

# Acupuncture relieves pelvic and low-back pain in late pregnancy

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**Background.** The study was designed to evaluate the analgesic effect and possible adverse effects of acupuncture for pelvic and low-back pain during the last trimester of pregnancy.

**Methods.** Following individual informed consent, 72 pregnant women reporting pelvic or low-back pain were randomized during pregnancy weeks 24–37 to an acupuncture group ( $n=37$ ) or to a control group ( $n=35$ ) at three maternity wards in southern Sweden. Traditional acupuncture points and local tender points (TP) were chosen according to individual pain patterns and stimulated once or twice a week until delivery or complete recovery in acupuncture patients. Control patients were given no sham stimulation. Throughout the study period each patient made weekly visual analog scale (VAS) evaluations of maximal and minimal pain intensity as well as three-point assessments of pain intensity during various activities.

**Results.** During the study period, VAS scorings of pain intensity decreased over time in 60% of patients in the acupuncture group and in 14% of those in the control group ( $p < 0.01$ ). At the end of the study period, 43% of the acupuncture patients were less bothered than initially by pain during activity compared with 9% of control patients ( $p < 0.01$ ). No serious adverse effects of acupuncture were found in the patients, and there were no adverse effects at all in the infants.

**Conclusion.** Acupuncture relieves low-back and pelvic pain without serious adverse effects in late pregnancy.

**Key words:** acupuncture; maternity care; pain; pregnancy; tender points

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This prospective, randomized, open study was designed to evaluate the analgesic effect and possible adverse effects of acupuncture for various kinds of nociceptive pain during the last trimester of pregnancy.

Pain in the pelvic and low-back regions during pregnancy is a common and sometimes serious clinical problem during a period of life with considerable professional, social and emotional demands and expectations. Between 49% and

76% of pregnant woman have low-back and/or pelvic pain (1,2), which often increases gradually during pregnancy (2). Pain is nevertheless often left insufficiently treated, for example because of fear of using analgesic drugs during pregnancy.

Acupuncture was considered in a recent National Institute of Health consensus agreement (3) to be a useful alternative to, or complement of, traditional analgesic methods for low-back pain. Acupuncture was considered to be effective in 87% of patients and found to have only slight side-effects in a current retrospective study on low-back and/or pelvic pain during late pregnancy

**Abbreviations:**

TP: tender point; VAS: visual analog scale; LR: liver; GV: governing vessel; SI: small intestine.

(4). Moreover, acupuncture has been found to reduce low-back pain during pregnancy more effectively than physiotherapy in a recent prospective, randomized study (5).

**Materials and methods**

After the Human Research Ethics Committee at Lund University, Sweden, had approved the study design, the study was undertaken during a 2-year period at three maternity ward centers in southern Sweden.

One hundred patients in the third trimester of pregnancy presenting at the maternity wards with girdle or low-back pain (including mixed pain patterns) were enrolled in the study and randomized to be given acupuncture (group A; *n*=50) or act as controls (group C; *n*=50). Following informed consent, each patient was randomized according to the code (A or C; obtained in advance by throwing dice in pairs of 10) enclosed in envelopes (marked with the corresponding order number of inclusion) and opened consecutively by the midwife on inclusion. Patients with study periods shorter than 3 weeks were excluded.

After approximately 12 months, one of the participating maternity ward centres could no longer include new patients, as rumours of successful acupuncture treatment during the study period had made further potential participants unwilling to accept the risk of being randomized to the control group. For this reason, 12 patients were incorrectly included at this center. Hence, the results reported here are based on the remaining 88 patients, of whom approximately four-fifths were seen by one of three midwives at the two remaining maternity centers.

Of these 88 patients, seven acupuncture and nine control patients were excluded. In the acupuncture group, three patients were delivered within the minimal 3-week study period, two found acupuncture too unpleasant, one filled out her evaluations inadequately and one patient was lost during the vacation period of a midwife. In the control group, the protocol was inadequately filled in by five patients, three patients insisted on being given acupuncture and one had intolerable pain and was admitted at a hospital for pain relief and rest. Of the remaining 72 patients, 37 patients were given acupuncture and 35 served as controls (Fig. 1).

In the acupuncture group, acupuncture was given according to written instructions and periosteal stimulation was used when possible. Initially the acupuncture points LR3 and GV20 (if the patient was nervous) were stimulated together with local tender points (TP). If the response was

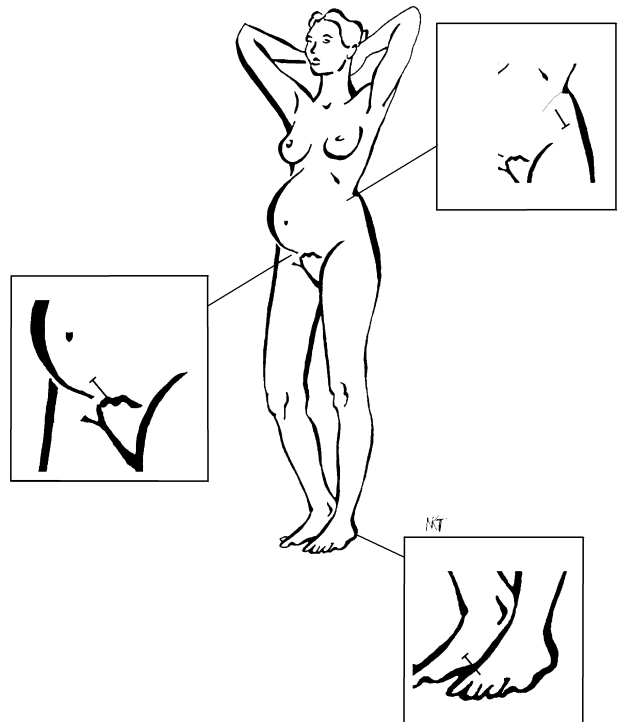


Fig. 2. Schematic positioning of acupuncture needles (shown clockwise from the upper right corner) used for stimulation of acupuncture or tender points (TP) at the proximal insertion of the minimal gluteal muscle tendon (TP), at the point LR3 and at the symphysis.

insufficient, stimulation at some of these points was combined with stimulation at the points BL60, SI3 or (using 2.5-inch needles) at one of the following locations (Figs 2,3): the lumbar and sacral bladder points BL22–26 (tangentially), the minimal gluteal muscle tendon 3–4 cm distal to the anterior superior iliac spine (tangentially), the sacroiliac tendons (obliquely towards the distal part of the ligament) or (using 1.0-inch needles) at the symphysis (perpendicularly).

On the first visit, Dechi (a Chinese word meaning “arrival of energy” and reported by patients as a characteristic feeling of local pain, heat, numbness or soreness) was achieved once at up to eight different acupuncture or trigger points. On later visits, manipulation of the needle was stopped as soon as Dechi was obvious but repeated after 30–60 s with the needle left in place between the two stimulations. After this, the needles were removed and the patient allowed to rest for at least 10 min. In the first 2-week period patients were given acupuncture twice a week and later on no more than once a week.

Each patient was asked to fill out a basic questionnaire on inclusion and to complete a follow-up protocol once a week throughout the study period. The midwife completed another follow-up protocol on each patient’s visit at the maternity ward. Initial information reported by each patient and midwife included week of pregnancy, diagnosis, former experience of and attitude to acupuncture, pain history before first visit to maternity ward, duration of pain during the past 24 h, other treatment for pain, current occupation and sick leave.

Follow-up information obtained once a week by each patient included visual analog scale (VAS) assessments of maximal and minimal pain intensity and assessments on a three-point scale (always; at intervals; never) of the influence of pain on each of eight defined kinds of physical

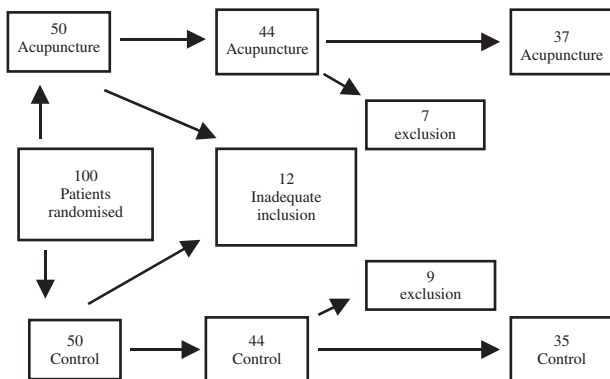


Fig. 1. Flow chart diagram showing patient exclusion after primary inclusion and randomization.

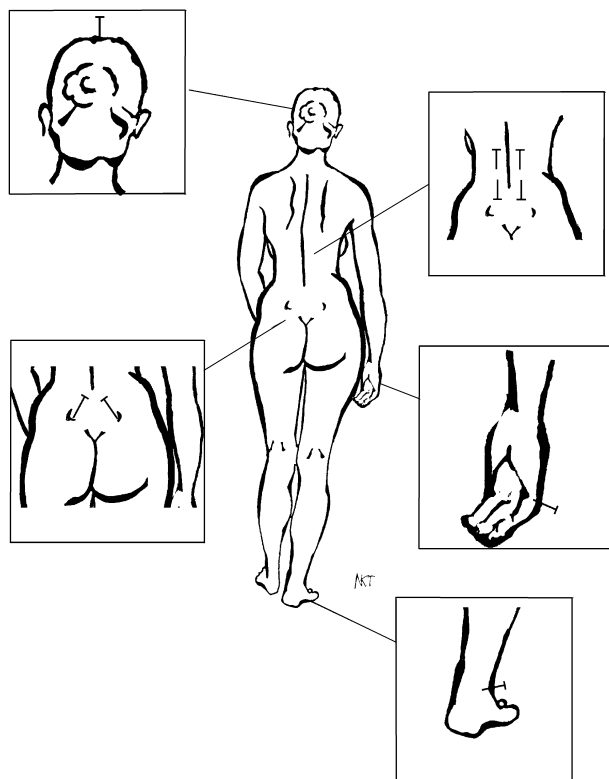


Fig. 3. Schematic positioning of acupuncture needles (shown clockwise from the upper right corner) used for stimulation along the bladder meridian bilaterally, at the points SI3 and BL60, at the sacroiliac ligament bilaterally and at the point GV20.

activity – sleeping, getting up, sitting down, sitting, walking and working (lightly or heavily) – together with other treatment for pain during the past week. On each visit to a maternity ward, the midwife also recorded how and where acupuncture was given and possible adverse events. The gestational week at delivery, birthweight of the infant and Apgar scores at 1, 5 and 10 min were recorded in the protocol by the midwife.

### Statistics

Before the study was carried out, a minimal number of 34 patients in each group had been calculated to be required to confirm statistically, with 80% power and 95% probability, a 30% difference in proportion of patients with decreasing pain intensity during the study period between the acupuncture and control groups. We expected problems associated with patient compliance and prediction of delivery dates with respect to the minimal 3-week follow-up period. Based on these considerations and the power analysis we included 50 patients in each group to allow 30% exclusion.

Statistical analysis of parametric data was made by comparing means between groups with the unpaired Student's *t*-test. For categorical outcome the  $\chi^2$ -test was used. The Statistica™ industrial software package (Stat Soft, Tulsa, Oklahoma, USA) was used for all statistical analysis.

Changes over time in VAS assessments of pain intensity and in physical activity scores for each patient were evaluated independently by two blinded investigators (N.K.T. and J.Å.). The results thus obtained were compared statistically by calculation of weighted kappa coefficients with 95% statistical confidence intervals (6).

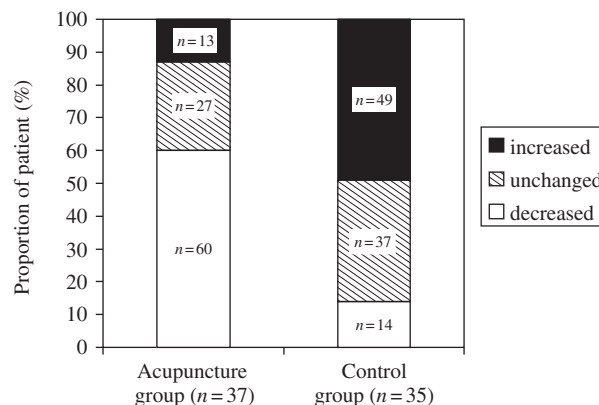


Fig. 4. Changes in pain intensity over time in acupuncture and control patients during the study period.

### Results

During the study period, pain intensity (Fig. 4) decreased in 60% of acupuncture patients and in 14% of patients in the control group ( $p < 0.01$ ). The two blinded investigators independently assessed the development of the patients' individual VAS scorings over time with a kappa coefficient of 0.68 (95% confidence interval 0.54–0.83). Two acupuncture and no control patients were found to be completely free of pain during their last 3 weeks of pregnancy.

Pain associated with various physical activities was found to decrease in 43% of acupuncture patients and in 9% of control patients during the study period ( $p < 0.001$ ). The kappa coefficient of the investigators' assessments of total change over time in pain during physical activities was 0.91 (0.82–1.00), whereas kappa coefficients for their assessments of changes over time in each of these defined physical activities ranged between 0.05 and 0.56.

There were no serious side-effects in the acupuncture group. Nevertheless, one or more of the following symptoms were reported by or found in 38% of patients given acupuncture: local pain ( $n = 6$ ), heat or sweating ( $n = 5$ ), local hematoma ( $n = 2$ ), tiredness ( $n = 2$ ), nausea ( $n = 2$ ) and weakness ( $n = 1$ ).

The acupuncture and control patients did not differ significantly in age ( $30 \pm 5.9$  years) or in gestational week ( $30 \pm 4.2$  weeks) at the first visit to the maternal care center. Approximately 75% of the patients were employed, 20% had been given acupuncture before and 20% reported a negative attitude to acupuncture with no significant differences between the groups.

At the time of inclusion, pain in the sacroiliac region or over the symphysis was reported by 78% of acupuncture patients and by 80% of control patients. No patient had clinical signs of

motor or sensory disturbances. Pain in the acupuncture group had lasted significantly longer than in the control group ( $8.8 \pm 5.6$  vs.  $6.0 \pm 3.8$  weeks;  $p < 0.001$ ), whereas there was no difference in the duration of pain during the past 24 h ( $9.8 \pm 7.1$  vs.  $9.2 \pm 7.4$  h). One patient in the acupuncture group and none in the control group was using analgesic drugs.

Between four and eight acupuncture points were used in most acupuncture patients, and those points stimulated most frequently were LR3, local TP and BL60. Acupuncture patients had, on average, 6.0 (range 3–11) and control patients 3.0 (1–8) visits to the maternal care center. During the study period, five patients in the control group and none in the acupuncture group ( $p < 0.05$ ) used analgesic drugs, and control patients used significantly more transcutaneous electrical nerve stimulation (6 vs. 0;  $p < 0.01$ ), sacroiliac belt (15 vs. 4;  $p < 0.01$ ) and physiotherapy (6 vs. 0;  $p < 0.01$ ) than acupuncture patients.

Acupuncture and control patients did not differ significantly in the birthweight of their infants ( $3.5 \pm 0.9$  kg). Ten-minute Apgar scores were 10 in all infants, and no single 1- or 5-min Apgar score was below 9.

## Discussion

Pain intensity, reflected in the VAS assessments, and pain associated with physical activity were both found to decrease over time in significantly more patients in the acupuncture group than in the control group. In accordance with this, the analgesic effects of acupuncture in late pregnancy have been reported in a recent retrospective study involving 167 patients (4) and in a prospective study on 28 patients (5). The above findings are further supported by the higher use of analgesic drugs and nonacupuncture analgesic techniques found in our control patients, indicating that the difference in pain intensity over time between the two groups would otherwise have been even larger. Accordingly, the use of other analgesic regimens was significantly lower in patients given acupuncture for labor pain in two other retrospective studies including almost 3500 patients (7,8). Comparing acupuncture and control patients by their changes in pain intensity during the study period can be considered as adequate, as these changes over time were found to be reliably assessable with high kappa coefficients.

Although only 72% of the patients completed the study, we still consider the statistical power to be high enough. First, the number of patients exceeded that calculated to be required in the

original power analysis. Second, this analysis was based on an assumed difference in reduction in pain intensity over time between acupuncture and control patients which was 35% lower than in the results obtained.

Even better analgesic effects than found here might be attained with a different acupuncture technique during pregnancy. Considering that there is still limited clinical experience of acupuncture for pain relief during pregnancy (9), we used fewer, shorter and less intensive stimulations in these patients than we would have used in nonpregnant chronic pain patients with similar complaints. On the other hand, perioral stimulation is more potent than traditional acupuncture in our opinion, and we also made sure Dechi was reached on each occasion.

The proportions of patients with lumbar or sacroiliac pain reported here conform to results obtained elsewhere (1,2). We consider randomization in the present study as adequate, as acupuncture and control patients were similar not only regarding pain distribution but also with respect to age, gestational week and short-term duration of pain. Nonetheless, we have no satisfactory explanation for the longer history of pain at inclusion of patients given acupuncture, and this difference was not caused by extreme values in single patients.

We are aware that little attention was paid to control patients (given no sham stimulation) in the present study, as is also indicated by their fewer visits to the maternal care centers. We decided to refrain from placebo treatment and instead designed the study with untreated controls to avoid unnecessary stress to the pregnant women. Furthermore, we considered the difficulties reported to be associated with placebo procedures, including skin penetration in clinical studies on acupuncture, for example the unspecific noxious inhibitory control effect of any needle penetrating the skin, also described as 'near-placebo' stimulation by Lewith and Vincent (10). Nevertheless, we are aware that an open study design means that the placebo effect should be expected to account for some difference in effect found when comparing treated patients with untreated control patients.

In southern Sweden acupuncture has been found to reduce clinical use of more traditional methods of analgesia and to have few and slight adverse effects during the second and third trimesters of pregnancy (4,5,7). The high rate of adverse effects reported by patients in the present study is unacceptable from a clinical point of view. This difference between the present study and the previous ones might be caused by different

definitions of adverse effects. In the present study the midwives had been told to ask for any kind of discomfort or sensation during and after each stimulation, and to record these carefully. Local pain during stimulation could result from frequent use of periosteal stimulation. Apart from this, most of the reported adverse effects are "hard-to-define" clinical entities that might have resulted from the achievement of Dechi or from visiting a maternity ward. No new unexpected adverse event occurred. Our data are in agreement with results reported by others as no maternal or obstetric side-effects have been found during or after 600 acupuncture stimulations in 91 pregnant patients (4,5,11,12). As acupuncture has previously been strongly abandoned during pregnancy because of fear of serious side-effects (9), the obstetric follow-up should still be meticulous.

We conclude that acupuncture decreases pelvic and low-back pain during late pregnancy. Although we found no serious complications, for example abortion or premature labor, we cannot exclude the possibility of unusual though serious adverse effects of acupuncture in the third trimester of pregnancy from results obtained in this limited number of patients. Prospective randomized and placebo-controlled clinical studies or clinical follow-up studies of large populations are hence desirable to confirm our findings and further evaluate the efficacy or adverse effects, respectively, of acupuncture in pregnancy. We consider a team approach including midwife and obstetrician as essential in any clinical study on acupuncture during pregnancy, as the theoretical and clinical knowledge of midwives and obstetricians on diagnosis and treatment of adverse events during pregnancy and labor is crucial.

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