

Acupuncture treatment during labour—a randomised controlled trial

Agneta Ramnerö^{a,b,*}, Ulf Hanson^{a,c}, Mona Kihlgren^b

Objective To investigate acupuncture treatment during labour with regard to pain intensity, degree of relaxation and outcome of the delivery.

Design Randomised controlled trial.

Setting Delivery ward at a tertiary care centre hospital in Sweden.

Population Ninety parturients who delivered during the period April 12, 1999 and June 4, 2000.

Methods Forty-six parturients were randomised to receive acupuncture treatment during labour as a compliment, or an alternative, to conventional analgesia.

Main outcome measures Assessments of pain intensity and degree of relaxation during labour, together with evaluation of delivery outcome.

Results Acupuncture treatment during labour significantly reduced the need of epidural analgesia (12% vs 22%, relative risk [RR] 0.52, 95% confidence interval [CI] 0.30 to 0.92). Parturients who received acupuncture assessed a significantly better degree of relaxation compared with the control group (mean difference -0.93 , 95% CI -1.66 to -0.20). No negative effects of acupuncture given during labour were found in relation to delivery outcome.

Conclusions The results suggest that acupuncture could be a good alternative or complement to those parturients who seek an alternative to pharmacological analgesia in childbirth. Further trials with a larger number of patients are required to clarify if the main effect of acupuncture during labour is analgesic or relaxing.

INTRODUCTION

Acupuncture has been in use in China for thousands of years. During the last decades of the 20th century, there has been an increased demand among Swedish parturients for acupuncture as an analgesic method during childbirth¹ as well as a wider interest in the approach among midwives, obstetricians and anaesthetists^{2–6}. In some studies, a majority of the women expressed willingness to receive acupuncture treatment in a future childbirth, although the results concerning the analgesic effects of acupuncture were not always successful^{2,4}.

Acupuncture is used in obstetrics and gynaecology not only during labour but also for other various reasons, e.g. infertility⁷, pelvic pain⁸, dysmenorrhoea⁹ and hyperemesis

gravidarum^{10,11}. Acupuncture points are also used for correction of breech presentation¹².

A literature review conducted in 1998–1999 (A Ramnerö, unpublished data) was unable to verify that any randomised controlled trials concerning the effectiveness of acupuncture during labour had been conducted. An analgesic effect of acupuncture treatment during labour is reported in some studies^{3,5,6}, others find poor analgesic effect of the treatment^{2,4}. These studies differ widely in methods, localisation and amount of acupuncture points. There are also differences in assessments of the analgesic effect as well as the person assessing the pain intensity, e.g. the parturient or any of the staff. A relaxing effect of acupuncture treatment is mentioned in some studies as well as in the acupuncture literature^{6,13}.

The World Health Organization (WHO) mentions acupuncture as a non-pharmacological method to use during labour¹⁴ and emphasises the necessity of ‘...clinical studies as a way of validating acupuncture, improving its acceptability to modern medicine and thus extending its use as a simple, inexpensive and effective therapeutic option’¹⁵.

Since acupuncture is being increasingly requested by parturients and no randomised controlled trials have been carried out, it is of great importance to investigate and document the effects of the treatment. Thus, the aim of the study was to investigate acupuncture treatment during

^aDepartment of Obstetrics and Gynaecology, Örebro University Hospital, Örebro, Sweden

^bCentre for Nursing Science, Örebro University Hospital, Örebro, Sweden

^cDepartment of Obstetrics and Gynaecology, Uppsala University Hospital, Uppsala, Sweden

* Correspondence: Ms A. Ramnerö, Department of Obstetrics and Gynaecology, Örebro University Hospital, SE-701 85 Örebro, Sweden.

labour, with regard to pain intensity, degree of relaxation, and the outcome of the delivery in relation to conventional analgesia alone.

METHODS

The study was carried out during a 14-month period, between April 1999 and June 2000 in a delivery ward at a tertiary care centre hospital in Sweden. The hospital has an average of 2200 deliveries per year. Ethical approval and permission to conduct the study were obtained from the Local Ethical Committee.

Women were recruited from antenatal clinics within the hospital's catchment area. Inclusion criteria were a normal singleton pregnancy ≥ 37 gestational weeks with a spontaneous onset of labour, cephalic presentation, a cervical dilatation ≤ 6 cm at admission and enough knowledge of the Swedish language to receive information and understand the protocol. Exclusion criteria were diagnosis of diabetes, pre-eclampsia, hypertension, kidney disease, thrombocytopenia, psychological distress or anorexia, infectious blood disease, atopic eczema or psoriasis. The parturients were given information about the project and

the acupuncture treatment by midwives at routine visits to the antenatal clinics and antenatal-class visits to the delivery ward. The verbal information was combined with an information leaflet.

The trial was randomised and stratified by parity (0 and ≥ 1) with block sizes of two. At admission to the labour ward, randomisation was carried out after informed consent to participate in the study was obtained. The parturients were informed that participation was voluntary and could be withdrawn whenever during labour. Randomisation took place by picking a sealed, opaque envelope from two separate boxes, one for primiparas and the other for multiparas. The envelopes contained a protocol for assignment either to the experimental or to the control group. The envelopes were shuffled and neither the midwives nor the women could predict the group allocation.

The study was completed after 100 women were recruited. In the statistical analysis, 90 women were included (Fig. 1, Table 1). Ten subjects were considered as missing cases, due to inclusion criteria not being fulfilled, e.g. not spontaneous onset of labour, breech presentation etc., together with no assessment made of pain intensity or degree of relaxation.

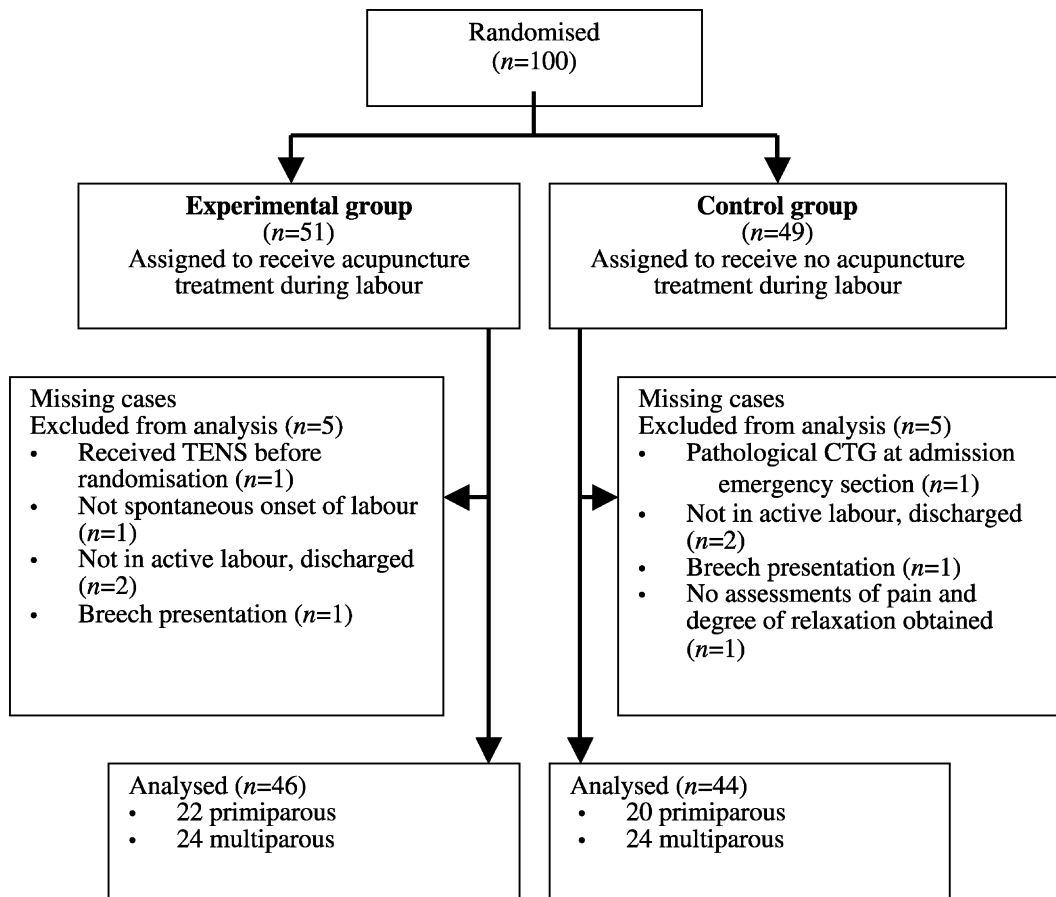


Fig. 1. Trial profile.

Table 1. Characteristics of the parturients participating in the study. Values are given as *n* (%) or mean (SD).

Characteristics	Acupuncture (<i>n</i> = 46)	Control (<i>n</i> = 44)
Parity		
Primiparous	22 (48)	20 (45)
Multiparous	24 (52)	24 (55)
Maternal age (years)	29.8 (5.6)	29.0 (4.6)
Gestational age (weeks)	39.6 (1.2)	39.9 (1.0)
Cervical dilation at admission (cm)	3.5 (1.2)	3.5 (1.1)
Pain assessment at admission (0–10)* (prior to any intervention)	6.6 (1.9)	6.6 (1.5)
Degree of relaxation at admission (0–10)* (prior to any intervention)	4.6 (2.0)	4.8 (2.4)

* 0 defined as no pain/well relaxed; 10 defined as worst pain imaginable/very tensed.

All women in the trial received care by midwives throughout childbirth, including delivery, according to Swedish standards. In most cases the partner was present. All the women had access to all conventional analgesia methods (Table 2) available at the delivery ward. The type of analgesia was chosen by the parturients assisted by the midwives. During the study period, the acupuncture treatment was only available in the experimental group.

Acupuncture has been available as an alternative to conventional analgesia for about a year prior to the start of the study. Eleven skilled midwives at the delivery ward had participated in a four-day course in basic and theoretical concepts of acupuncture for labour pain. These midwives, who were also in charge of the deliveries, gave the acupuncture treatment to the experimental group.

The acupuncture treatment was individualised, whereby each midwife chose points suitable for the pain localisation as labour progressed (Table 3, Fig. 2). As a rule, relaxing points were combined with local and distant analgesic points. The acupuncture needles (Hologon Products, Danderyd, Sweden, disposable surgical steel in sleeves) were mostly inserted bilaterally at 45° or 90°, stimulated manually until *de qui* was achieved. *De qui* is a feeling of numbness, heaviness or tightness at the site of insertion and the operator feels tightness around the needle¹³. The needles were left *in situ* and removed after one to three hours and when and if, inconvenience appeared together with absence of, or terminated, effect. The needles that were inserted at 45° were taped to the skin, which meant that the parturient had the possibility to be mobile.

A protocol was constructed to assess pain intensity and degree of relaxation throughout the labour. The assessments

were always obtained at least once every hour, prior to any given analgesia and 15 minutes after. The assessment was numeric on an 11-point scale. Painless and well relaxed were defined as 0, worst pain imaginable and very tensed were defined as 10.

All data, including the use of analgesia, pharmacological and non-pharmacological, as well as gestational age, augmentation of labour with oxytocin, duration of labour, outcome of birth, antepartum haemorrhage, Apgar scores and infant birthweights, were collected and recorded by the midwife in charge of the delivery. Each midwife was informed, both verbally and in writing, by the first author, about the study and instructed how to administer the protocol. In a pilot study, the protocol was found to be well understood and of no inconvenience either to the women in labour or to the midwives.

Data analysis

Data were analysed using the computer software Statistical Package for Social Sciences (SPSS 9.0 for Windows). The strategy for analysis was by intention-to-treat. In the analysis of pain and relaxation, mean values were based upon all assessments made of pain and degree of relaxation.

Data are presented as relative risks (RR) with 95% confidence interval (CI) for discrete data and mean difference with 95% CI for continuous data. Group differences are calculated with Student's *t* test and differences in frequencies with the χ^2 test.

Table 2. Analgesic methods available for both experimental and control group.

Non-pharmacological	Pharmacological
Transcutaneous electrical nerve stimulation	Entonox (nitro oxygen)
Intra-cutaneous injections of sterile water	Epidural analgesia (EDA), continuous infusion (bupivacaine 0.625 mg/ml + sufentanil 1 µg/ml)
Warm rice bag	Intra-muscular meperidine injections (50–100 mg)
Bath/shower	Paracervical nerve block (bupivacaine 2.5 mg/ml 10 ml + saline 10 ml)
	Pudendal nerve block (bupivacaine 2.5 mg/ml, 10 ml bilateral)
	Local infiltration analgesia (bupivacaine 2.5 mg/ml)

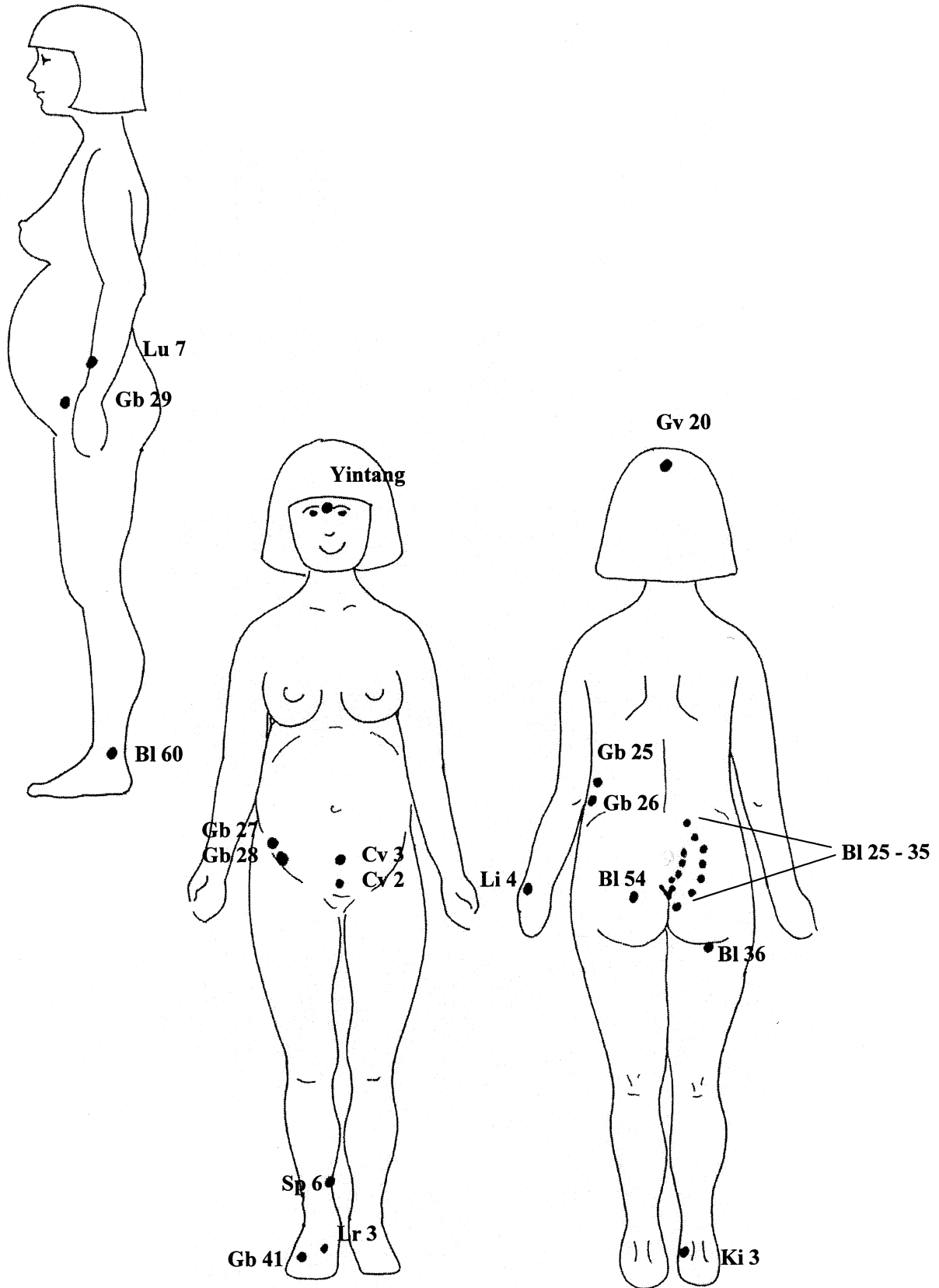


Fig. 2. Acupuncture points.

Table 3. Acupuncture points used in the trial*.

Main purpose	
Relaxing	Governing vessel (GV) 20 Yintang Lung (LU) 7
Analgesic	Urinary bladder (BL) 25–36, 54 Gall bladder (GB) 25–29 Conception vessel (CV) 2, 3 Subcutaneous points Liver intestine (LI) 4 Gall bladder (GB) 41 Liver (LR) 3 Urinary bladder (BL) 60 Kidney (KI) 3 Spleen (SP) 6

* Abbreviations are according to the *Standard Acupuncture Nomenclature* (WHO³⁰).

RESULTS

All parturients randomised to the experimental group received acupuncture. The acupuncture treatment generally followed close on randomisation, still always prior to any other requested analgesia. Seven parturients, all of them multiparous, received only acupuncture, with no supplement of any other analgesia during childbirth.

There were no significant differences in labour outcome, e.g. frequency of vaginal births, caesarean sections, duration of labour, *etc.* (Table 4). Augmentations of labour with oxytocin infusion were the same in both groups and no differences in antepartum haemorrhage bleedings or outcome of the infants were found. The need for epidural analgesia was significantly reduced (12% vs 22%, RR 0.52, 95% CI 0.30 to 0.92) in the acupuncture group (Table 5). At administration of a possible epidural analgesia, the cervical dilatation did not differ significantly between the two groups. Regarding other analgesic methods, no differences were seen besides the use of some of the non-pharmacological methods, which were significantly reduced in the acupuncture group (Table 5).

The acupuncture group assessed a significantly better degree of relaxation (mean difference -0.93 , 95% CI -1.66 to -0.20), but the assessments of pain intensity were equal between the two groups (mean difference -0.29 , 95% CI -0.90 to 0.32) (Table 6).

Most parturients reported satisfaction with the given analgesia, 95.6% in the acupuncture group and 88.6% in the control group.

DISCUSSION

The main finding of this study was that acupuncture treatment significantly reduced the need of epidural analgesia, although the two groups assessed the same degree of pain intensity. Furthermore, parturients receiving acupuncture assessed a significantly better degree of relaxation during childbirth. With regard to the outcome of the delivery, the trial found no negative effects of acupuncture given during labour.

The authors considered it impossible to conduct a blind study, since the parturients receiving acupuncture would be aware of the needling. In 1998, Streitberg and Kleinhentz¹⁶ reported their development of a placebo acupuncture needle, which had been proven to be sufficiently credible to use in trials of acupuncture. The study can be questioned since none of the needles, neither the acupuncture needle nor the placebo needle, were stimulated/twisted to achieve a sensation of *de qui*. This specific sensation would be anticipated by those parturients who previously have undergone acupuncture treatment. Thus, the placebo needle has its shortcomings.

All women participating in the present trial had access to all analgesia that was available, apart from acupuncture, which was only available to the experimental group. Hence, the analysis had to focus on possible differences in delivery outcome, pain intensity and degree of relaxation between parturients who, in any part of their labour, received acupuncture, compared with those who never had the option to choose acupuncture.

Table 4. Labour and fetal outcome. Values are given as *n* (%) or as mean (SD).

	Acupuncture (<i>n</i> = 46)	Controls (<i>n</i> = 44)	RR (95% CI) mean difference (95% CI)
Vaginal birth	43 (93.5)	42 (95.5)	0.98 (0.89 to 1.08)
Vacuum extraction	2 (4.3)* [†]	1 (2.3)**	1.91 (0.18 to 20.35)
Caesarean section	1 (2.2)*	1 (2.3)**	0.96 (0.06 to 14.83)
Duration of labour (h, measured as the interval from ≥ 4 cm to birth)	5.3 (3.33)	5.6 (3.85)	-0.25 (-1.75 to 1.26)
Augmentation of labour with oxytocin	16 (34.8)	15 (34.1)	1.02 (0.58 to 1.80)
Antepartum haemorrhage (ml, estimated by midwife in charge)	435 (163)	482 (256)	-47 (-136 to 42)
Infant birthweight (g)	3670 (492)	3760 (342)	-90 (-268 to 88)
Apgar score <7 at 1 min	0 (0)	2 (4.5)	—
Apgar score <7 at 5 min	0 (0)	0 (0)	—

* Fetal heart rate abnormalities in labour.

** Prolonged labour.

[†] Exhausted mother.

Table 5. Pain relief data. Values are given as *n* (%) or as mean (SD). TENS = transcutaneous electrical nerve stimulation.

	Acupuncture (<i>n</i> = 46)	Controls (<i>n</i> = 44)	RR (95% CI) mean difference (95% CI)
Epidural analgesia (EDA)	12 (26.1)	22 (50.0)	0.52 (0.30 to 0.92)
Cervical dilation at epidural administration (cm)	5.3 (1.71)	4.2 (1.33)	1.1 (−0.01 to 2.15)
Entonox (nitro oxygen)	34 (73.9)	32 (72.7)	1.02 (0.79 to 1.30)
Paracervical nerve block	2 (4.3)	0 (0)	—
Pudendal nerve block	1 (2.2)	0 (0)	—
Intra-muscular meperidine injections	1 (2.2)	1 (2.3)	0.96 (0.06 to 14.83)
Local infiltration analgesia	1 (2.2)	1 (2.3)	0.96 (0.06 to 14.83)
TENS	0 (0)	14 (31.8)	—
Intra-cutaneous injections of sterile water	0 (0)	1 (2.3)	—
Warm rice bag	7 (15.2)	23 (52.3)	0.29 (0.14 to 0.61)
Bath	1 (2.2)	7 (15.9)	0.14 (0.02 to 1.07)
Shower	2 (4.3)	9 (20.5)	0.21 (0.05 to 0.93)

The randomisation in the present study was successful since the description of the sample is similar (Table 1).

The chosen acupuncture points and the duration of the needling may be a subject for discussion. Campbell¹⁷ mentions the variety of point selection, methods and duration of needling that exists among acupuncturists. The selected acupuncture points, together with the method and duration of the needling in the present study, were chosen in relation to the experience of the participating midwives. These acupuncture points are among those points recommended by Carlsson and Anckers¹⁸ in their textbook on obstetric acupuncture. The use of manual acupuncture together with access to cardio-tocographs with telemetry when fetal heart monitoring was required fulfilled the wish of most parturients, which is to be mobile instead of being referred to bed during labour. Abouleish and Depp² found that electro-acupuncture during labour limited the patients' movement.

A matter of concern is always whether or not the method to assess pain intensity and degree of relaxation is appropriate. The midwives at the current ward were accustomed with the Visual Analogue Scale (VAS), which is used for continuous assessments during epidural analgesia in labour. Use of Numeric Rating Scale (NRS), instead of the VAS, was based upon negative experiences, where the parturients showed irritation concerning the slide rule. The VAS is a validated instrument in assessing pain¹⁹ and has been used in trials concerning labour pain^{20,21} as well as acupuncture treatment^{4,8,16}. The NRS is found to be well correlated with the VAS^{22–24}.

In previous studies concerning pain and childbirth, the pain assessments have been recorded either once²⁵ or repeatedly, due to time intervals²⁶ or to the cervical dilatation²⁷. The latter, to perform a vaginal examination during the course of a trial, was considered to be both unethical and disturbing for the parturients. In the present study, all assessments were made at a minimum hourly and always prior to an intervention, thus assuring an assessment when a change in the pain or the degree of relaxation was so severe that intervention was requested. Previous studies have found labour pain to increase as labour progresses²⁷, consequently all assessments of pain and degree of relaxation are included in the analysis.

Pain is a personal psychological and emotional experience²⁸ and, consequently, cannot be estimated correctly by an observer. Thus, it is important that all assessments are made by the parturient, as was done in the present study. Previous studies have demonstrated a discrepancy in pain assessments between the perceptions of patients *versus* professionals; e.g. midwives, physicians²⁹.

The midwife in charge of the delivery performed the acupuncture treatment together with the collection and the recording of the data. Thus, disturbing elements, such as persons not normally present during labour, were minimised.

The results of the present study imply that acupuncture in labour provides relaxation (Table 6). These findings are consistent with the results found by Fant and Strömberg⁶ as well by Skelton and Flowerdew³. If the parturient is more relaxed, she is likely to have more control and consequently be more able to cope with the pain. This is

Table 6. Ratings of in-labour pain and relaxation in the two groups. Values are given as mean (SD).

Type of score	Acupuncture (<i>n</i> = 46)	Control (<i>n</i> = 44)	Mean difference (95% CI)
Mean pain score (0–10)*	6.6 (1.51)	6.8 (1.40)	−0.29 (−0.90 to 0.32)
Mean relaxation score (0–10)*	4.2 (1.52)	5.1 (1.94)	−0.93 (−1.66 to −0.20)

* 0 defined as no pain/well relaxed; 10 defined as worst pain imaginable/very tensed.

in congruence with a study made by Niven and Gijsbers²¹, who found relaxation to be important in coping of labour pain.

The finding of the reduced use of epidural analgesia is in accordance with Kvorning Ternov *et al.*⁵ and Fant and Strömberg⁶. However, this finding conflicts with other studies where acupuncture was found to not reduce the need of analgesics. In this latter studies the methods differs from the present study; e.g. the treatment was given repeatedly during the last month prior to childbirth⁴. Abouleish and Depp² performed electro-acupuncture, which limited the patients' movement; furthermore, the acupuncturist was an anaesthesiologist, without having professional reason to be present during most of the labour, which might have been a disturbing factor. In the present study, the midwives performed the acupuncture treatment as part of their total patient care and thereby minimising persons not normally present during childbirth.

The non-pharmacological (Table 2) analgesia methods transcutaneous electrical nerve stimulation (TENS), bath, shower and warm rice bag were used in a higher degree by the control group, probably because these parturients did not have access to acupuncture treatment, thus choosing other non-pharmacological methods as their first choice of treatment. Together with the fact that when the experimental group were not satisfied with the acupuncture treatment, they might have been likely to proceed with a pharmacological instead of a non-pharmacological method.

In the present study, acupuncture treatment had no effect, positive or negative, on the duration of labour. These findings are consistent with one of the Swedish studies⁶. However, Skelton and Flowerdew³ found the duration of labour to be shortened by acupuncture treatment.

The present authors were aware of the possibility of bias concerning the satisfaction of analgesia received, due to the randomisation, since the control group had not received acupuncture. Nonetheless, both groups were satisfied with the analgesia given, and thus the care received may be regarded as being similar and independent of group allocation.

CONCLUSION

We suggest acupuncture to be a good alternative or complement to those women seeking an alternative to pharmacological analgesia in childbirth. Further trials with a larger numbers of patients are required to establish the main effects of acupuncture during labour, i.e. analgesic or relaxing.

Acknowledgements

The authors wish to thank the midwives and the parturients at the delivery ward at Örebro University

Hospital for their co-operation. The study was supported by grants from Örebro County Council Research Committee and Centre for Nursing Science, Örebro University Hospital.

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Accepted 13 February 2002