

OBSTETRICS

Auricular acupuncture as a treatment for pregnant women who have low back and posterior pelvic pain: a pilot study

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OBJECTIVE: The primary aim of this study was to examine whether 1 week of continuous auricular acupuncture could reduce low back and posterior pelvic pain associated with pregnancy.

STUDY DESIGN: A randomized controlled trial was conducted on pregnant women who have lower back and posterior pelvic pain. These women were randomly assigned into an acupuncture group, a sham acupuncture group, or a waiting list control group. All participants were monitored for 2 weeks.

RESULTS: Baseline and day 7 showed significant group differences in pain ($F = 15$; $P < .0001$) and in the disability rating index score

($F = 7$; $P < .0001$). The participants in the acupuncture group reported a significant reduction of pain and improvement of functional status as compared with those in the sham acupuncture and control groups.

CONCLUSION: One week of continuous auricular acupuncture decreases the pain and disability experienced by women with pregnancy-related low back and posterior pelvic pain.

Key words: auricular acupuncture, pain relief, pregnancy, pregnancy-related low back pain and posterior pelvic pain

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Low back pain is the second most common neurologic ailment in the United States,¹ and pregnancy is also considered as 1 of the major contributing factors to the development of this clinical entity.^{2,3} Pregnancy-related low back and posterior pelvic pain (PRLP) consists of generalized lower back pain and distinct pains located in the posterior pelvic area distal and lateral to the lumbar-sacral junction.⁴ In the United States, more than 2 million pregnant women are affected by PRLP annually,²

★ EDITORS' CHOICE ★

and PRLP is reported to be 1 of the most common reasons for sick leave during pregnancy.⁵⁻⁷ The current literature supports that the earlier the onset of PRLP, the more severe the pain and disability become as the pregnancy progresses and the greater the incidence of prolonged postpartum low back pain and chronic low back pain.⁸ Furthermore, 10-20% of women who have chronic low back pain

report that the onset of the pain originated during their pregnancy.⁹

Chronic/recurrent low back pain is often initiated by an acute episode of low back pain with local irritation and inflammation, followed by immobilization and abnormal posture caused by this pain.¹⁰ The immobilization and abnormal posture leads to worsening of local irritation and inflammation, ultimately resulting in the development of chronic low back pain.¹¹ If an effective intervention that reduces pain is applied at the onset of acute low back pain, it may facilitate the early resumption of daily activities and lead to a decrease in the incidence of recurrent and chronic low back pain.^{10,11} The introduction of drug therapy during pregnancy, however, is challenging because of the uniqueness of the maternal-fetal circulation and the potential for drug transfer to the fetus.¹² This means that nonpharmacologic treatment for PRLP is potentially very attractive, both as a means to decrease pain during pregnancy and also to decrease the risk of chronic back pain throughout life. Although massage, yoga, acupuncture, and related interventions have been recommended as potential treatments for this clinical entity,¹³⁻¹⁵ there is a pau-

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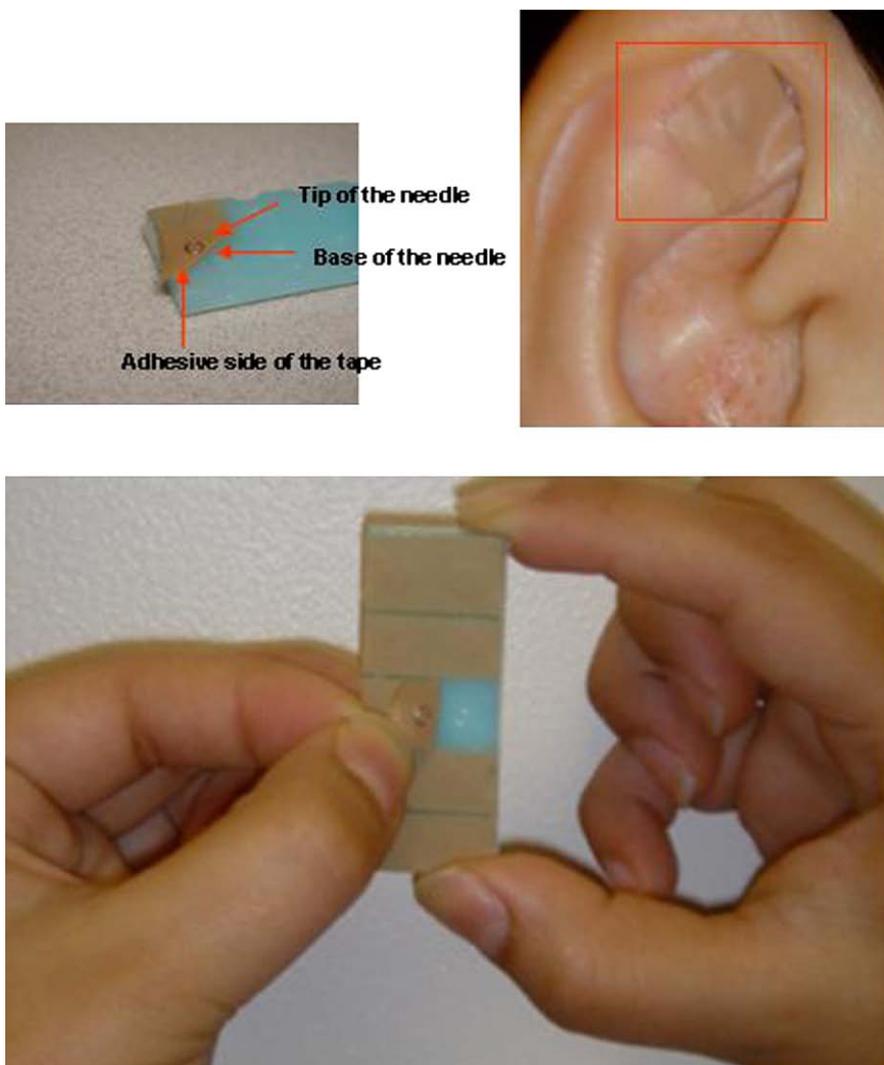
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FIGURE 1

The press needle-semipermanent needles

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Japan) (Figure 1) allows the provision of continuous acupuncture intervention while the patient continues with her daily activities. These observations provided the basis for this study of whether auricular acupuncture alone can be used as a treatment for PRLP.

The primary hypothesis of this study is that 1 week of continuous acupuncture stimulation at 3 specific auricular points will reduce the severity of pain in pregnant women with late-trimester PRLP. The secondary hypothesis of this study is that an effective reduction of pain caused by PRLP would be concomitant with an improvement in the functional status of these women.

MATERIALS AND METHODS

Design and settings

This randomized controlled clinical trial was conducted at the Center for the Advancement of Perioperative Health at Yale-New Haven Hospital after obtaining approval from the Human Investigation Committee at Yale University School of Medicine. Participants were randomly assigned to receive 1 of the following 3 interventions: (1) acupuncture at specific auricular points, (2) acupuncture at nonspecific auricular points, or (3) no-intervention control. To reduce bias affecting the study results, all prospective participants were informed that they had a 33.3% chance of receiving no treatment until after the completion of a 2-week study period.

Subjects

Participants were pregnant women with a gestational age of 25-38 weeks, who had lower back and/or posterior pelvic pain. All participants were healthy women with a physical status II in the American Society of Anesthesiologists (ASA) classification and had no prior experience with acupuncture. PRLP was classified based on the classification defined by Norén et al,²² and exclusion criteria included any associated nerve root syndrome, neurologic deficit, fever, abdominal pain, other systemic manifestations, and active uterine contractions.

city of randomized control trials to support the benefit of using any of these interventions in pregnant women. In fact, 2 recent review articles reveal that there is an urgent need for high-quality clinical trials in the evaluation of the current treatment options for PRLP.^{14,15}

Several clinical studies and 2 review articles indicate that traditional body acupuncture may serve as a treatment for PRLP,¹⁴⁻¹⁹ but only 1 study has used auricular acupuncture as an adjunct for body acupuncture. Wedenberg et al¹⁶ showed that the combination of auricular and body acupuncture was superior to physiotherapy in relieving the severity

of pain and the disability related to PRLP, but the intervention protocol was very time consuming, often consisting of 1-hour treatments and 10 treatments per month of acupuncturist office visits. Sato-Katzenschlager et al²⁰ demonstrated that auricular acupuncture was effective in providing relief to nonpregnant patients with chronic back pain. Auricular acupuncture²¹ is preferable to body acupuncture, because it is easy to apply without undressing the patient or using sophisticated needle manipulations, as in traditional body acupuncture. Last, the use of auricular press needles (Small; Seirin Pyonex, Shizuoka,

Group assignments

Acupuncture group

Participants in this group received auricular press needles at 3 points (kidney, analgesia, and shenmen) (Figure 2). These points were selected based not only on the close location to the auricular somatotopic map of the hip and the lumbar spine²¹ but were also pretested on 50 pregnant women with PRLP during the preparation phase of this randomized trial by our research group.

Sham acupuncture group

Participants in this group received auricular press needles at 3 nonspecific auricular acupuncture points (shoulder, wrist, and extraauricular point), which were used in previous studies and showed a minimum effect (Figure 2).^{23,24} The sham acupuncture group was included as a control to address issues specifically related to the clinical acupuncture trial, such as placebo effects, blinding, and subjects' beliefs.

Control group

Participants in this group received no acupuncture treatment. No-treatment control group was included, because several clinical acupuncture studies have suggested that any needle intervention might result in some physiologic responses and pain relief.²⁵

Measures

Background characteristic

The questionnaire was designed to gather demographic information, as well as State and Trait Anxiety Inventory (STAI).²⁶

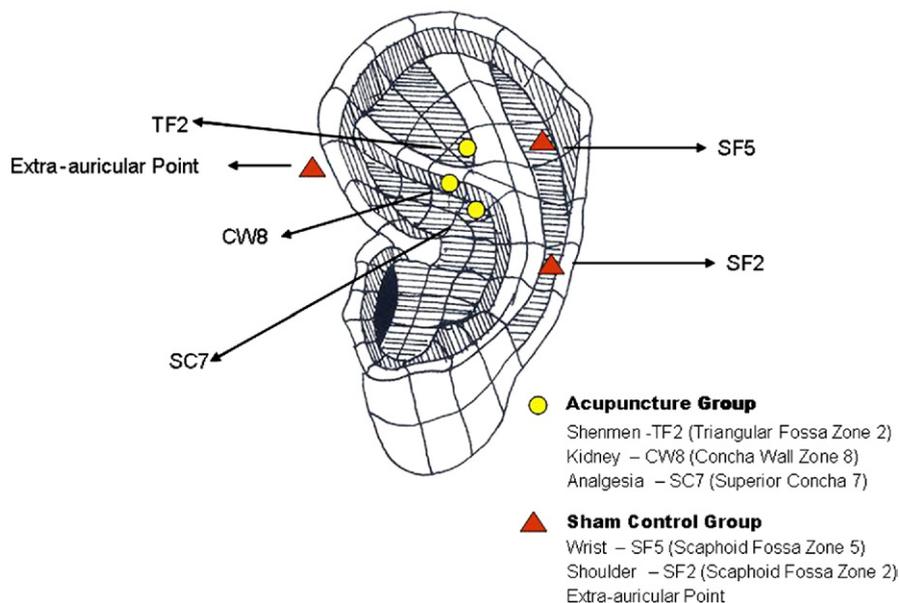
Visual Analog Scale for Pain (VAS-P)²⁷

The VAS rating system consists of a 100-mm line that represents 2 extremes, that is, no pain (a score of 0) and extreme pain (a score of 100). There are ample data regarding the excellent reliability and validity of this instrument.

Disability Rating Index (DRI)²⁸

This instrument contains 12 common daily activities and requires the participants to rate their level of disability in each activity, with 0 denoting no disability and 100 denoting maximum disability (ie, inability). The measure has dem-

FIGURE 2
The locations of auricular acupuncture points



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onstrated satisfactory test-retest and interrater/intrarater reliabilities, as well as internal consistency.

Study protocol

Prenatal health care providers referred all participants to the study who had back pain without any suspected obstetric and/or medical reasons. Prospective participants were instructed by their prenatal care providers to call the PRLP hotline and a research assistant would explain the nature of the study and conduct a preliminary interview of participants' symptoms and conditions. If inclusion criteria were met, the women were invited to participate in the study, and verbal consent was obtained. Prospective participants followed up with an appointment with 1 of the physician coinvestigators for further evaluation and possible enrollment. A detailed history was taken, and a general physical examination, combined with special focus on neurologic testing pertinent to back and lower extremities, was conducted to ensure these potential participants met the enrollment criteria. After this evaluation, 1 pregnant woman was referred for further workup because of the more complicated nature of her back pain, and

1 pregnant woman decided not to participate in the study, because she was not comfortable signing the HIPPA consent.

Once a participant was enrolled, a written consent was obtained, and baseline assessments of anxiety (STAI), pain (VAS-P), and functional status (DRI) were completed. Participants were randomly assigned into 1 of the 3 treatment groups based on a computer-generated randomization sheet. The acupuncturist (S-M.W.), who is a board-certified anesthesiologist and a certified acupuncturist with 9 years of clinical acupuncture experience, applied 3 auricular press needles to the respective auricular points in the acupuncture and sham acupuncture groups based on the randomization scheme. Because of the inconsistencies and nonspecifics of commercially made skin conductors in the literature,²⁹ the auricular points used were identified on the basis of the auricular zone system.²¹ To avoid any bias caused by the acupuncturist and the assessor (research assistant), the acupuncturist adhered to a scripted speech during interaction with the participants and inserted the needles without the presence of the assessor. If a participant was to receive acupuncture

FIGURE 3
Trial flowchart

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or sham acupuncture treatment, the acupuncturist told her that a total of 3 auricular press needles would be inserted into 1 side of her ear, and these needles would be left in place for a 1-week period before being removed. After the placement of these auricular press needles, the acupuncturist instructed the participants to inspect the integrity of the occlusive tape over these needles daily but not to apply any pressure or manipulation over the needle insertion site. If any adverse reaction, such as local redness or increased pain, occurred, the participant was instructed to contact the study center immediately and return for reinspection, adjustment, and/or possible removal of the press needles. All participants, including those in the control group, were told that they would be asked to report their average level of pain (VAS-P) and functional status (DRI) on day 7 and again report their average level of pain on day 14 after enrollment in the study. The assessor telephoned every participant, including participants in the control group, daily over the study period to ensure the study protocol was followed. The participants in the control group, after the 2-week observation, were offered to return to the center

and receive auricular acupuncture treatment.

All participants were directed to adhere to PRLP self-care, that is, continuing to rest as desired, taking acetaminophen 650 mg every 6 hours if needed, and/or applying topical warm and cold compresses to relieve low back pain during the 2-week study period. However, participants were instructed not to use any other complementary and alternative treatments (CAM), such as massage, chiropractic manipulations, or physical therapy.

Blinding and credibility

To test blinding to treatment and to assess the credibility of the respective treatment methods,³⁰⁻³² all participants who received auricular acupuncture treatment were asked to complete a credibility questionnaire (Appendix) on day 7 after the removal of auricular press needles. All assessors were blinded to the group assignment. The statistician who performed the final analysis was blinded to the group assignment.

Sample size and statistical analysis

The primary aim of this study was to compare 1-week changes from baseline in pain scores measured by a VAS-P. The

secondary aims of this study were to assess the functional status of the participants 1 week after intervention, as measured by DRI, and to determine the therapeutic effect of a 1-week auricular intervention. Sample size was calculated using Sample Power statistical software version 1.2 (SPSS, Inc, Chicago, IL). A 30% reduction in VAS-P (primary outcome)³³ from the baseline was considered to be clinically meaningful for the purpose of the study. The estimated standard deviation of change from baseline is about 25 for VAS in a previous study.¹⁶ As enrollment gestational age in this study ranged from 25-38 weeks, we stratified participants into 3 groups: 25-29 weeks' gestation, 30-34 weeks' gestation, and 35-38 weeks' gestation. With a power of .85 and a significance level of .05, calculations based on previous data yielded a sample size of 135 women for the trial. Given an estimated dropout rate of 15%, however, we recruited an additional 24 patients, for a total of 159.

Baseline demographic data, prognostic variables, and credibility evaluations were compared using *t* tests and χ^2 tests, as deemed appropriate. A mixed-effect model, with random intercept analysis,³⁴ was performed for the outcomes, and the

TABLE 1
Baseline characteristics of the participants

Characteristic	Acupuncture group (n = 58)	Sham acupuncture group (n = 54)	Control group (n = 47)
Age, mean (SD), y	33 (5)	32 (5)	32 (5)
Gestational age, %			
25-29 wk	42	40	51
30-34 wk	36	42	30
35-38 wk	22	18	19
Mean (SD), wk	30 (5)	29 (7)	29 (5)
Location of pain, %			
LBP	47	38	57
PPP	42	38	28
LBP-PPP	6	8	11
Nonspecific LBP	5	0	4
Previous LBP, %			
Yes	47	46	55
No	53	54	45
Previous pregnancy LBP, %			
Yes	26	28	20
No	21	29	24
Not applicable	53	43	56
First pregnancy, %			
Yes	53	43	56
No	47	57	44
Beliefs in acupuncture, mean (SD)	7 (2)	7 (2)	7 (2)
Baseline anxiety			
State, mean (SD)	35 (9)	35 (9)	38 (11)
Trait, mean (SD)	37 (8)	37 (8)	37 (9)
Education level, mean (SD), y	16 (3)	16 (3)	16 (3)
Baseline VAS-P, mean (SD)	70 (20)	62 (22)	66 (26)
Baseline DRI, mean (SD)	63 (25)	57 (28)	63 (28)

No statistical differences between groups. $P > .05$.

DRI, disability rating index; LBP, lumbar back pain; PPP, posterior pelvic pain; SD, standard deviation; VAS-P, visual analog scale for pain.

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therapeutic effect of 1-week intervention predictors included the indicator variables of all 3 groups, at day 7 and day 14, and the interaction terms between the indicator variables of time and group. Subject was treated as a random effect to account for within-subject correlation. If any measure for a time point was missing, the mixed model accounted for the mechanism of missing at random. After an overall test of treatment effect, the

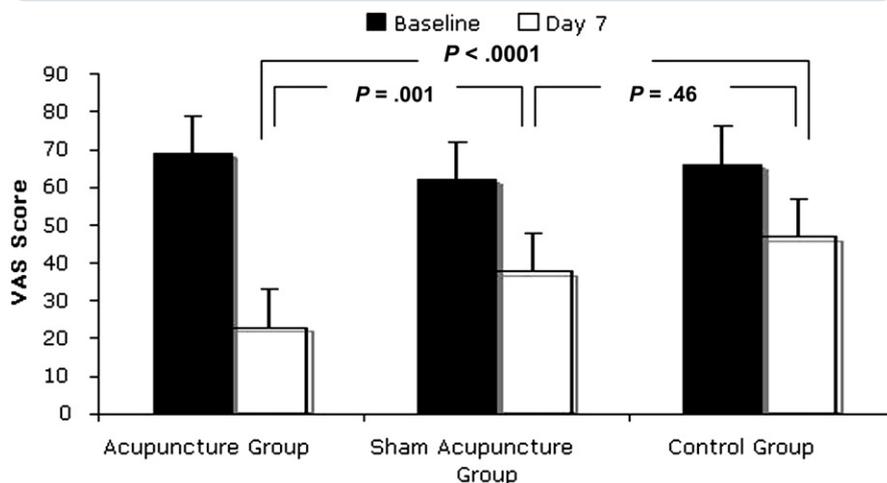
Fischer protected test was used for pairwise comparisons to determine the group differences. $P < .05$ was considered significant and SPSS was used for analysis.

RESULTS

Between Feb. 1, 2005-Jan. 31, 2008, a total of 311 pregnant women with lower back/posterior pelvic pain were referred as potential participants for this study.

After an initial telephone screening, 172 subjects who had met the inclusion criteria were invited to participate in the study. A total of 161 subjects presented for the preenrollment appointment, 159 subjects enrolled into the study and 152 subjects completed the 2-week study period (retention rate of 95.6%) (Figure 3). There were no significant differences in baseline variables between the 3 study groups (Table 1).

FIGURE 4
The level of pain at baseline and day 7



VAS, visual analog scale.

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Primary outcome

Pain at day 7

As can be seen in Figure 4, participants in all groups reported a decrease in pain in varying degrees ($F = 186$; $P < .0001$), and the participants in the acupuncture group reported a significant reduction in pain compared with those of the sham acupuncture group ($P = .001$) and those of the control group ($P < .0001$). In contrast, the reduction of pain between the sham acupuncture

and control groups ($P = .46$) was not significant. A mixed-model analysis demonstrated that there is a significant group \times time interaction ($F = 15$; $P < .0001$). More participants in the acupuncture group had a clinically significant reduction in pain (eg, 30% reduction) than those of the sham acupuncture group and the control group (81% vs 59% vs 47%; $P = .015$). In addition, 37% of participants in the acupuncture group, 22% of partici-

pants in the sham acupuncture group, and 9% of participants in the control group became pain-free (VAS-P score = 0) at day 7 ($P = .003$).

Secondary outcomes

Functional status at day 7

Similarly, all the participants, regardless of their group assignment, reported improvement in the functional status after the first week ($F = 126$; $P < .0001$). As can be seen in Figure 5, participants in the acupuncture group reported a significant improvement of functional status compared with those of sham acupuncture and control groups: $P = .03$ and $P = .001$, respectively. In contrast, the differences of functional status between the sham acupuncture and control groups did not reach statistical significance ($P = .60$). A mixed-model analysis reveals a significant group \times time interaction ($F = 7$; $P < .0001$).

Therapeutic outcome during

2-week study period

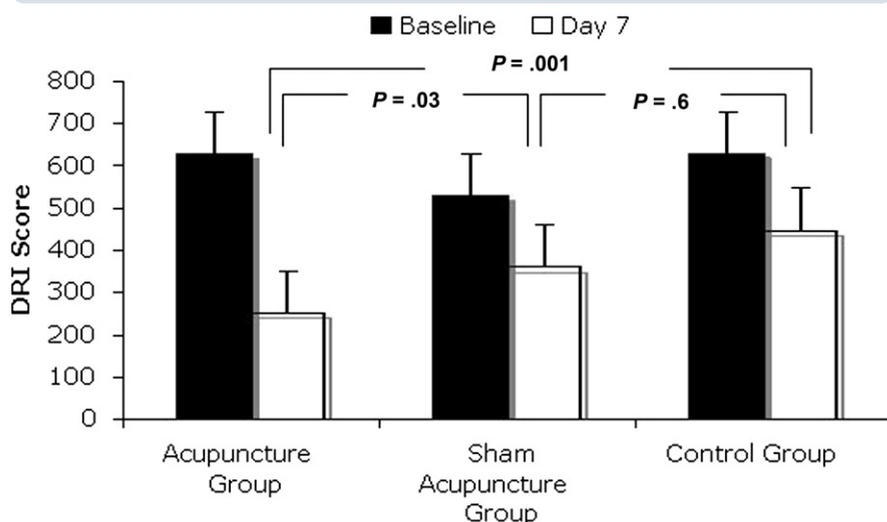
A mixed-model analysis indicated a significant reduction of pain over time ($F = 42.7$; $P < .0001$) in all 3 groups and a significant group \times time interaction ($F = 4.7$; $P = .013$) (Figure 6). At day 14, 68% of participants in the acupuncture group had a clinically significant reduction of pain, whereas only 32% of participants in the sham acupuncture group ($P = .02$) and 18% of participants in the control group had a clinically significant reduction of pain ($P < .001$). However, the number of participants who remained pain free at day 14 did not show a significant difference among the groups (16% vs 9% vs 6%; $P = .25$).

Only 3 participants in the study (acupuncture vs sham acupuncture vs control = 1 vs 2 vs 0) used acetaminophen as an adjunct for pain treatment. The total consumption of acetaminophen ranged between 1300-1950 mg, and none of the participants reported that acetaminophen was helpful for their back pain.

Adverse effects experienced during study period and postpartum

During the first week of the study period, 1 of 54 participants in the acupuncture group and 3 of 50 participants in the sham acupuncture group experienced

FIGURE 5
The functional status at baseline and day 7



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transient ear tenderness, which resolved spontaneously. No participants experienced preterm labor. However, 1 of 54 participants in the acupuncture group, 1 of 50 participants in the sham acupuncture group, and 1 of 47 participants in the control group were placed on bed rest after the study period was completed. No adverse pregnancy outcomes were reported.

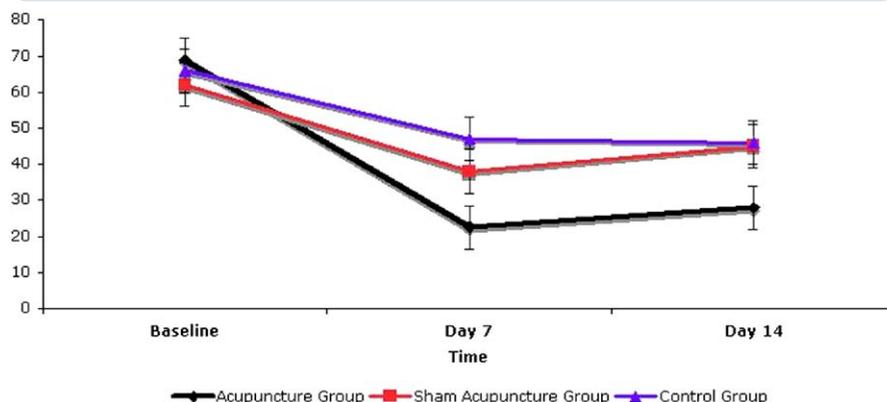
COMMENT

Under the conditions of this study, we found that pregnant women who received a 1-week continuous auricular acupuncture treatment reported significantly less pain compared with those of the sham acupuncture and control groups. At the day 7 follow-up, we found that about 80% of the participants in the acupuncture group experienced a clinically significant reduction in pain compared with 56% of participants in the sham acupuncture group and 36% of participants in the control group. This clinically important outcome was associated with an improvement in functional status as the pain decreased. The reduction of pain continued to the day 14 follow-up. However, the reduction of pain was not sustained for every participant, as the number of the participants who remained pain free was fewer at day 14 than day 7. This observation suggests that after removing press needles, there was a return of pain in some of the participants. Thus, it is important to explore whether an extended continuous auricular acupuncture is needed to have a sustained effect, as well as the characteristics of acupuncture responders vs nonresponders in future studies.

Because there are no safety data using auricular press needles in delivering auricular acupuncture continuously in pregnant women, we chose 1 week as the treatment period, which was derived from our clinical experience as a conservative treatment duration. Based on the results of this study, we are confident that a 1-week auricular acupuncture can be safely administered in pregnant women with low back and posterior pelvic pain at the last trimester of pregnancy, because we did not observe any

FIGURE 6

The therapeutic effect of 1-week intervention



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major local irritation, infection, or adverse outcome in pregnancy. For a majority of participants receiving therapeutic acupuncture, pain relief was substantial and led to improvement of functional status. Hence, this study supports that use of acupuncture at specific auricular points is a safe and effective nonpharmacologic treatment of an important clinical entity for which there are currently few, if any, effective treatments. Interestingly, participants in the control group also experienced reduction of pain without additional treatment other than PRLP self-care. This reduction of pain may be caused by the self-care package prescribed in this study or by the daily inquiry performed by the assessor, or the combination of both. The psychologic impact and effect of

daily inquiry should be assessed in a future study. Although an economic analysis was beyond the scope of this study, the cost for the auricular acupuncture press needle is about \$17-20 for 100 per pack, and this intervention can be administered in 3 minutes by an experienced operator. Thus, a future, large-scale randomized controlled trial is definitely indicated to confirm the potential benefits of using this intervention.

Other methodologic issues related to this study that should be addressed are as follows. (1) Issues related to VAS-P as the primary measuring tool for pain disorders. Although pain disorders are generally considered to have more than 1 dimension, for example, affective and sensory aspects, we used the VAS-P as

TABLE 2

Credibility test

Variable	Acupuncture group (n = 54)	Sham acupuncture group (n = 50)	
Think the treatment received is a reasonable strategy	9 (2)	8 (2)	0.2
Relieves lower back pain	8 (3)	7 (3)	0.2
Will use the treatment again	9 (3)	9 (2)	0.9
Will recommended to a friend	9 (2)	8 (3)	0.6
Satisfied with the treatment	8 (3)	8 (3)	0.6

All rating scales based on 0 = not at all and 10 = definitely; data are mean (SD). SD, standard deviation.

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the assessment tool for the primary outcome of this study, because it is not only effective in assessing the improvement of pain in clinical settings^{33,35-37} but also is well defined in assessing the clinical significance of pain reduction.³³ Thus, the results of this study can be more meaningful for the practitioners who encounter PRLP on a daily basis. As pain disorders are usually complex, VAS-P might not be ideal. Future studies should also consider additional multidimensional pain assessment tools, such as the Brief Pain Inventory³⁸ and McGill Pain Scale,³⁹ to name a few, to address different aspects of pain. (2) Issues related to credibility testing. Although the credibility test is critical in assessing the successfulness of blinding for clinical acupuncture studies,²⁵ auricular acupuncture performed in this study is different from the traditional acupuncture, for example, the type and manipulation of needles, as well as the duration of the needles' retention. Furthermore, there are no data in the literature to determine whether the intervention technique and duration introduced in this study are acceptable treatment strategies for pregnant women with PRLP. Thus, some of the questions in the credibility test³² were modified to answer our inquiry. (3) Issues related to a single acupuncturist. Although only 1 acupuncturist performed all the auricular acupuncture interventions, the participants not only think the treatment strategy was acceptable but also believe the intervention they received improved their lower back and pelvic pain regardless of the group assignment (both the acupuncture and sham acupuncture groups; Table 2). Therefore, we are confident that neither the acupuncturist nor the intervention selected in this study introduced any bias to the participants who received the auricular acupuncture intervention or affected the validity of the study results.

In summary, we found that the participants who received a 1-week continuous acupuncture treatment at the specific auricular points had a significant reduction in pain compared with those of the sham acupuncture and control groups, but the treatment effect was not sustained in some of the

pregnant women. Thus, long-term efficacy of auricular acupuncture as a treatment for PRLP is still inconclusive but clearly shows promise. A future large-scale randomized control study is indicated to explore the characteristics of acupuncture responders vs non-responders, the optimal duration of treatment to achieve the sustained therapeutic effect, and the potential mechanisms of auricular acupuncture analgesia, as well as detailing the pregnancy outcomes. ■

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APPENDIX

Answer each question by circling the number that seems to best fit your opinion about the acupuncture treatment you received:

1. Did this seem like a reasonable strategy to reduce the level of low back pain during pregnancy?

1 2 3 4 5 6 7 8 9 10
unreasonable *very reasonable*

2. How much did this treatment help you reduce your low back pain?

1 2 3 4 5 6 7 8 9 10
not at all *very much so*

3. Would you recommend this treatment to a friend who might be having low back pain during pregnancy?

1 2 3 4 5 6 7 8 9 10
would not recommend *definitely would recommend*

4. Was this treatment what you had expected?

1 2 3 4 5 6 7 8 9 10
not what I expected *just what I expected*

5. Was the time involved reasonable?

1 2 3 4 5 6 7 8 9 10
unreasonable *very reasonable*

6. If you had more back pain in the future, would you try this treatment again?

1 2 3 4 5 6 7 8 9 10
not at all *definitely*

7. How satisfied are you with this way of treating low back pain?

1 2 3 4 5 6 7 8 9 10
not at all *very satisfied*