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Acupunct Med 2004 22: 60-67
doi: 10.1136/aim.22.2.60

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Acupuncture for low back pain in pregnancy

– a prospective, quasi- randomised, controlled study

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Summary

This study was undertaken to investigate the effects of acupuncture in low back and pelvic pain during pregnancy under real life conditions, as compared with patients undergoing conventional treatment alone. A total of 61 conventionally treated pregnant women were allocated randomly into two groups to be treated or not by acupuncture. Twenty-seven patients formed the study group and 34 the control group. They reported the severity of pain using a Numerical Rating Scale from 0 to 10, and their capacity to perform general activities, to work, and to walk. We also assessed the use of analgesic drugs. Women were followed up for eight weeks and interviewed five times, at two-week intervals. All women completed the study. In the study group the average pain during the study period showed a larger reduction (4.8 points) than the control group (-0.3 points) ($P<0.0001$). Average pain scores decreased by at least 50% over time in 21 (78%) patients in the acupuncture group and in five (15%) patients in the control group ($P<0.0001$). Maximum pain and pain at the moment of interview were also less in the acupuncture group compared with the control group. The capacity to perform general activities, to work and to walk was improved significantly more in the study group than in the control group ($P<0.05$). The use of paracetamol was lower in the acupuncture group ($P<0.01$). These results indicate that acupuncture seems to alleviate low back and pelvic pain during pregnancy, as well as to increase the capacity for some physical activities and to diminish the need for drugs, which is a great advantage during this period.

Keywords

Acupuncture, low back pain, pelvic pain, pregnancy, analgesic drugs.

Introduction

Low back and pelvic pain in pregnancy are often treated as minor and inevitable,¹ but they are one of the most common complaints reported, with a prevalence varying from 48% to 76% according to different authors.²⁻⁶

The most commonly cited causes of lower back pain are mechanical, hormonal and circulation problems, or a combination of these.⁷ They include changes in balance mechanics between the pelvis and the lumbar segment of the spinal column, hyperlordosis due to an increase in the uterine volume, and ligamentous relaxation in the pubic symphysis and sacroiliac joints induced by release of relaxin, a peptide hormone found in the corpus luteum of the pregnant woman, in the decidua and the placenta. The weight of the foetus on the lumbosacral nerve roots and the reduction in the blood flow due to compression of the great vessels by the gravid uterus are also important factors for

the appearance of low back and posterior pelvic pain.^{7,9} Pain is usually worse later in the day, with physical exercise, with certain movements and with the evolution of the pregnancy. Young women frequently suffer more than older women, although repeated births are a risk factor.⁷

Obstetric textbooks pay little attention to low back and pelvic pain but it is a common topic in scientific journals, including those directed at orthopaedic surgeons,⁷ rheumatologists,⁴ and nurses.¹⁰ These professionals are concerned to find non-pharmacological solutions for the problem, such as posture counselling groups, exercises, water gymnastics, appropriate shoes and the use of elastic stockings.¹⁰⁻¹²

Acupuncture has frequently been studied for treatment of low back pain, with many positive results.^{13,14} The underlying mechanisms of action are not totally clear but it seems that the somatic and autonomic nervous system, the neuroendocrine

systems and the endogenous opioids play important roles. Low back pain in pregnancy, however, has not been properly studied and there are few publications in the international literature. Thomas & Napolitano presented a case report, and were surprised by the improvement in the pain, the reduced need for medicines and the improvement in the quality of life of the pregnant woman treated by acupuncture.¹⁵ Wedenberg and colleagues studied 60 pregnant women randomised to treatment with acupuncture or physiotherapy.¹⁶ They found a significant improvement in the pain, and a greater ability to perform daily routine activities (as assessed by the Disability Rating Index) in the acupuncture group when compared with the physiotherapy group. In a retrospective observational study with 167 pregnant women, Kvorning and colleagues found that 72% of patients had good analgesic effects and no major adverse effects.¹⁷ In a subsequent RCT, the same authors found that patients from the acupuncture group had significantly less pain – and specifically pain associated to physical activities over time – when compared to control patients who had no acupuncture. They did not find serious adverse effects in the patients or in the infants.¹⁸

A systematic review by Young and Jewell concluded that, although more information is necessary, there are indications that acupuncture is useful in the treatment and prevention of low back and pelvic pain during pregnancy.¹⁹

The aim of this study was to determine the effects of using acupuncture for the treatment of low back and pelvic pain under real life conditions by comparing two groups treated conventionally, where one of them was also treated with acupuncture.

Methods

The Research Ethics Committee of the Federal University of São Paulo, Brazil, approved this study, which ran from July to December 2002. A project was initiated offering acupuncture to pregnant women attending the prenatal programme of Santa Casa of São José do Rio Preto (São Paulo State), with the aim of treating the most common non-obstetric complaints. This is a state funded service that receives pregnant

women from the local area who participate in a prenatal programme. This report deals only with those patients who complained of low back or pelvic pain. From the total group of 79 women (39 in the study group and 40 in the control group), 61 (77.2%) complained of low back and pelvic pain. Of these, 27 were treated using acupuncture and 34 were treated conventionally.

After giving their informed consent, the pregnant women who attended programmes on Tuesdays and Thursdays (study group) were referred to acupuncture and conventional treatment with the analgesic drug paracetamol (500mg) and the anti-spasmodic drug hyoscine (10mg). Those attending the Monday and Wednesday programmes (control group) were given the conventional treatment only. With the exception of the acupuncture treatment, there was no difference between the groups.

The inclusion requirements were: age from 15 to 39 years, 15 to 30 weeks of pregnancy and at least minimal low back or pelvic pain. They should not have had any chronic handicapping back pain before pregnancy or any organic lesion such as disc hernia. They should not belong to a high risk pregnancy group and they also should not have been treated by acupuncture in the preceding year.

Although some authors suggest that it is important to distinguish low back pain from isolated pelvic girdle pain,^{5,20} in this study lumbar back pain and pelvic pain are both included. Differentiating between back and posterior pelvic problems is a challenge, and there is no accepted method to distinguish them,²¹ even using proposed new syndromes.²² Pain drawings are likely to be insufficient to differentiate between the two types of pain because women cannot always distinguish between low back and pelvic pain,³ and must be supported by a typical history and clinical examination by an experienced examiner. In general, pelvic and low back pain are often considered together.¹⁶⁻¹⁸

Outcome measures

At the baseline and at final interview, the women estimated the severity of their pain using a numerical rating scale (NRS) from 0 to 10, where 0 meant no pain and 10, the greatest imaginable

pain. Three time frames were used for pain intensity: now, average during the previous 14 days and maximum during the previous 14 days. Women were asked to report their dosage of medication, where one 500mg tablet of paracetamol was considered one dose. At the same time points, the pregnant women were invited to evaluate, by means of the NRS, their functional capacity: general activities, working and walking. For this they also used a 0 to 10 scale, where the higher score indicated a greater disability (ie lower capacity).

At baseline, all women were also requested to fill in a questionnaire covering background data, pain history before the first visit and previous obstetric history. Then they were referred to their obstetricians (control group) or to the acupuncturist (study group). The patients of the study group also visited their respective obstetrician after the acupuncture sessions.

Additionally, at two weekly intervals, the women scored the average severity of their pain and the use of medications in the previous 14 days.

A medical student, appropriately trained, performed all the interviews, and had minimal contact with other members of the study.

Acupuncture treatment

Treatment with acupuncture was normally performed once a week, though occasionally twice when it was deemed necessary for severe pain, over an eight-week period, making a minimum of eight and a maximum of 12 sessions.

Traditional acupuncture was used, respecting the classical acupuncture points including the depth of insertion. Sterile stainless steel needles of 40mm in length and 0.2mm in diameter were used. Neither electro-stimulation nor ear acupuncture was used. On average 12 needles were inserted and an attempt was made to elicit *de qi* at each point. Needles were left in place for about 25 minutes.

The acupuncturist in the study had completed 600 hours of postgraduate training in acupuncture, including the theory and practice of traditional Chinese medicine. He has 15 years experience treating at least 50 patients a day in a publicly provided service. In order to facilitate the treatment protocol, a decision was made to use

standard points, with an option of up to four additional points. The most commonly used points were: K13, S13, BL62, BL40, TE5, GB30, GB41 and the *huatojiaji* points, located along the spinal column, 1cm from the midline.

Control group

This group was treated conventionally with paracetamol and hyoscine, which is often used in this obstetric unit for low back pain.

Statistical analysis

The Anderson-Darling test for normality was performed to test the distribution of the data. Results are reported as differences of means and standard deviations (SD) or medians and interquartile ranges (IQR). Changes over time in the NRS assessments of pain intensity were analysed by the Fisher exact test. Differences between initial and final sessions for average and maximum pain scores were compared using a two-sample *t* test. The other outcomes reported by the two groups (current pain, use of paracetamol and functional capacity) were compared using Mood's test for medians. The level for significance was set at $P < 0.05$.

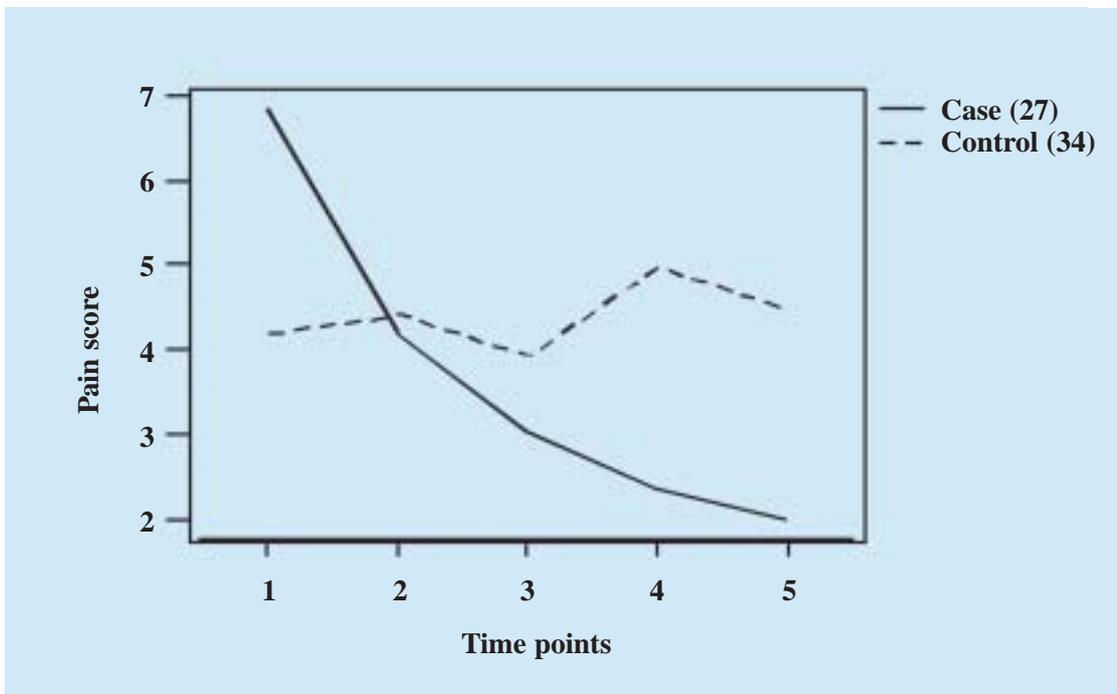
Results

All the 61 pregnant women completed the treatment and concluded all the interviews. There were no important adverse effects from acupuncture. Two women mentioned small bruises, three reported ecchymosis at one or two points, and one of them experienced a higher level of pain during a few hours after the first session. The birth weights of the infants in the two groups did not differ significantly, being 3179g (SD 355g) in the acupuncture group and 3260g (SD 292g) in the control group ($P=0.35$). The mean value for the one-minute Apgar score was 8.8 (SD 0.7) in the acupuncture group and 8.4 (SD 0.4) in the control group ($P=0.58$). One infant in the acupuncture group scored six at one minute, and two in the control group scored seven. The mean value for five-minute Apgar was 9.8 for both groups ($P=0.9$). The two groups were similar in respect to age, number of previous pregnancies, number of previous miscarriages, physical build, weight and body mass index as can be seen in Table 1.

Table 1 Background data for 61 pregnant women in controlled trial of acupuncture for back pain

	Study group		Control group	
	Mean	(SD)	Mean	(SD)
Age in years	27.4	(6.1)	25.3	(5.7)
Height in centimetres	162.0	(6.8)	161.0	(7.5)
Current weight in kg	64.2	(11.2)	64.8	(13.2)
Pre-natal weight in kg	58.8	(10.1)	60.2	(13.4)
Pre-natal BMI	22.2	(3.2)	23.0	(4.6)
BMI corrected for gestational age	24.3	(3.7)	24.8	(4.7)
Gestational age in weeks	19.9	(4.6)	21.0	(4.4)
Start of pre-natal program in weeks*	10.0	(6.0)	13.0	(6.0)
Total gestations including this*	1.9	(1.0)	2.5	(2.0)
Parity*	0.6	(1.0)	1.2	(2.0)
Miscarriages*	0.2	(0.0)	0.2	(0.0)

Values are means (SD) unless otherwise indicated
*median (interquartile range)

**Figure 1** Average VAS pain scores in the two groups at different time points through the study.

Pain

During treatment, a reduction in NRS scores was apparent in the acupuncture group, while the values fluctuated around the same level in the control group, as can be seen in Figure 1. Over the course of treatment, the reduction in average pain score in the acupuncture group was significantly higher than in the control group: acupuncture 4.8 (SD 2.3), controls -0.3 (SD 4.2) ($P<0.0001$). The same difference was shown for the changes in scores for maximum pain: acupuncture 4.8

(SD 3.2), controls 0.1 (SD 3.9), ($P<0.0001$); and for current pain: acupuncture 0.0 (IQR 5.0), controls 0.0 (IQR 0.3) ($P<0.001$) (Table 2). Considering the responder rate, the average pain intensity decreased by at least 50% in 21 (78%) patients in the acupuncture group compared with only five (15%) of the control group ($P<0.0001$).

Other outcomes

Over the course of the treatment, the acupuncture

Table 2 Mean differences (initial minus final) of average pain, worst pain and pain now, in acupuncture and control groups

	Acupuncture (n=27)		Control (n=34)	
Average pain ^a	4.8	SD 2.3	-0.3	SD 4.2
Worst pain ^b	4.8	SD 3.3	0.1	SD 3.9
Pain now ^c	0.0	IQR 5.0	0.0	IQR 0.3

^a and ^b: data normally distributed, compared using t test, $P < 0.0001$ for both

^c: data skewed, compared using Mood's test, $P = 0.001$

group took fewer doses of paracetamol than the control group. Differences in the median number of daily doses between the initial and final interviews were 2.0 (IQR 6.0) vs 0.0 (IQR 0.0) ($P = 0.005$). The results with hyoscine doses were similar (data not shown).

After treatment, functional capacity improved significantly more in the acupuncture group than in the control group (Figures 2, 3 and 4). Differences in median scores between initial and final interviews for general activity were: 1.0 (IQR 3.0) in the acupuncture group, and 0.0 (IQR 2.2) in the control group, ($P = 0.01$). For work, the differences in median scores were 0.0 (IQR 3.0) in the acupuncture group and -1.0 (IQR 3.0) in the control group ($P < 0.001$). For walking, the differences in median scores were 0.0 (IQR 3.0) in the acupuncture group and -2.0 (IQR 4.0) in the control group ($P < 0.001$).

Discussion

Low back pain is one of the most common complaints seen in antenatal care. In our cohort, we observed an incidence of 77% (61/79), a proportion that conforms to results obtained elsewhere.²⁻⁶ Acupuncture proved in this study to be associated with a significant reduction of pain, diminished need for analgesics, and improved functional capacity. The pain intensity was reduced in all three time-frames: current pain; average in the last 14 days; and maximum in the last 14 days. In addition, functional capacity in terms of general activities, working and walking, were significantly improved after acupuncture compared with the control group. The age, number of previous pregnancies and body mass index were similar in the two groups, excluding them as the reason for the differences between the outcomes.

The study design has certain limitations. The control patients did not receive a sham acupuncture

intervention and thus could not be blinded. In order to reduce bias we minimised the contact between therapist and interviewer, and talked to the pregnant women about bias. The acupuncture group received more attention, which clearly may have a positive effect. The study design was similar to that of Vickers,²³ ie a pragmatic study comparing a policy of using acupuncture with one of avoiding acupuncture, therefore a sham treatment was not considered. It should be noted that at least one previous study has shown that real acupuncture is superior to placebo in treating low back pain.²⁴

Much has been written about the choice of the control group in acupuncture research, and it is not yet clear what is meant by the term 'placebo acupuncture'. It appears that even locations that are not traditional points can have important effects,²⁵ and that sham procedures on true or dummy points, with the use of cocktail sticks for example, can produce effects.^{26,27} Our aim therefore, was to observe the result of treatment by acupuncture on low back and pelvic pain under real life conditions and on the wellbeing of the patients compared with a group of patients who were not treated in this way. This matches the third category of a classification offered by Hammerschlag, acupuncture plus standard care versus standard care only.²⁸ This may be the most ethical option in that there is no attempt to deny subjects effective standard treatment.²⁹

One strength of this study is that its results are similar to those of some previous studies on acupuncture for low back and pelvic pain in pregnancy. Effects found in this trial that have been reported before include: observed analgesic effect which was greater than in the control group,¹⁵⁻¹⁸ decrease in analgesic use,¹⁸ and increase in activity.^{16,18}

Many acupuncturists are reluctant to use acupuncture in pregnant women, as they believe that some points might trigger uterine contractions.

In this work no important adverse effects were seen. There were no significant differences between weight or Apgar scores of the infants of the two groups. These data are congruent with

results reported by other authors, as no maternal or obstetric side-effects have been found during or after more than 2300 acupuncture stimulations in 421 pregnant women.^{16-18,30,31}

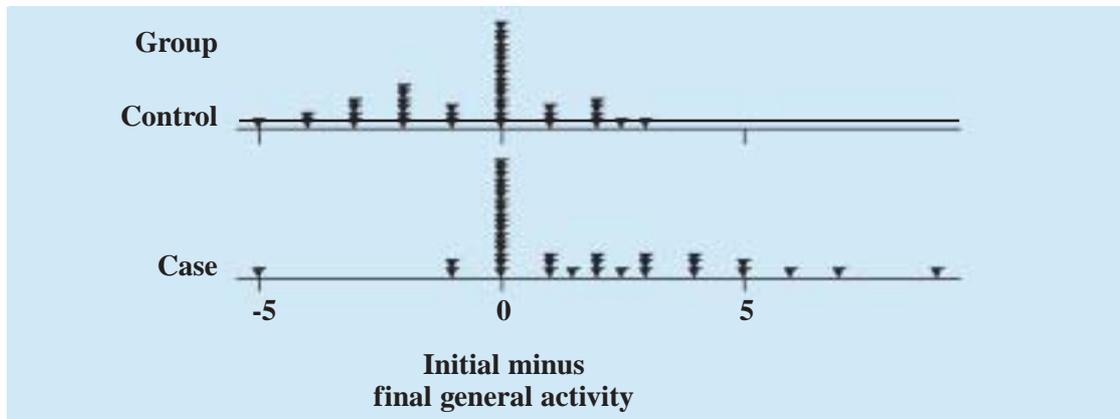


Figure 2 Differences in capacity [not 'of disability'] for general activity.

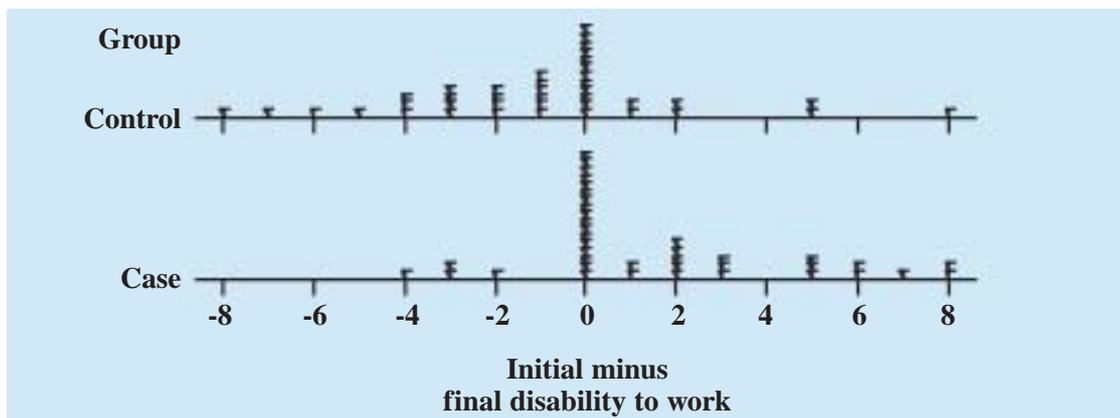


Figure 3 Differences in capacity for work, before and after treatment, according to groups ($P=0.001$).

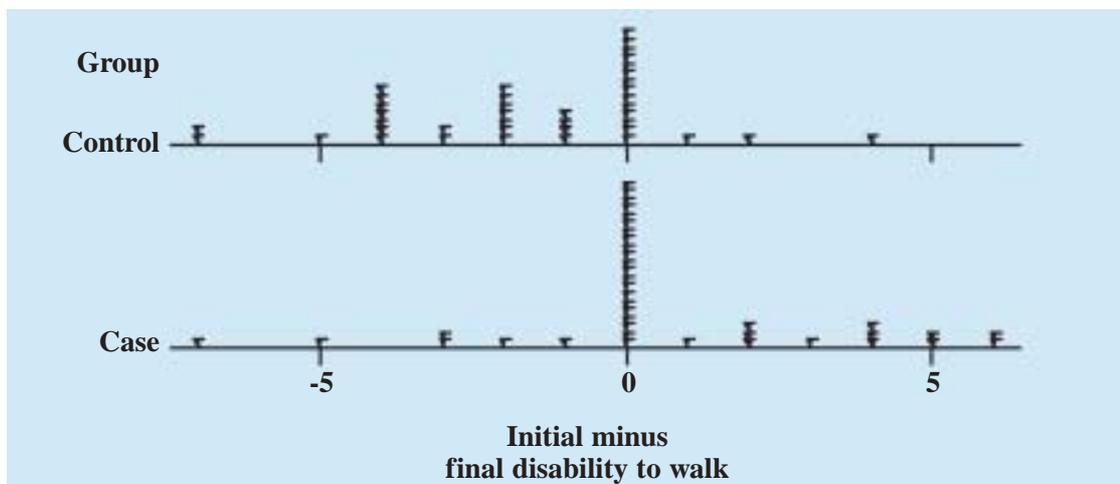


Figure 4 Differences in capacity [not 'of disability'] for walking, before and after treatment, according to groups ($P=0.001$).

Conclusion

Low back and pelvic pain are common problems in pregnancy. The use of medications is always a risk. According to this study and those previously conducted, acupuncture appears to be an effective means of reducing the symptoms and improving the quality of life of pregnant women. This technique should be further studied in prospective randomised studies of large populations to confirm our findings in efficacy and the absence of adverse effects. It is simple to apply and if used in an appropriate manner can reduce the necessity of medications.

Summary points

Low back and pelvic pain are common in pregnancy and drug therapy should be avoided if possible

Two previous randomised controlled trials have found acupuncture to be superior to either physiotherapy or no additional care

This quasi-randomised study in 61 women adds further evidence of the effect and safety of acupuncture in low back and pelvic pain in pregnancy

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