

OBSTETRICS**Acupuncture for pelvic and back pain in pregnancy: a systematic review**

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The objective of our study was to review the effectiveness of needle acupuncture in treating the common and disabling problem of pelvic and back pain in pregnancy. Two small trials on mixed pelvic/back pain and 1 large high-quality trial on pelvic pain met the inclusion criteria. Acupuncture, as an adjunct to standard treatment, was superior to standard treatment alone and physiotherapy in relieving mixed pelvic/back pain. Women with well-defined pelvic pain had greater relief of pain with a combination of acupuncture and standard treatment, compared to standard treatment alone or stabilizing exercises and standard treatment. We used a narrative synthesis due to significant clinical heterogeneity between trials. Few and minor adverse events were reported. We conclude that limited evidence supports acupuncture use in treating pregnancy-related pelvic and back pain. Additional high-quality trials are needed to test the existing promising evidence for this relatively safe and popular complementary therapy.

Key words: acupuncture, back pain, pelvic pain, pregnancy

Pelvic and back pain are among the most common “minor” complications in pregnancy.¹ Estimates of prevalence of pelvic and back pain in pregnancy range from 24-90%.² This difference is most probably due to the

use of different definitions, and some experts advocate differentiating pelvic from back pain in pregnancy.³

The exact etiology remains unclear⁴ and is thought to be related to the interaction between physiological changes in pregnancy and risk factors such as physical work and previous back or pelvic pain.^{2,5} The pain can result in significant morbidity. Twenty-five percent of women with pelvic pain in pregnancy will seek medical help for their pain, 8% are severely disabled, and 7% continue to have pain beyond the pregnancy.⁶ The majority of women with back pain in pregnancy report disturbed sleep from their pain.⁷ Disability often involves simple activities of daily living⁸ and can result in significant absenteeism.⁹ Back pain in pregnancy also increases the risk of postpartum back pain.⁵

Provision of education, advice, and the prescription of exercise by a physiotherapist appear to be the standard recommendations for treatment.¹⁰ Evidence for the benefits of physical therapies and support belts is inconclusive.^{3,11,12} A Cochrane review found that water gymnastics helps reduce sick leave in pregnancy, a specially shaped pillow improves back pain and

sleep in late pregnancy, and both acupuncture and physiotherapy may improve pain.¹³ Several case reports and 1 retrospective case series have suggested that acupuncture may relieve pelvic and back pain in pregnancy.¹⁴⁻¹⁷

Complementary and alternative therapies are growing in popularity and are used by more than a third of the US population.¹⁸ They continue to be used during pregnancy,¹⁹ and 60% of women with lower back pain in pregnancy report that they would accept complementary therapies for treatment of their pain.²⁰

Acupuncture is used by more than 2 million people in the US annually.¹⁸ It involves stimulation of anatomical locations on the skin (acupoints) by various measures, most commonly by penetration of the skin by metallic needles (needle acupuncture). Acupuncture analgesia involves complex neurohumoral mechanisms involving endogenous opiates and monoamines,²¹ with evidence of sustained depression of dorsal horn neurons in the spinal cord.²² Adverse events are reported to be minimal,²³ and life-threatening events such as pneumothorax are considered rare in the hands of a trained practitioner.²⁴

Our aim in this review was to determine whether acupuncture is more effective than “standard treatment,” no additional treatment, placebo acupuncture, “sham” acupuncture, or other treatments in the management of pain and disability due to pregnancy-related pelvic and back pain. We chose to include both pelvic and back pain in our review, as many investigators do, because of the ongoing debate and uncertainty regarding etiology and treatment of this problem.

MATERIALS AND METHODS

We searched the following electronic databases from their inception until July 2006:

From the Department of General Practice, University of Melbourne, Melbourne, Australia (Drs Ee and Pirota); Center for Integrative Medicine, University of Maryland School of Medicine, Baltimore, MD (Mr Manheimer); Peninsula School of Medicine and Dentistry, University of Plymouth, Plymouth, UK (Dr White).

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The Cochrane Central Register of Controlled Trials (CENTRAL), National Library for Health Complementary and Alternative Medicine Specialist Library, CINAHL, EMBASE, AMED, and Acubriefs. We searched MEDLINE from its inception until November 2006. Due to funding limitations, we only searched for trials written in or translated into English.

We based our MEDLINE search strategy on the Cochrane highly sensitive search strategy²⁵ and combined this with specific intervention and disease identifiers. The key MeSH terms and keywords used were “acupuncture,” “acupuncture therapy,” “electroacupuncture,” “Medicine, Chinese traditional,” “pregnancy complications,” “pregnancy,” “peripartum,” “prenatal care,” “pelvic pain,” “back pain,” “low back pain,” “lumbar back pain,” “sacroiliac joint pain,” and “symphysis pubis pain.”

We attempted to identify unpublished trials by contacting prominent acupuncture researchers in the US, UK, Europe, Australia, and Sweden and by searching reference lists of identified trials. We also searched Computer Retrieval of Information on Scientific Projects (CRISP) and Current Controlled Trials (CCT) for ongoing trials.

Two reviewers independently assessed study eligibility. Our inclusion criteria were randomized controlled trials comparing acupuncture therapy against a control group for pelvic and back pain in pregnancy. We defined acupuncture as needle insertion into acupoints, whether the acupuncture was described as “traditional” Chinese acupuncture, “Western”/segmental/tender point acupuncture, or other. Comparison interventions could be placebo/“sham” acupuncture, no additional treatment, “standard treatment,” or any other treatment. Our accepted outcome measures were pain, disability, overall improvement, analgesic use, time off work, and adverse events. We included unpublished trials.

We excluded trials that were quasi-randomized. If the trial had a crossover design, we intended to analyze only the data prior to the crossover. We excluded trials that enrolled women who may

TABLE 1

Modified Cochrane Back Review Group (BRG) criteria for methodological quality assessment of randomized, controlled trials

1. Was the method of randomization adequate?
2. Was allocation concealment adequate?
3. Was an appropriate sample size calculation used to ensure adequate power to detect significant differences due to treatment?
4. Were participants blinded to intervention?
5. Were caregivers blinded to intervention?
6. Were cointerventions avoided or similar?
7. Were cointerventions reported for each group separately?
8. Was the acupuncture treatment adequate?
9. Was the withdrawal and dropout rate described and acceptable?
10. Did the analysis include an intention-to-treat analysis?
11. Was the outcome assessor blinded to the intervention received?
12. Was the timing of outcome assessment in both groups similar?

Details of operationalization available from the authors upon request.

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have had a nonmusculoskeletal cause for their pain (eg, malignancy, urinary tract infection, obstetric complication). Trials using laser therapy alone without the use of needles were excluded from our review. We included auricular acupuncture trials, but only if this was combined with body acupuncture, and intended to perform a separate analysis for such trials. We postulated that the neurohumoral mechanisms involved in these other therapies may differ from those involved in needle acupuncture; in addition, we noted that most experts would agree that acupuncture by definition involves insertion of needles into the skin.^{26,27}

Two reviewers independently extracted data from eligible trials as defined above. We used a modified version of a data extraction spreadsheet that was previously used.²⁸ Where possible, we extracted baseline, end-of-treatment, and interval data.

We extracted participant data regarding diagnosis, age, gestation, and parity. We also extracted details of acupuncture treatment, including type of acupuncture (Chinese/“Western”/or mixed), acupoints used, frequency and duration of treatment, number of sessions, type of stimulation, and whether or not de qi was obtained (De qi, literally meaning “arrival of energy,” is a term used in acupuncture and refers to a sensation of numbness or distension sometimes generated by stimulating acupuncture nee-

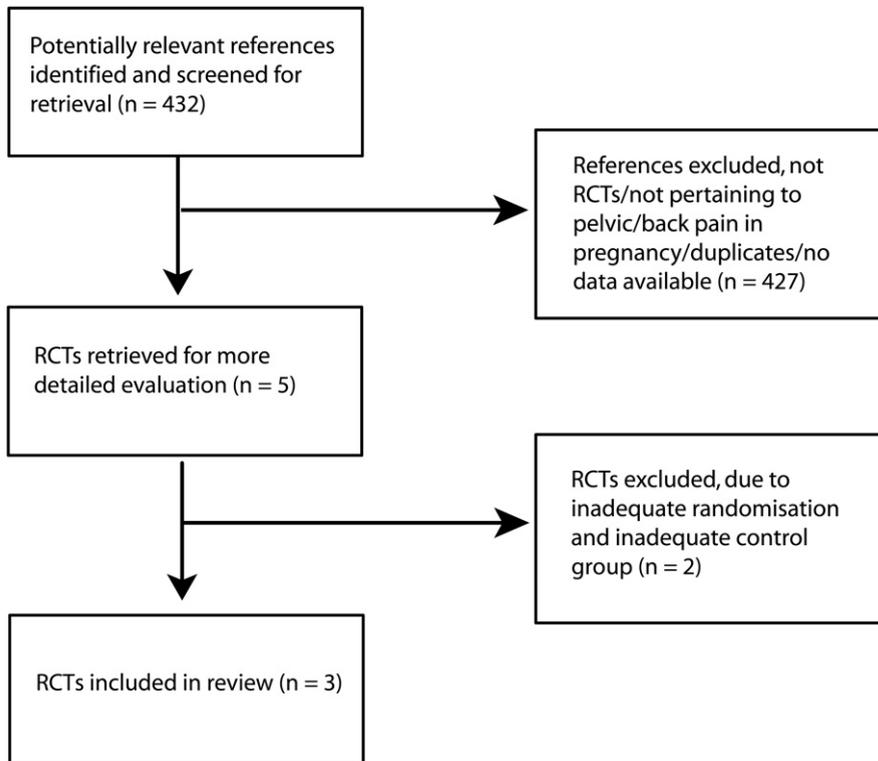
dles. According to acupuncture theory, activation of de qi may be one indication that acupuncture is exerting its beneficial effects). Details of the control group intervention and cointerventions were also extracted. We attempted to contact the chief investigators for missing trial data.

Trial quality was assessed by 2 independent reviewers according to 2 scales. The first scale used was a modified Jadad scale assessing adequacy and reporting of the randomization method, participant blinding, testing of participant blinding after treatment, and reporting of dropouts and withdrawals. We regarded a score of 2 points or less out of a total of 5 points as indicating a poor quality trial.

The second scale used was modified from Cochrane Back Review Group criteria²⁹ (Table 1). We added criteria for adequate acupuncture treatment³⁰ and adequate sample size calculation. Both reviewers are practicing acupuncturists. We regarded a score of 5 or less out of a total of 12 points as indicating a poor quality trial.

We intended to combine data, if sufficient data were available, in a metaanalysis using Cochrane Review Manager software (RevMan software, version 4.2, Nordic Cochrane Centre, Copenhagen, Denmark), first performing chi-square testing to assess heterogeneity. We intended to use a random effects model if significant statistical heterogeneity ($P < .1$) was found. Alternatively, we planned to use a narrative synthesis if significant

FIGURE
Summary of trial flow



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clinical heterogeneity and too few trials were found. If appropriate, we intended to generate sensitivity analysis and a funnel plot.

RESULTS

The **Figure** summarizes the trial flow. We found 10 papers from our MEDLINE search and 421 papers from searching other databases. We excluded the vast majority of papers after a careful initial screen because we found them to be duplicates, not randomized controlled trials (RCTs), or not pertaining to acupuncture for pelvic/back pain in pregnancy. We found 1 ongoing trial of acupuncture for back pain in pregnancy (CRISP-Computer Retrieval on Scientific Projects. Acupuncture and Low Back Pain during Pregnancy. Available at: http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?textkey=7012732&p_grant_num=5R21AT00161302&p_query=&ticket=27900274&p_audit_session_id=192845617&p_keywords=. Retrieved July 14, 2006). The investigators did not have any data that could be in-

cluded in our review at the time of writing (personal communication, Shu-Ming Wang, 2006). We contacted 12 acupuncture researchers, and from this communication we identified 1 other ongoing trial, which was investigating acupuncture for pelvic pain in pregnancy. No data were available from this trial either at time of writing (personal communication, Helen Elden, 28 March 2007). We retrieved full text articles for 5 RCTs.

We excluded 2 trials from the initial 5 that were retrieved. One was inadequately randomized (according to days of the week),³¹ and the other compared 2 different types of acupuncture (superficial vs deep stimulation of acupuncture points) without a nonacupuncture control group.³² We included the final 3 trials, with a total of 448 women analyzed, in our review.³³⁻³⁵ As the trials were clinically heterogeneous and few in number, we could not combine them in a metaanalysis.

Table 2 summarizes the characteristics and main findings of the 3 included tri-

als. None of the trials reported using an intention-to-treat analysis; therefore, we have reported the numbers allocated, numbers analyzed, and the percentage of women who dropped out after allocation. No standard deviations were reported in any of the trials; hence, we were unable to calculate confidence intervals. Where available, we have reported *P* values. We obtained unpublished end-of-treatment data for Elden et al’s trial from the chief investigator. We were unable to establish communication with researchers from the other trials.

Wedenberg et al³³ reported acupuncture to be superior to individualized physiotherapy in their small trial. It is important to note here that the acupuncture group received auricular acupuncture plus body acupuncture “if needed.” It was unclear how many patients received auricular acupuncture alone, and if the acupuncture group received any cointerventions. Duration of treatment and time of follow-up varied between the 2 groups. The trial’s major flaw was that large numbers of women dropped out of the physiotherapy group.

Kvorning et al³⁴ compared an acupuncture group with a control group that received no additional treatment. Cointerventions were allowed in both groups. The dropout rate was significant in both groups, and we judged the trial to be underpowered. Interestingly, the acupuncture needles were withdrawn after de qi was obtained, whereas in accepted clinical practice they are usually retained for 20 minutes when treating pain. We noted the risk of contamination in this trial, with the authors reporting “12 patients were incorrectly included” because “rumors of successful treatment . . . had made further potential participants unwilling to accept the risk of being randomized to the control group.” Although the authors report assessing pain using a VAS, no data on VAS were published. It was reported that more women in the acupuncture group reported a decrease in their pain at end of treatment, compared with the control group.

The largest and highest quality trial in our review was a multicenter trial conducted by Elden et al.³⁵ Women with well-defined pregnancy-related

TABLE 2

Study characteristics and main findings of randomized controlled trials of acupuncture for pelvic and back pain in pregnancy

First author, year	Participants		Description of intervention	Quality	Main findings																				
	Numbers allocated, (numbers analyzed), [dropout rate]	Age median (y), trimester, primipara/multipara (%)																							
Wedenberg, 2000	Acupuncture	30 (28) [7%]	28.6, 2nd and 3rd, 30/70	Chinese acupuncture—auricular points plus body acupuncture points if needed, for 4 weeks. Unclear if cointerventions allowed in acupuncture group. Physiotherapy plus physical therapies (pelvic belt, warmth, massage, soft tissue mobilization-individualized) for 6-8 weeks.	Modified Jadad 3/5; Cochrane Back Review Group (BRG) 3/12; overall quality rated poor	Pain: Statistically significant reduction of pain in both groups, with greater relief of pain reported by the acupuncture group (decrease in mean evening VAS from 7.4/10 baseline to 1.7/10 end-of-treatment) compared with control group (6.6/10 baseline to 4.5/10 end-of-treatment). $P < .01$ in both groups. Function: Nonstatistically significant reduction of Disability Rating Index in acupuncture group, and increase in control group. Other: 27/28 women in acupuncture group reported “good or excellent help from treatment” compared with 14/18 in control group. Statistical significance not provided.																			
	Control	30 (18) [40%]					Kvorning, 2004	Acupuncture	50 (37) [26%]	30, 3rd, unclear	Chinese acupuncture plus tender points, plus cointerventions as desired. Duration of treatment and end-of-treatment follow-up point unclear. No additional treatment, but cointerventions (physiotherapy, analgesics, etc) allowed in both groups.	Modified Jadad 3/5; Cochrane BRG 6/12; overall quality rated high	Pain: More women in acupuncture group reported decrease in pain (60% acupuncture group vs 14% control group, $P < .01$). Function: 43% of women in acupuncture group reported decrease in pain during physical activity compared with 9% in control group ($P < .001$). Analgesic use: 14% in control group used analgesics; no women in acupuncture group needed analgesics ($P < .05$).	Control	50 (35) [30%]		Elden, 2005	Acupuncture	125 (107) [14%]	30.3, 2nd, 27/73	Mixed Western and Chinese acupuncture plus standard treatment (see Control) for 6 weeks. Standard treatment consisting of advice, education, exercises, pelvic belt for 6 weeks. Stabilizing exercises plus standard treatment for 6 weeks.	Modified Jadad 3/5; Cochrane BRG 7/12; overall quality rated high	Pain (at 1 week): Statistically significant difference in median evening VAS (0-100) at 1 week between intervention and control groups, with lowest VAS in acupuncture group (<i>Acupuncture group:</i> baseline 65, 1-week 31; <i>Stabilizing exercises group:</i> baseline 60, 1-week 45; <i>Control group:</i> baseline 63, 1-week 58; $P < .001$ for acupuncture-control comparison; $P < .05$ for stabilizing exercises-control comparison). Pain (at end-of-treatment): Median evening VAS at end-of-treatment was lowest in acupuncture group (35) compared with control group (59) and stabilizing exercises group (50). Statistical significance not provided and unable to be calculated from median values given. Other: Fewer women in acupuncture group complained of pain when turning in bed at end-of-treatment compared with those in the control and stabilizing exercises group (66% acupuncture group vs 88% control group vs 71% stabilizing exercises group; $P < .001$ for acupuncture-control comparison).	Control	130 (108) [17%]
Kvorning, 2004	Acupuncture	50 (37) [26%]	30, 3rd, unclear	Chinese acupuncture plus tender points, plus cointerventions as desired. Duration of treatment and end-of-treatment follow-up point unclear. No additional treatment, but cointerventions (physiotherapy, analgesics, etc) allowed in both groups.	Modified Jadad 3/5; Cochrane BRG 6/12; overall quality rated high	Pain: More women in acupuncture group reported decrease in pain (60% acupuncture group vs 14% control group, $P < .01$). Function: 43% of women in acupuncture group reported decrease in pain during physical activity compared with 9% in control group ($P < .001$). Analgesic use: 14% in control group used analgesics; no women in acupuncture group needed analgesics ($P < .05$).																			
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pelvic pain in their second trimester were randomized into 3 groups. All groups received standard treatment, with 1 group receiving acupuncture as an adjunct and another receiving stabilizing exercises as an adjunct. The researchers reported median instead of mean values. The combination of acupuncture and standard treatment was found to be the superior treatment in this trial, at both the 1 and 6 weeks follow-up visits.

No serious adverse events were reported across the 3 trials. There were less than 6 reports each of minor adverse events, such as local pain or bruising, sweating, nausea, weakness and tiredness in Kvorning et al's³⁴ trial. Wedenberg et al³³ reported that "most women" complained of tiredness and 2 women reported subcutaneous auricular hematomata. We judged the acupuncture regime to be adequate in all 3 trials.

COMMENT

Limited evidence suggests that acupuncture given in addition to standard treatment is more effective than standard treatment alone, physiotherapy, or stabilizing exercises in relieving pelvic and back pain in pregnancy. Although the trials found in our review were small in number and clinically heterogeneous, the trial by Elden et al³⁵ is well-conducted and provides good evidence for the effectiveness of acupuncture in pregnancy-related pelvic pain.

Difficulties in this review included making the decision to include both pelvic and back pain in pregnancy. There is disagreement in medical circles as to whether pelvic and back pain in pregnancy are separate clinical entities. Some experts believe that the 2 can and should be distinguished clinically and that they respond to different treatments and have different risk factors.³ The counter argument has been that the prognosis for both is similar, previous studies have not been able to convincingly distinguish between the 2, and that back pain probably forms a subset of pregnancy-related pelvic pain.³⁶ In our view, the proposed physiological mechanisms (joint laxity,

increase in lumbar lordosis, muscular insufficiency)^{5,37,38} causing pelvic and/or back pain appear similar. At any rate, the etiology and treatment of the syndromes remains a matter of debate, and we decided to include both syndromes in our review.

A limitation of our review was the few trials found in our search. However, the search was comprehensive—we used the Cochrane highly sensitive Medline search strategy,²⁵ contacted key acupuncture researchers, and searched trial databases. Its main limitation was the English language restriction, hence excluding most studies from China. We felt this would not impact greatly, as there is a significant bias toward publishing positive findings in China³⁹ and studies tend to suffer from poor design. It is interesting to note that all 3 trials were conducted in Sweden, although we see no reason why these results should not apply in other countries.

A third problem was that no trials included in our review had a placebo acupuncture arm. The issues of placebo and nonspecific effects in acupuncture are complex and have been extensively debated in the literature.^{30,40} A detailed discussion is beyond the scope of this paper. The issues relevant to this review are whether the expectations, beliefs, and subsequent behaviors of patients and/or practitioners influenced outcomes, as none of the trials were blinded. As such, our findings reflect the overall effectiveness (specific and nonspecific effects) of acupuncture for pregnancy-related pelvic and back pain, rather than its efficacy (specific effects).

It has been demonstrated that both patient expectation and practitioner behavior can result in greater placebo analgesia.^{41,42} In fact, some have postulated that acupuncture may have a "placebo-enhancing effect."⁴³ Kvorning et al reported that 12 women had to be excluded because rumors were circulating about the success of acupuncture treatment; the expectancy of the acupuncture group in this trial may have overinflated the positive results. "Placebo needles" have been developed that do not involve penetration of the skin or induce de qi, but simulate true acupuncture in most

other aspects.⁴⁴ This would control for patient expectations, but it is probably impossible to blind needle acupuncture practitioners.

Within these limitations, our review method was robust and its main findings are consistent with Young and Jewell's 2002 Cochrane review¹³ which included Wedenberg's trial. Our results are also consistent with the hypothesis that acupuncture relieves pain and that it is a relatively safe procedure. Few and minor adverse events were reported, which may be reassuring for practitioners who feel nervous about treating pregnant women. Though the sample sizes were relatively small, they add to the findings from Ternov and colleagues' case series of 167 women treated in pregnancy with no serious adverse events.¹⁵

Overall, our review finds limited, though promising, evidence for the effectiveness of acupuncture in managing pelvic and back pain in pregnancy. In particular, there seems to be good evidence that acupuncture, in addition to standard treatment, is superior to standard treatment alone and stabilizing exercises for well-defined pregnancy-related pelvic pain. Given that acupuncture is a relatively safe procedure, these findings should encourage primary health care providers, obstetricians, and midwives to consider referring women to trained acupuncturists for management of this common, painful, and disabling condition. Stronger evidence is needed, and we look forward to the results of the 2 ongoing trials identified. Additionally, we feel that a consensus as to the nature, etiology, and "standard treatment" of pregnancy-related pelvic and back pain is essential to prevent further dilution of the evidence through heterogeneity. Systematic reviews of acupuncture frequently conclude with a recommendation for more trials. However, it is not simply a matter of numbers. Larger trials would be a start. There is also a pressing need for these to be based on rigorous methodology and a careful consideration of the issues inherent in acupuncture research, such as its nonspecific effects, and reported according to the STandards for Reporting In-

Interventions in Controlled Trials of Acupuncture (STRICTA) guidelines.⁴⁵ ■

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