (14.9)
Back pain VAS score[c]	54.8 (21.9)	54.4 (23.2)	55.3 (20.7)
SFBI[e]			
Frequency	14.2 (3.9)	13.9 (3.8)	14.5 (4.0)
Bothersomeness	13.6 (3.9)	13.5 (3.7)	13.8 (4.1)
SF-36[f]			
Physical health	29.4 (10.4)	30.5 (10.5)	28.2 (10.2)
Mental health	48.6 (11.0)	48.3 (10.8)	48.9 (11.3)
Credibility score	0 (2.9)	−0.1 (2.7)	0.1 (3.1)
Expectancy score	0 (2.8)	0.1 (2.6)	−0.1 (2.9)

Abbreviations: BMI, body mass index calculated as weight in kilograms divided by height in meters squared; NSAIDs, nonsteroidal anti-inflammatory drugs; ODI, Oswestry Disability Index; SF-36, 36-item Short Form Health Survey; SFBI, Sciatica Frequency and Bothersomeness Index; VAS, visual analog scale.

[a] Neurotrophic drugs included mecobalamin, vitamin B1, vitamin B12, etc.

[b] Site was determined by magnetic resonance imaging or computed tomography.

[c] Scores for leg pain and back pain ranged from 0 (no pain) to 100 (worst pain possible).

[d] ODI assesses the effect of pain on normal daily activity including the ability to and intensity of lifting, caring for oneself, walking, sitting, sexual function, standing, social life, sleep, and travel, ranging from 0 (no disability) to 100 (maximum disability possible).

[e] SFBI assesses the frequency and bothersomeness of sciatica with scores ranging from 0 to 24, respectively. Higher scores indicate more severe symptoms.

[f] SF-36 assesses the quality of life through physical and mental dimensions with scores ranging from 0 to 100, respectively. Higher scores indicate a better quality of life.

assessment at weeks 4, 26, and 52.[27] Moreover, researchers (W.W., T.S., X.W.) evaluated the credibility and expectancy of patients using the Credibility/Expectancy Questionnaire[28] before treatment. As blinding assessments, at weeks 2 and 4 all participants were asked to guess which treatment they were receiving. After each treatment session, researchers screened for potential adverse events (AEs) by directly asking participants. AEs were also identified through patient self-reporting. All AEs were categorized based on relevance to acupuncture treatment. The results of functional magnetic resonance imaging will be reported in a future article.

The 2 coprimary outcomes were changes in leg pain intensity and disability from baseline to week 4. The average intensity of leg pain over the previous 24 hours was measured with VAS (0-100 mm). Disability was measured through a 10-item ODI scale ranging from 0 (no disability) to 100 points (maximum disability possible). The minimal clinically important differences (MCIDs) on the VAS and ODI were preset at 15 mm[5,29] and 7 points,[30] respectively. Acupuncture was considered to be an effective therapy only if both primary outcomes achieved statistical significance. Secondary outcomes were the VAS for low back pain, SFBI, SF-36, use of rescue medicine, and patient's global assessment. Safety was assessed from the frequency of AEs.

Statistical Analysis

The sample size was calculated using PASS (Power Analysis and Sample Size), version 11 (Number Cruncher Statistical Systems). Following a power of 90% and a 2-sided α of .05, 32 patients in each group were needed to detect a mean (SD) between-group difference of 15 (18) mm on VAS. At the same statistical level, a sample size of 86 patients in each group was required to detect a mean (SD) between-group difference of 7 (14) points on ODI. The sample size was increased to 216

patients (108 patients in each group), considering a dropout rate of 20%.

The analyses were performed based on the intention-to-treat principle with all randomly assigned patients included. For VAS for leg pain and ODI, a repeated-measure linear mixed-model was used including mean changes from baseline to each visit assessment and using baseline value as a covariate. Missing data of primary outcomes were imputed using the multiple imputation method, with the MI procedure in SAS, version 9.4 (SAS Institute). The imputation models included variables at baseline and weeks 2, 4, 8, 26, and 52. The fully conditional method and linear regression model were used to generate the imputation data and create 5 imputed datasets. Then, each dataset was analyzed using the prespecified methods. The overall estimates were calculated using Rubin rules. To address the robustness of the results, a per-protocol analysis for coprimary outcomes was performed including patients who completed at least 8 sessions of acupuncture with no major violations (usage of painkillers other than rescue medicine or evaluation outside of the time period). Similar analyses were performed for secondary outcomes including back pain, SFBI, SF-36, and patient's global assessment. The James blinding index (range 0-1) was used to assess blinding (0 = total absence of blinding; 0.5 = completely random blinding; 1 = complete blinding). Binary outcomes were compared using the χ^2 test. Statistical tests were 2-sided and $P < .05$ was to be considered statistically significant for all analyses. Analyzes were completed from December 2022 to March 2023 using SAS, version 9.4 (SAS Institute).

Results

The 2 groups included a total of 216 participants (mean [SD] age, 51.3 [15.2] years; 147 females [68.1%] and 69 males [31.9%]) were included in the analyses. Self-reported patient demographic characteristics were similar between the groups at baseline (**Table 1**). Twenty-two (10.2%) patients were lost to follow-up (8 in the acupuncture and 14 in the sham acupuncture group), and 194 (89.8%) completed the assessment at week 52 (Figure 1). In all, 104 participants (96.3%) in the acupuncture and 96 (88.9%) in the sham acupuncture group provided data of coprimary outcomes.

Acupuncture Efficacy

The VAS for leg pain at week 4 decreased 30.8 (95% CI, 27.1 to 34.5) mm in the acupuncture group and 14.9 (95% CI, 11.0 to 18.7) mm in the sham acupuncture group (mean difference, −16.0; 95% CI, −21.3 to −10.6; $P < .001$). The ODI at week 4 decreased 13.0 (95% CI, 10.8 to 15.1) points in the acupuncture group and 4.9 (95% CI, 2.7 to 7.0) points in the sham acupuncture group (mean difference, −8.1; 95% CI, −11.1 to −5.1; $P < .001$). For both leg pain and ODI, the between-group difference became apparent starting in week 2 and persisted through week 52 (**Table 2**; **Figure 2**). Results of per-protocol analysis were consistent: −17.4 (95% CI, −22.7 to −12.1; $P < .001$) mm for VAS leg pain at week 4; and −9.2 (95% CI, −12.4 to −6.1; $P < .001$) points for ODI at week 4 (eTable 4 in Supplement 2).

At each assessment time point, the acupuncture group had better results than the sham acupuncture group on the VAS for back pain, SFBI frequency score, SFBI Bothersomeness score, SF-36 physical health, and patient's global assessment (Table 2; eTable 5 in Supplement 2). No difference was found between the groups in the SF-36 mental health score except at week 52 (Table 2). Seventeen patients in the acupuncture and 24 in the sham acupuncture group received analgesic therapy during the study (eTable 6 in Supplement 2).

Blinding Test

At week 2, patients were unaware of assigned treatments (James blinding index, 0.5; 95% CI, 0.4-0.6]). The success of blinding was maintained at week 4 (James blinding index, 0.5; 95% CI, 0.42-0.53) (**Table 3**).

Adverse Events

Among the 108 participants in each group, AEs occurred in 26 participants (24.1%) in the acupuncture and 5 participants (4.6%) in the sham acupuncture group (eTable 7 in Supplement 2). Subcutaneous hemorrhage and minor bleeding were the most common AEs. All acupuncture-related AEs were mild and self-limiting, and none required special medical intervention. There were no serious AEs, ie, none required hospitalization or surgery or were associated with exacerbation of a preexisting condition or death. AEs unrelated to acupuncture were infrequent and balanced between groups (eTable 8 in Supplement 2).

Discussion

In this randomized clinical study, patients with chronic sciatica from herniated disk who received acupuncture had less leg pain and better function after 4 weeks than did patients who received sham acupuncture. Moreover, the differences between acupuncture and sham acupuncture groups remained statistically significant at week 52.

Compared with sham acupuncture, the effect of acupuncture on both VAS for leg pain and ODI is clinically important. The MCID on the VAS for leg pain was 5 to 15 mm in previous trials.[5,29,31,32] Although a rigorous MCID of 15 mm was preset in this trial, the difference between groups at weeks 4 was 16 mm. Furthermore, all the confidence interval of benefit at weeks 8, 26, and 52 covered 15 mm. Similarly, the MCID on the ODI was preset at 7 points and the differences between groups at weeks 4, 8, and 26 were all greater than 7 points (8.1, 7.9, and 7.4, respectively). The confidence interval of benefit at week 52 covered the preset MCID of ODI.

A recent trial[31] suggested that acupuncture could decrease the VAS for leg pain by 11.3 mm and the ODI by 4.5 points compared with sham acupuncture in patients with chronic sciatica from herniated disk at week 4. The better results in our trial may be associated with more individualized treatment based on traditional Chinese syndrome and the greater number of acupoints used. Our results align with those of a recent meta-analysis that showed acupuncture to be superior to sham acupuncture in improving the 10-point VAS score for sciatic

Table 2. Coprimary and Key Secondary Effectiveness Outcomes

Follow-up time	Mean (95% CI)			*P* value
	Acupuncture group	Sham acupuncture group	Difference between groups	
Participants, No.	108	108	NA	NA
Leg pain VAS score[a]				
Week 2	42.7 (39.0 to 46.3)	50.4 (46.6 to 54.3)	−7.8 (−13.0 to −2.5)	.004
Week 4	28.8 (25.1 to 32.5)	44.8 (41.0 to 48.6)	−16.0 (−21.3 to −10.6)	<.001
Week 8	27.5 (23.7 to 31.2)	40.9 (37.2 to 44.6)	−13.4 (−18.6 to −8.2)	<.001
Week 26	25.1 (21.3 to 28.8)	36.7 (32.8 to 40.6)	−11.6 (−17.1 to −6.1)	<.001
Week 52	22.8 (19.0 to 26.6)	33.6 (29.3 to 37.8)	−10.8 (−16.3 to −5.2)	<.001
ODI[b]				
Week 2	26.7 (24.6 to 28.8)	32.0 (29.9 to 34.1)	−5.3 (−8.4 to −2.3)	.001
Week 4	21.4 (19.3 to 23.6)	29.5 (27.4 to 31.7)	−8.1 (−11.1 to −5.1)	<.001
Week 8	17.0 (14.7 to 19.2)	24.8 (22.5 to 27.1)	−7.9 (−11.1 to −4.6)	<.001
Week 26	15.1 (13.0 to 17.3)	22.6 (20.3 to 24.8)	−7.4 (−10.5 to −4.4)	<.001
Week 52	15.7 (13.5 to 17.8)	20.4 (18.2 to 22.7)	−4.7 (−7.8 to −1.7)	.003
Back pain VAS score[a]				
Week 2	37.2 (33.6 to 40.8)	46.8 (43.1 to 50.6)	−9.7 (−14.9 to −4.5)	<.001
Week 4	27.0 (23.3 to 30.6)	39.6 (35.8 to 43.4)	−12.7 (−17.9 to −7.4)	<.001
Week 8	26.5 (22.8 to 30.1)	36.7 (33.0 to 40.5)	−10.3 (−15.5 to −5.0)	<.001
Week 26	23.1 (19.4 to 26.8)	35.8 (32.1 to 39.6)	−12.8 (−18.0 to −7.5)	<.001
Week 52	21.9 (18.2 to 25.6)	33.3 (29.5 to 37.1)	−11.4 (−16.7 to −6.1)	<.001
SFBI frequency score[c]				
Week 2	10.7 (9.8 to 11.5)	12.7 (11.8 to 13.7)	−2.1 (−3.4 to −0.8)	.001
Week 4	7.4 (6.5 to 8.3)	11.7 (10.7 to 12.6)	−4.3 (−5.5 to −3.0)	<.001
Week 8	6.3 (5.4 to 7.2)	10.1 (9.2 to 11.0)	−3.8 (−5.1 to −2.5)	<.001
Week 26	5.3 (4.4 to 6.2)	9.5 (8.5 to 10.4)	−4.1 (−5.4 to −2.8)	<.001
Week 52	4.9 (4.0 to 5.8)	8.4 (7.5 to 9.3)	−3.5 (−4.8 to −2.2)	<.001
SFBI bothersomeness score[c]				
Week 2	10.7 (9.8 to 11.5)	12.7 (11.8 to 13.7)	−2.4 (−3.6 to −1.3)	<.001
Week 4	7.4 (6.5 to 8.3)	11.7 (10.7 to 12.6)	−4.1 (−5.3 to −2.9)	<.001
Week 8	6.3 (5.4 to 7.2)	10.1 (9.2 to 11.0)	−3.6 (−4.8 to −2.4)	<.001
Week 26	5.3 (4.4 to 6.2)	9.5 (8.5 to 10.4)	−3.9 (−5.1 to −2.7)	<.001
Week 52	4.9 (4.0 to 5.8)	8.4 (7.5 to 9.3)	−3.5 (−4.7 to −2.3)	<.001
SF-36 physical health[d]				
Week 4	37.6 (35.7 to 39.6)	31.9 (29.9 to 34.0)	5.7 (2.8 to 8.6)	<.001
Week 8	41.4 (39.5 to 43.4)	35.4 (33.3 to 37.5)	6.1 (3.2 to 8.9)	<.001
Week 26	43.8 (41.8 to 45.8)	37.5 (35.5 to 39.6)	6.3 (3.4 to 9.2)	<.001
Week 52	44.3 (42.3 to 46.3)	39.0 (36.9 to 41.0)	5.4 (2.5 to 8.3)	<.001
SF-36 mental health[d]				
Week 4	50.2 (48.6 to 51.8)	48.5 (46.8 to 50.2)	1.7 (−0.7 to 4.0)	.16
Week 8	51.2 (49.6 to 52.8)	49.6 (47.9 to 51.3)	1.6 (−0.7 to 4.0)	.17
Week 26	51.6 (50.0 to 53.2)	50.0 (48.3 to 51.7)	1.6 (−0.8 to 3.9)	.18
Week 52	54.6 (52.9 to 56.2)	51.1 (49.4 to 52.8)	3.5 (1.1 to 5.8)	.004

Abbreviations: NA, not applicable; ODI, Oswestry Disability Index; SF-36, 36-item Short Form Health Survey; SFBI, Sciatica Frequency and Bothersomeness Index; VAS, visual analog scale.

[a] Scores for leg pain and back pain could range from 0 (no pain) to 100 (pain as bad as you can imagine).

[b] ODI assesses the effect of pain on normal daily activity including the ability to intensity of lifting, care for oneself, walk, sit, sexual function, stand, social life, sleep and travel, ranging from 0 (no disability) to 100 (maximum disability possible).

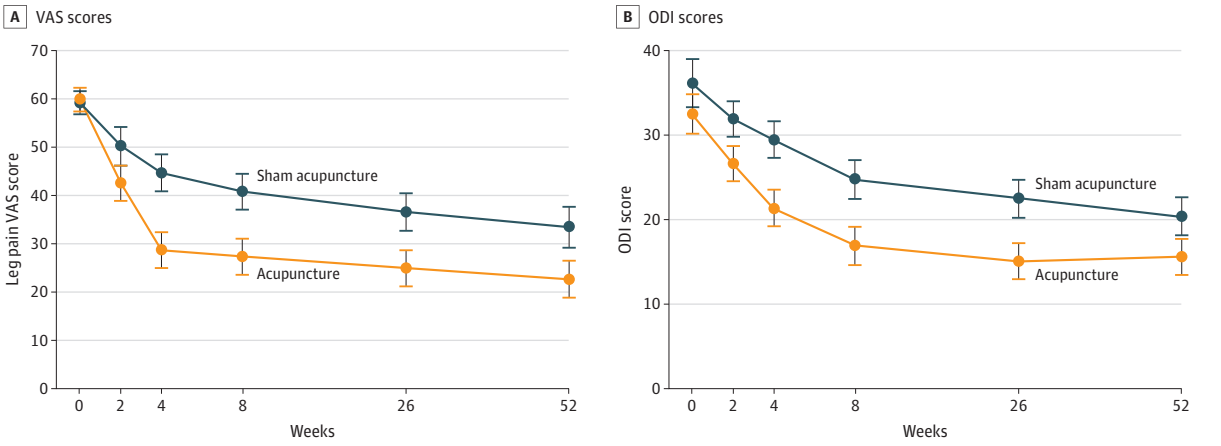
[c] SFBI assesses the frequency and bothersomeness of sciatica with scores ranging from 0 to 24, respectively. Higher scores indicate more severe symptoms.

[d] SF-36 assesses the quality of life through physical and mental dimensions with scores ranging from 0 to 100, respectively. Higher scores indicate a better quality of life.

pain (mean difference,−1.1; 95% CI, −1.7 to −0.6).[14] Moreover, acupuncture was recommended by a network meta-analyses based on the 14.9 points of improvement on pain intensity compared with sham control.[33]

Differences were also evident for secondary outcomes. The results of back pain, SFBI frequency score, SFBI Bothersomeness score, SF-36 physical health, and patient's global assessment all favored acupuncture. Moreover, exploratory analysis at week 26 and 52 follow-ups indicated that differences between acupuncture and sham acupuncture were still significant. Although the differences between the acupuncture and the sham acupuncture groups cannot be explained by the intake of analgesics, there seems to be a trend toward fewer patients receiving other analgesic therapies in the acupuncture group. Given the large effect sizes that this trial found, acupuncture should be considered to be a potential treatment option for patients with chronic sciatica from herniated disk. Future trials comparing acupuncture with NSAIDs and surgery are needed to evaluate the potential of acupuncture as a first-line treatment for patients with chronic sciatica from herniated disk.

Figure 2. Trajectory of Primary Outcomes Scores Over Time in the Acupuncture and Sham Acupuncture Groups



ODI indicates Oswestry Disability Index, and VAS, visual analog scale.

The present study is, to our knowledge, among the largest and most rigorous trials available on the efficacy of acupuncture for chronic sciatica. Its strengths include a pilot study,[34] a prepublished protocol,[16] interventions based on recent expert consensus,[20] acknowledged and validated coprimary outcomes with preset MCIDs, and high follow-up rate (92.6% at week 4 and 89.8% at week 52). A pilot study is an essential prerequisite for a large-scale research project. Our pilot evaluated feasibility and process coordination, optimized the program and processes, and provided the basis of sample-size calculations before launching this trial. The prepublished trial protocol (Supplement 1) details the study design and statistical analysis plan, which can reduce the risks of reporting bias and enhance the transparency of the trial. The treatment plan was based on our recent expert consensus[20] in which 80 clinical specialists were invited to participate in 2 rounds of semi-open clinical investigation, and a 3-round Delphi survey was undertaken by 30 experienced acupuncturists. Two coprimary outcomes—pain and function—were adopted in this trial and the MCID was preset for the acknowledged and validated VAS and ODI. As 2 of the most common methods, the VAS and ODI have good validity and reproducibility and are recommended by guidelines.[22]

Limitations

This trial had limitations. First, due to the nature of acupuncture manipulation, acupuncturists in this trial could not be blinded. To reduce the impact, we provided detailed training to acupuncturists, including standardized communication with patients. Second, 10 sessions of acupuncture with 7 acupoints were used in this study; however, evidence suggests that there may be an enhanced effect associated with an increase in acupoints or treatment sessions.[35] Third, the coprimary outcomes (VAS and ODI) were assessed according to patients' self-reported data because there is a lack of objective evaluation methods for pain and disability, the core components of sciatica.

Table 3. Blinding Assessment

Treatment guess	No. (%)		James blinding index (95% CI)[a]
	Acupuncture	Sham acupuncture	
Week 2			
Acupuncture	54 (51.4)	5 (5.0)	0.5 (0.4-0.6)
Sham acupuncture	13 (12.4)	49 (48.5)	
Unsure	38 (36.2)	47 (46.5)	
Week 4			
Acupuncture	65 (62.5)	11 (11.5)	0.5 (0.4-0.6)
Sham acupuncture	10 (9.6)	41 (42.7)	
Unsure	29 (27.9)	44 (45.8)	

[a] Ranges from 0 to 1 (0 = total absence of blinding; 0.5 = completely random blinding; and 1 = complete blinding).

Conclusions

This randomized clinical trial found that among patients with chronic sciatica from herniated disk, acupuncture resulted in less pain and better function at week 4 compared with sham acupuncture, and the benefit persisted through week 52. Acupuncture should be a potential treatment option for patients with chronic sciatica from herniated disk.

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