

STERILE WATER INJECTIONS AND ACUPUNCTURE AS TREATMENT FOR LABOUR PAIN

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*Those who are in love with practice without knowledge
are like the sailor who gets into a ship without rudder or
compass and who never can be certain whither he is going.
Practice must always be founded on sound theory.*

Leonardo da Vinci 1452-1519

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ABSTRACT

Most women experience pain during labour. Complementary pain relief methods such as sterile water injections and acupuncture are two alternatives for the child birthing women. The lack of knowledge about the use of these methods in clinical practice creates the need to develop and evaluate them.

Aims and methods: To elucidate whether the new subcutaneous method of administering sterile water, as well as the previously described intracutaneous injection method, were effective for the relief of labour pain. Ninety-nine women in labour were randomized to either intracutaneous- , subcutaneous injections of sterile water or to placebo (*Paper I*). To investigate if there was any difference in perceived pain between the intracutaneous and subcutaneous techniques during injection of sterile water. One hundred female volunteers were given injections with both techniques in a cross-over trial (*Paper II*). To elucidate the clinical use of acupuncture and sterile water injections as pain relief and relaxation during childbirth in Swedish delivery wards. Five hundred and sixty-five midwives answered a questionnaire about their use of these methods (*Paper III*). To elucidate if there were any differences between acupuncture and sterile water injections in terms of pain relief and relaxation during labour. One hundred and twenty-eight pregnant women in childbirth were randomized to either sterile water injections or acupuncture (*Paper IV*).

Results: *Paper I:* VAS pain scores were significantly lower in both treatment groups 10 minutes ($p=0.001$) and 45 minutes ($p=0.005$) after treatment, compared with the placebo group. *Paper II:* subcutaneous injections were still perceived as less painful than intracutaneous injections after trial, day and injection location were taken into consideration ($p<0.001$). *Paper III:* the midwives' estimated frequency of administration of acupuncture was much higher than that of sterile water injections, 25 % versus 2 %. The intracutaneous injection technique was more common in clinical practice than the subcutaneous technique. Sterile water injections were used exclusively for pain relief during labour while acupuncture was used for both pain relief and relaxation during labour. *Paper IV:* women given sterile water injections experience significantly less labour pain and a higher degree of relaxation in labour, compared to women given acupuncture ($p<0.001$).

Conclusions: The results indicate that the subcutaneous injection technique is preferable when using sterile water injections for low back pain during labour. Sterile water injections seem to provide more pain relief and a higher degree of relaxation, compared to acupuncture. However, acupuncture is a more common pain relief method in clinical practice.

Key words: Labour pain, pain relief, sterile water injections, acupuncture, survey

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ABBREVIATIONS

β	Beta
CNS	Central Nervous System
DNIC	Diffuse Noxious Inhibitory Controls
EDA	Epidural analgesia
Ic	Intracutaneous
NaCl	Isotonic saline
PCB	Paracervical nerve block
RCT	Randomised Controlled Trial
Sc	Subcutaneous
TENS	Transcutaneous Electrical Nerve Stimulation
VAS	Visual Analogue Scale

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INTRODUCTION

Childbirth is probably one of the most unique events in a woman's life and the overall experience of giving birth may be either positive or negative. Most childbirth entails pain of varying intensity. Labour pain is caused by several factors which together create the woman's experience of pain. It is impossible to predict what the pain experience will be like as this is extremely individual. There is a need for pain relief methods to ease the pain, traditionally pharmacological methods as well as complementary alternatives. In most cases the woman knows about the various existing pain relief alternatives and she may also have an idea of which she will require or prefer during delivery. Our goal regarding pain relief during labour is to give the birthing woman safe and high-quality care based on the best available knowledge about pain relief methods. Therefore all methods must be evaluated and developed continuously. The focus in this thesis is on two complementary pain relief alternatives, i.e. sterile water injections and acupuncture.

BACKGROUND

Definition of pain in general

There are several definitions of pain in general. The International Association for the Study of Pain (IASP) (1) defined pain as follows: *An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.* According to this definition, pain in general indicates something threatening or dangerous or is a symptom of something wrong. IASP (1) further stated that *Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life.* Pain in general, including labour pain, is considered to be a subjective experience influenced by physiological, psychological and socio-cultural factors. It is thus difficult to measure pain in an objective manner. It is only the person experiencing the pain that can express its severity. McCaffery (2) focuses on the latter in the following description: *Pain is whatever the experiencing person says it is, existing whenever he says it does.* Even if pain is quite common in a global perspective, it is not fully understood (3, 4).

Pain perception

The sensation of pain is distinct from that of touch, heat and cold. It is associated with tissue changes and may also change a person's behaviour. An individual's perception of pain depends on three parallel dimensions, i.e. sensory-discriminative, affective-motivational and cognitive-evaluative. These three dimensions function as a network and their contributions create the individual's perception of pain. Awareness of all these dimensions is important in order to understand an individual's pain reaction (5, 6).

Sensory-discriminative dimension

The purpose of the sensory-discriminative dimension is to pass signals from different stimuli all over the body to the central nervous system (CNS). Specialised nociceptive receptors are located throughout the body: there are three main types that react to different types of stimuli. *Chemical receptors* react not only to external chemicals but also to chemical substances produced in the body. *Mechanical receptors* react to mechanical pressure, while *thermal receptors* react to changes in temperature. These nociceptors activate fast myelinated A-delta afferents that transmit sharp, acute pain and unmyelinated C afferents that transmit deep or dull pain. The process from the occurrence of a pain stimulus to the experience of pain is divided into four phases: the occurrence of the stimulus, the transfer from the receptors to the CNS, the modulation of the information and, finally, in the fourth

phase, the brain perceives the information as painful. Nociception is a peripheral phenomenon and it is not until the impulses reach the cortex that the phenomenon is called pain. In summary the sensory-discriminative component underlies the individual's ability to describe pain in terms of intensity, duration and location (7).

Affective-motivational dimension

This dimension of pain is associated with pleasant or unpleasant emotions (8, 9). There are many affective variables that apparently influence the experience of labour pain, some examples of which are psychological factors such as fear and anxiety (10-13), fear of the unknown, death, suffering, potential maternal and/or perinatal complications (10, 14) and the relationship to the child's father (15).

Cognitive-evaluative dimension

This dimension is associated with factors such as thoughts, mood, behaviour, and thought patterns (16). Previous experiences of pain, especially memory from previous childbirth, may influence the experience of labour pain, either positively or negatively (17).

Pain mechanisms

Recently, it has been proposed that pain be classified according to aetiology (18). This could be achieved by categorization of the pain based on its mechanisms (19). The proposed categories are; *nociceptive* pain, in response to a noxious stimulus without tissue damage; *inflammatory* pain, an increased sensitivity to pain due to tissue damage and inflammation; *neuropathic* pain, an increased sensitivity to pain due to damage or lesions in the nervous system and *functional* pain, increased sensitivity to pain due to abnormal central processing without any known tissue damage (19).

Endogenous pain inhibitory system

Knowledge about the body's own system for decreasing the experience of pain is incomplete at present. However, there are some important mechanisms that require mention.

The gate control theory

According to the gate control theory, there is a physiological gate mechanism in the gelatinous substance in the spinal cord's dorsal horn. This means that sensory signals can only pass through the cells in the gelatinous substance when the gate is open. Sensory information is blocked when the gate is closed, followed by stimulation of A β fibres which stimulates inhibitory interneurons in the dorsal horn.

For example, when the skin in the lumbar area is stimulated in different ways, a cutting type of pain will be generated, thus creating a block to the slower signals from uterine contractions (20).

Descending pain relief system

A painful stimulus activates the central pain inhibitory system's production of endogenous opioids. Sensory signals from the painful area pass ascending pathways to the brain. These signals stimulate areas such as the peri-aqueductal grey matter to produce β -endorphin and neurotensin and stimulate the great raphe nucleus to produce noradrenalin and serotonin. These substances proceed through descending pathways back to the dorsal horn and inhibit the nociceptive transmission at the spinal level (21).

Diffuse Noxious Inhibitory Control

Diffuse Noxious Inhibitory Control (DNIC) is another mechanism, i.e. a physiological system based on the concept that pain can be controlled by stimulation at points distal to its source. The idea is to apply a painful stimulus elsewhere than the area to which the initial pain is projected, thus achieving a pain relief effect. The endorphin system is involved and it is not necessary to administer pain stimuli in the affected area since of the effect is general according to this explanatory model (22, 23).

Endorphins during pregnancy and childbirth

Naturally occurring analgesics were demonstrated in the early 1970s. These substances, of which β -endorphin, enkephalins and dynorfin are considered to be the most important, are similar to opiate drugs such as morphine as they bind to the same receptors (8, 24, 25). The role of endorphins in pregnancy is partly unclear even if it is known that maternal β -endorphin blood levels increase during gestation (26, 27) and rise further in most women during delivery (27-29). It is unclear to what extent these high levels of β -endorphin levels influence labour pain (28, 30, 31) because women with high levels of β -endorphins also experience severe pain in connection with labour (32). Studies have shown that the woman's threshold for pain and discomfort increases during the later part of pregnancy, especially during the 16 days prior to delivery, with a significant increase during the last nine days (33-35).

Labour pain

The uterus and cervix are supplied by afferent neurons ending in the dorsal horns of spinal segments T10-L1. The pain can be projected to a skin area supplied by the spinal segment that receives the stimuli. In the clinical situation, this means that the woman may experience severe pain in the back and/or groin simultaneously with uterine contractions. This phenomenon is called referred (transmitted) pain and implies that the spinal cord neuron receives impulses both from the internal organs and from the surface of the skin but the sensory cortex can not distinguish between the two sources (36-38).

In the beginning of the first stage of labour, the pain is assigned to segments T11 and T12 and the woman experiences it as moderate, dull, aching, often diffusely located, cramps called visceral pain. Later, when labour is established and at the end of the first stage of labour, the pain is assigned to segments T10 and L1. In this phase, pain is often experienced as more severe. When the presenting part descends into the vagina, the pain is assigned to segments S2-S4 and the pain experience changes due to the pressure on other pelvic structures. This is a predominantly somatic pain, albeit combined with visceral pain from the uterine contractions (36-38).

Most data indicate that first-stage labour pain is caused by dilation of the cervix and the lower uterine segment. A relatively rapid stretching and pulling occurs in these structures during contractions. The internal organs are sparsely supplied with A-delta and C afferents; the pain is thus often experienced as diffuse and aching and pain localisation may vary during this phase. The impulses from the uterine contractions are carried along A-delta and C afferents to the spinal cord, the site of transmission to nerve cells that in turn transmit the information all the way to the cortex where an interpretation of the impulses takes place (37, 39).

Definition of labour pain

Labour pain might be categorized as nociceptive pain, according to the classification given above (19). This pain also includes components that differ completely from pain in general. It is an acute pain that is neither dangerous nor threatening during a normal delivery; on the contrary, it provides information on a normal process. Labour pain during normal conditions is not life-threatening; on the contrary, it is life-giving. It is the result of natural events and has a special meaning, leading in most cases to something extremely positive, the birth of a healthy child. When labour starts, the pain is a signal for the woman to prepare herself for coming events and to find a safe place for giving birth. Labour pain is most often not continuous; it occurs with a certain regularity and with primarily painless intermissions and it is limited in time. The birthing woman can also

prepare herself well in different ways before delivery to manage labour pain (38, 40).

There is no generally accepted definition of labour pain but there are some attempts at definitions/descriptions in the literature. In her thesis, Fridh (41) describes labour pain as follows: *The sensory and emotional experience a woman has in connection with childbirth, that is a result of tissue influence by uterine contractions, dilation of the cervix and the passing of the child through the distal birth channel. Furthermore this experience is dependent on general, physiological, mental and socio-cultural factors.* Heiberg's (42) description of labour pain is more philosophical: *...different from any other pain experience. Labour pain is creating; it is the innermost power of life. The pains billow throughout the body like waves over and over again – stronger and stronger toward their peak, toward liberation, delivery for mother and child. A characteristic of labour pain is its rhythmic quality. Labour pain is never constant, it comes with the contractions and the intermissions are always painless.*

The prevalence and experience of labour pain

Pain is hard to describe and is contradictory was one of several themes in Lundgren's and Dahlberg's (43) study on women's experience of pain during childbirth. However, researchers had nonetheless previously tried to describe and explain the variation of labour pain in several studies. In the early 1980s, a comparison was made between different pain conditions, using a McGill Pain Questionnaire, the results of which indicated that the experience of labour pain was exceeded only by unintentional amputation of fingers or toes and causalgia during chronic pain conditions (15). Pain during childbirth has been characterised as very severe (44, 45). Lundh (46) showed that 35-58 % of women experience labour pain as unbearable or severe. One study, including 2 700 deliveries from 121 delivery units in 35 different countries, shows that 20 % experience extremely severe pain, 30 % experience severe pain, 35 % experience moderate pain and 15 % of the birthing women experience no or slight pain (47). Another study indicated a difference between the labour pain experiences of women giving birth to their first and second child. Sixty-one per cent of the women having their first child experienced the labour pain as severe or very severe, while the corresponding percentage for second-time parturients was 46 % (15). Fridh (41) also found that women experienced the first delivery as more painful than the second. Paech (48) reported similar results. However, Ranta et al. (49) found that even grand multiparas suffer from intense pain during labour. A positive correlation between fear and pain was found by Alehagen (50) more pronounced in primiparas during the first part of the first stage of labour. Furthermore, ethnic differences can influence the labour pain experience (51-53). It has also been suggested that a

primipara's perceived pain during childbirth is probably more correlated to psychogenic rather than to physical factors (54).

Although the experience of labour pain in different studies varies greatly, all results can be said to indicate that most women experience labour pain as severe or unbearable at least sometime during childbirth. However, childbirth is complex in nature and the experienced pain intensity is also dependent on anxiety, midwife support and duration of labour, among other factors. Despite its severity, labour pain it is not described as an entirely negative experience (55).

Treatment of labour pain

The body's own pain inhibitory system notwithstanding most women use some kind of pain relief method when available. In Sweden, 96 % of all women in childbirth use some pain relief method at some time during childbirth (56).

History of pain relief during childbirth

Pain relief during delivery has not always been a matter of course. For a long time, the Christian Church banned women from using pain relief methods referring to the biblical words, *I will greatly increase your pain in childbearing; with pain will you give birth to children* (57). In 1847, ether was used during childbirth. Its use started a wave of discussion because of the unwanted effects such as hallucinations, nightmares and cramps (58). The same year, chloroform was used as an alternative. This was heavily criticized by Calvinistic ministers, based on the biblical words. It was not until the mid-1800s, after Queen Victoria of England was administered chloroform during her eighth and ninth deliveries in 1853 and 1857, that pain relief during delivery finally was accepted (59).

Pain relief methods

During the 1900s in Sweden, pharmacological pain relief methods were expanded from only entonox and, later, pethidine to more effective methods such as paracervical nerve block and epidural analgesia (56) (Figure 1).

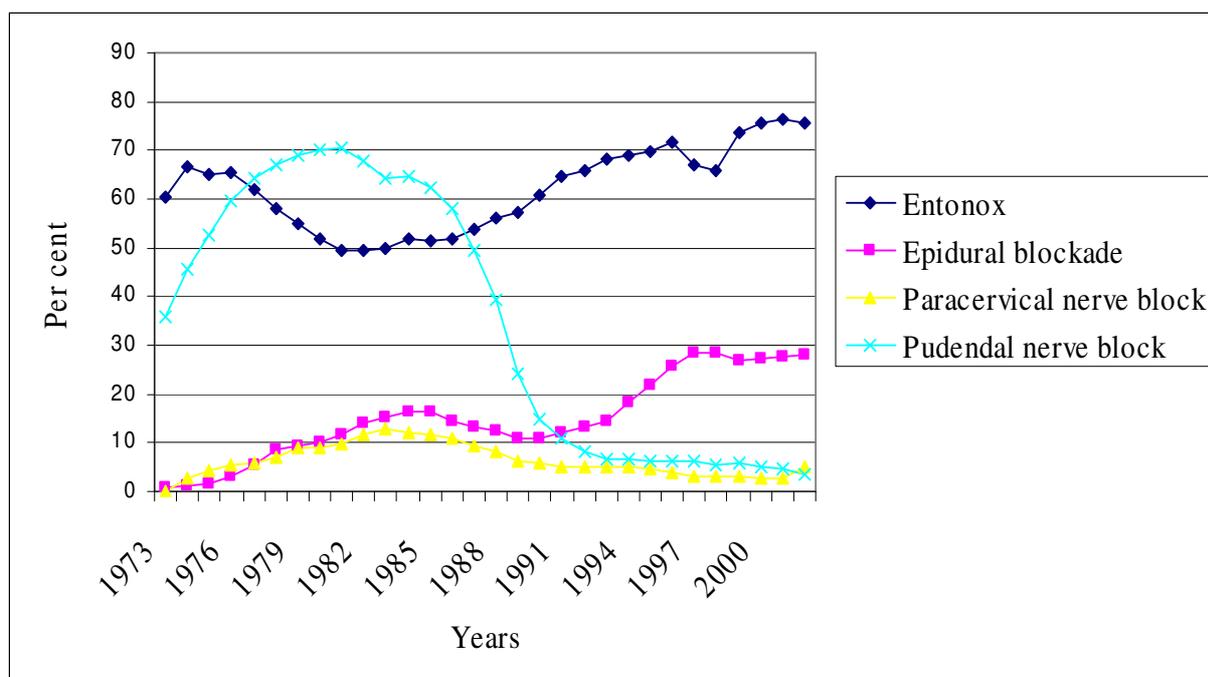


Figure 1. Prevalence of pharmacological pain relief methods 1973-2002 (56).

Swedish women’s demands for pain relief during delivery resulted in legislation, passed in 1971, awarding them that right (60). This statute resulted in considerable development of pain relief opportunities in Swedish labour units, with a focus on epidural analgesia. Women’s attitude to pain relief changed during the latter part of the 1980s and demands arose for a more natural delivery with an absolute minimum of pharmacological pain relief (61).

There are several complementary pain relief methods in use in Sweden. The prevalence of some of these methods is shown in Figure 2. There is some missing data in the Medical Birth Register (62) due to underreporting; thus, the true use of these methods is probably somewhat higher. In this thesis, however, the focus is on only two methods, sterile water injections and acupuncture.

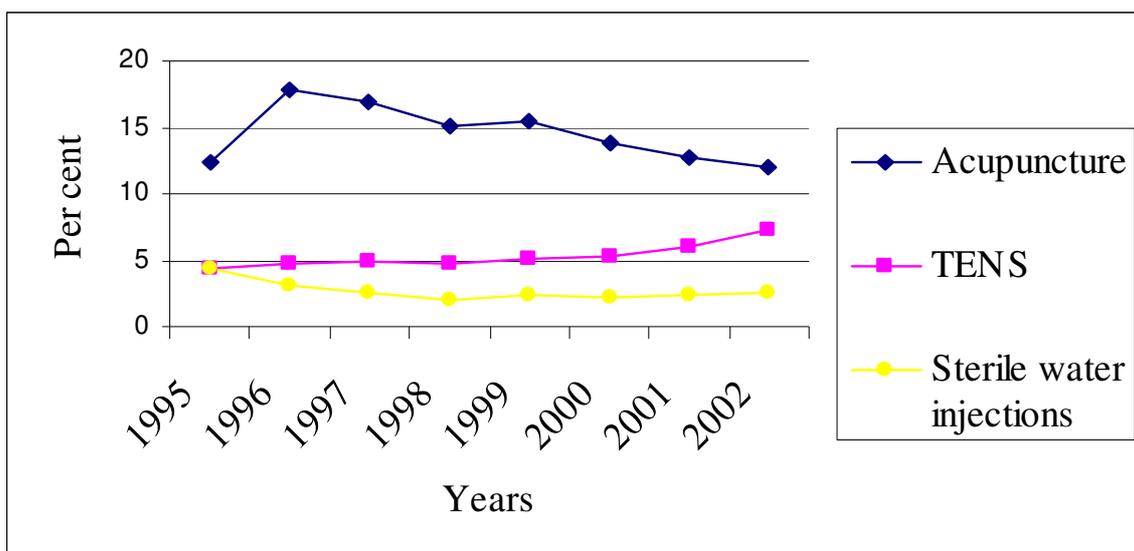


Figure 2. Prevalence of some complementary pain relief methods 1995-2002 (56).

Sterile water injections

History

The technique is very old and was mentioned in the literature by Halsted (63) when he wrote *The skin can be completely anaesthetised to any extent by cutaneous injections of water*. It was initially used as a local anaesthetic during minor surgery. Dr. Samuel G. Gant tested the method in the beginning of the 1900s in connection with haemorrhoid, fistula and polyp surgery. The mechanism of action was explained thus: the sterile water injections stretched the tissue, resulting in a paralysing effect on the nerve fibre function. The more distended tissues, the better the analgesia. The method was considered difficult due to discomfort in connection with administration, but could nevertheless constitute a good alternative for those patients with hypersensitivity to the drugs used during general anaesthesia (64). Another method was developed with positive results in which a mixture of sodium chloride, sodium sulphate and distilled water was injected at different depths into the skin for treatment of sciatica pain (65).

The method began to be used in the obstetric field in the late 1920s. Two studies from that time describe how cutaneous injections were administered but some type of local anaesthetic was injected. Back pain as well as lower abdominal pain was treated in this manner. Treatment of abdominal pain was considered more effective than treatment of back pain (66, 67).

Administration technique

The procedure for treating back pain in connection with labour is simple. Four to six injections of 0.1 ml sterile water are administered intracutaneously in the lower back area. Onset of pain relief is fast, most often within only a few minutes, and it persists for up to two hours. The treatment can be repeated. The lumbar region is the most common treatment location but the method is also used for pubic symphysis pain, lower abdominal pain and inguinal pain (68). In Sweden, no special training is required to administer the injections since Swedish midwives learn the injection technique during their nursing training (69).

Prior research

Several studies have consistently proven that the method provides good pain relief during labour, particularly for low back pain (70-75). The results of these studies are shown in Table 1. The only negative effect is the intense burning pain women experience in connection with administration of the injections. The pain can be described as similar to a bee sting, with a duration of approximately 20-30 seconds, an observation in almost all studies in which the method was studied in connection with labour pain (70, 71, 73-75). Even women experiencing good pain relief as a result of the injections will often choose to manage without further injections because of this troublesome injection pain (68).

Table 1. Summary of scientific evaluations of sterile water injections as relief for labour pain.					
Author Periodical	Objective	Inclusion criteria	Design	Measuring instrument	Results
Labrecque et al 1999 The Journal of Family Practice	To compare sterile water injections and TENS for low back pain during labour.	- Pregnancy wk >36 - Low-risk - Active first stage of labour - Low back pain	RCT <i>Group 1</i> n=11 4 x 0.1 ml sterile water ic <i>Group 2</i> n=12 TENS <i>Group 3</i> n=12 standard care (bath, massage, mobilization)	VAS	Sterile water injections are more effective than standard care and TENS for low back pain.
Dahl & Aarnes 1991 Tidsskr Nor Laegeforen	The objective was to reevaluate the method and factors possibly influencing its efficacy.	- Healthy women - Pregnancy wk 38-42 - Single gestation	<i>Group 1</i> n=101 2-4 injections of sterile water ic <i>Group 2</i> n=50 dry needle injections <i>Group 3</i> n=117 (Control group) conventional treatment Lumbosacral and / or suprapubic injections were given	VAS ungraded 10 cm: 0=no pain, 10= unbearable pain	Sterile water papules provided better relief for labour pain in the intracutaneous group compared with the dry needle group. Early treatment yields best effect.
Trolle et al 1991 Am J Obstet Gynecol	Evaluate the analgesic effect of intradermal sterile water block for back pain during labour.	- Active labour - Back pain	RCT <i>Study group</i> n=141 4 x 0.1 ml sterile water ic <i>Control group</i> n=131 4 x 0.1 ml NaCl ic Lumbosacral injections were given	VAS ungraded 10 cm: 0=no pain, 10= unbearable pain	Significantly greater reduction of VAS score in the sterile water group compared with the NaCl group, up to 90 min after treatment.
Ader et al 1990 Pain	Investigate the efficacy of sterile water papules for back pain during labour.	- Pregnancy wk. ≥ 37 - First stage of labour - Back pain - Pain relief required	RCT <i>Study group</i> n=24 4 x 0.1 ml sterile water ic <i>Control group</i> n=21 4 x 0.1 ml NaCl sc Lumbosacral injections were given	VAS ungraded 10 cm: 0=no pain, 10= unbearable pain	Significantly greater reduction of VAS score in the sterile water group compared with the NaCl group. The analgesic effect remained up to 90 min.
Lytzen et al 1989 Acta Obstet Gynecol Scand	Evaluate if sterile water papules can be an alternative for alleviating back pain during labour.	- Established labour	<i>Study group</i> n=83 4 x 0.1 ml sterile water ic Lumbosacral injection were given	VAS ungraded 10 cm: 0=no pain, 10= unbearable pain	VAS score reduced significantly 3 hours after injection compared with just prior to administration.
Trolle et al 1986 Ugeskr Laeger	Evaluate if back pain during labour can be treated with intracutaneous sterile water papules.	- Primipara - Pregnancy wk. ≥ 37 - Cervix dilatation ≤ 4 cm	RCT <i>Study group</i> n=38 4 x 0.1 ml sterile water ic <i>Control group</i> n=38 no treatment Lumbosacral injections were given	VAS ungraded 10 cm: 0=no pain, 10= unbearable pain	The treatment group experienced significantly better pain relief compared with the control group, up to 60 minutes after treatment.

Acupuncture

History

Acupuncture (Latin: *acus* – needle and *punctum* – puncture) is an ancient method and component of traditional Chinese medicine, in use for centuries. Acupuncture entails penetration of the skin with thin needles at certain points on the surface of the body. These points follow a predictable pattern and the lines linking the points are known as meridians (76, 77). A short course on acupuncture in obstetrical care, including practical training, is required before Swedish midwives may use this method. During recent years, different educational programs lasting from two days to ten weeks have been offered, the latter at the university level (personal communication, Lilleba Anckers 2005-04-13). Use of the method for labour pain relief has increased rapidly in the 1990s in Sweden. There was, however, a lack of scientific evaluation of this method for this purpose when the method came into use. Therefore restriction of its use to research, with the objective of clarifying any pain relief effect has been recommended (78).

Administration technique

The principle for acupuncture treatment is to activate the endogenous pain inhibition system. Local acupuncture points are used to stimulate pain inhibition at the segmental level. The needles are then inserted in the painful area. For stimulation at higher levels in the central nervous system, both segmental and distal points are used. It is generally believed that the best effect of the needles at distant points is reached by using acupuncture points on the forearm/hand and/or lower part of the leg/foot (79). The acupuncture points are selected individually, depending on where the pain is perceived. When an acupuncture point is located, the needle is inserted and manually stimulated to evoke needle sensation, i.e. a feeling of soreness, heaviness, numbness and distension. This sensation is called De Qi and reflects activation of afferent fibres: it is most often repeated every ten minutes during treatment. It also gives the midwife an indication that the needle has been correctly placed (77). Stimulation of the needles in order to achieve De Qi several times during a treatment period of 30-40 minutes is recommended (79).

Prior research

There are some studies about the efficacy of acupuncture, in terms of pain relief and degree of relaxation, in connection with childbirth (80-83). The results of these studies are not concordant, as seen in Table 2.

Author Periodical	Objective	Inclusion criteria	Design	Measuring instrument	Results
Ziaei & Hajipour 2006 Int J Gynecol Obstet	Obtain an indication of the efficacy of acupuncture in decreasing pain and maintaining relaxation during labour.	- Normal singleton pregnancy - Pregnancy wk ≥ 37 - Spontaneous onset of labour - Cephalic presentation - Cervical dilatation 3-6 cm at admission	RCT Group 1 n=30 given acupuncture Group 2 n=30 given mock acupuncture Group 3 n=30 no intervention	Pain intensity and degree of relaxation assessed by linear 10 cm VAS	No effect on pain intensity and degree of relaxation.
Nesheim et al 2003 Clin J Pain	Find out whether acupuncture could reduce the use of meperidine during labour.	-Regular contractions - Pregnancy wk 37-42	RCT Group 1 n=106 given acupuncture Group 2 n=92 no acupuncture Group 3 n=92 control group matched with the no acupuncture group	VAS ranging from "no effect" to "no pain"	The use of meperidine and other analgesia (epidural, entonox, sterile water papules) was reduced in the acupuncture group.
Skilnand et al 2002 Acta Obstet Gynecol Scand	Obtain an indication of the efficacy of acupuncture as a treatment for labour pain.	- Healthy parturient - Singleton cephalic presentation - Anticipated normal delivery - Spontaneous active labour Gestational wk 37-42	RCT single blind Study group n=106 given real acupuncture Control group n=102 given mock acupuncture	VAS linear 10 cm: 0=no pain, 10=worst possible pain	Significantly lower mean VAS score in the real acupuncture group than in the mock acupuncture group up to two hours after treatment.
Ramnerö et al 2002 Br J Obstet Gynaecol	Investigate acupuncture treatment during labour with regard to pain intensity, degree of relaxation and the outcome of the delivery compared to conventional analgesia alone.	- Normal singleton pregnancy - Pregnancy wk ≥ 37 - Spontaneous onset of labour -Cephalic presentation - Cervical dilation ≤ 6 cm at admission	RCT Experimental group n=51 given acupuncture Control group n= 49 no acupuncture	VAS 0=no pain/very relaxed 10=worst imaginable pain/very tensed	The two groups reported the same degree of pain intensity. The acupuncture group reported a significantly better degree of relaxation and the use of epidural analgesia was reduced.

Mechanisms of actions

The anti-nociceptive mechanisms of sterile water injections and acupuncture are not fully understood but several theories have been found in the literature. According to one theory, both methods cause afferent activity that inhibits nociceptive transmission in the spinal cord via pre- and postsynaptic inhibitory mechanisms, according to the gate control theory (20). Another theory involves the previously described descending pain relief systems as well (21, 84). A third theory is that sterile water injections and acupuncture activate the DNIC system. The

endorphin system is involved in the DNIC effect and it is not necessary to administer pain stimuli in the affected area (22, 85). Accordingly, the most effective way to block neurons projecting from the cord seems to be an activation of myelinated and unmyelinated fibres (86).

Sterile water is salt-free and thus causes osmotic irritation as well as mechanical stimulation of the skin due to increased local pressure in the tissue (87), which in turn results in an activation of afferent nerve fibres, probably A-delta and C fibres. Sterile water injections are painful and might activate of all pain relief systems described above. Acupuncture needles placed and stimulated in the referred pain area activate A-delta and possibly C fibres in the muscle (88). The acupuncture stimulation does not always cause pain, even if it activates high-threshold afferents, and it is unclear whether acupuncture activates all system described.

The role of the midwife and pain relief during childbirth

The word midwife means *with woman* (89); a midwife's job is to help women in childbirth (90). The midwife's ability to be "with the woman" is based on her personal qualifications in combination with knowledge and practice (89, 91). Modern midwifery ranges between *the art of doing nothing well* which means supporting normalcy, being present and not intervening unless necessary (92), and high-tech care when a normal process becomes abnormal (93). The midwife's role during childbirth has been described as being an anchored companion available to the woman (94). Several studies have pointed out the positive meaning of the midwife's support during childbirth (95-100).

In Sweden, the midwife is independently responsible for the woman during normal pregnancy and childbirth (69, 101) and sees her in several consultations, individually and/or together with her partner, during pregnancy (102). It is rather common that the woman and her partner also participate in antenatal classes in which considerable information, e.g. on childbirth, breastfeeding and parenthood is provided (103). During pregnancy the midwife has the opportunity to support and strengthen the woman's faith and confidence in her own ability to cope with labour pain. The midwife assists the woman in clarifying her personal views and expectations about pain during labour (104). However, as it is difficult to understand in advance how to cope with the pain and what/how much pain relief might be required, the woman is also informed about pain relief alternatives available at the respective hospital (102). This information is required to be based on both scientific knowledge and clinically tested experience (105).

During childbirth, the goal is to continue supporting the woman throughout labour based on the concept that it is a normal process and that she has her own resources to cope with this situation (106). Assessing the woman's need for and expectations

concerning pain relief, while showing respect for her need to remain in control and her own wishes and choices (107, 108) is one of the midwife's more important tasks. The midwife must be knowledgeable about the pain sensation mechanisms during labour, particularly about the relationships between the sensory, affective and cognitive dimensions and how they interact (6, 109). It is also important that the midwife be well-informed about all pain relief methods, both their advantages and disadvantages, and about when to recommend one specific method.

OBJECTIVES

The overall aim

While it is valuable to offer complementary pain relief methods to women in childbirth there is also a need to continuously develop and evaluate the use and effectiveness of these methods. Therefore, the overall aim of this thesis was to acquire more knowledge about sterile water injections and acupuncture in order to offer child birthing women as effective and comfortable pain relief as possible.

The specific aims were:

- » To elucidate whether the new subcutaneous method of administering sterile water, as well as the previously described intracutaneous injection method, were effective for the relief of labour pain (Paper I).
- » Investigate if, during injections of sterile water, there was any difference between the respective perceived pain associated with the intracutaneous and subcutaneous techniques (Paper II).
- » To elucidate the clinical use of acupuncture and sterile water injections for pain relief and relaxation during childbirth in Swedish delivery wards (Paper III).
- » To elucidate if there were any differences between acupuncture and sterile water injection effects in terms of pain relief and relaxation during labour (Paper IV).

METHODS

The designs, study population and the statistical analysis of the four studies are shown in Table 3.

Table 3. An overview of the study design, population and statistical analysis.			
Paper	Design	Study population	Statistical analysis
I	Prospective randomized controlled single-blind trial	99 women in childbirth	Mann-Whitney <i>U</i> Chi-square
II	Prospective randomized controlled single-blind trial with cross-over design	100 female volunteers	A general linear model for repeated measures
III	Survey, structured questionnaires	565 midwives	Descriptive statistics Two-tailed sign test
IV	Prospective randomized controlled trial	128 women in childbirth	Fisher's permutation test Fisher's exact test Chi-square Pitman's test Mantel's test

Paper I

The study design was a prospective randomized controlled trial. Women in labour were randomized to one of three groups (Figure 3). Randomization was accomplished by computer and the individual envelopes with the randomization results were kept in sealed outer envelopes in the delivery ward. Block randomization in groups of nine was used in order to balance the participants in different groups.

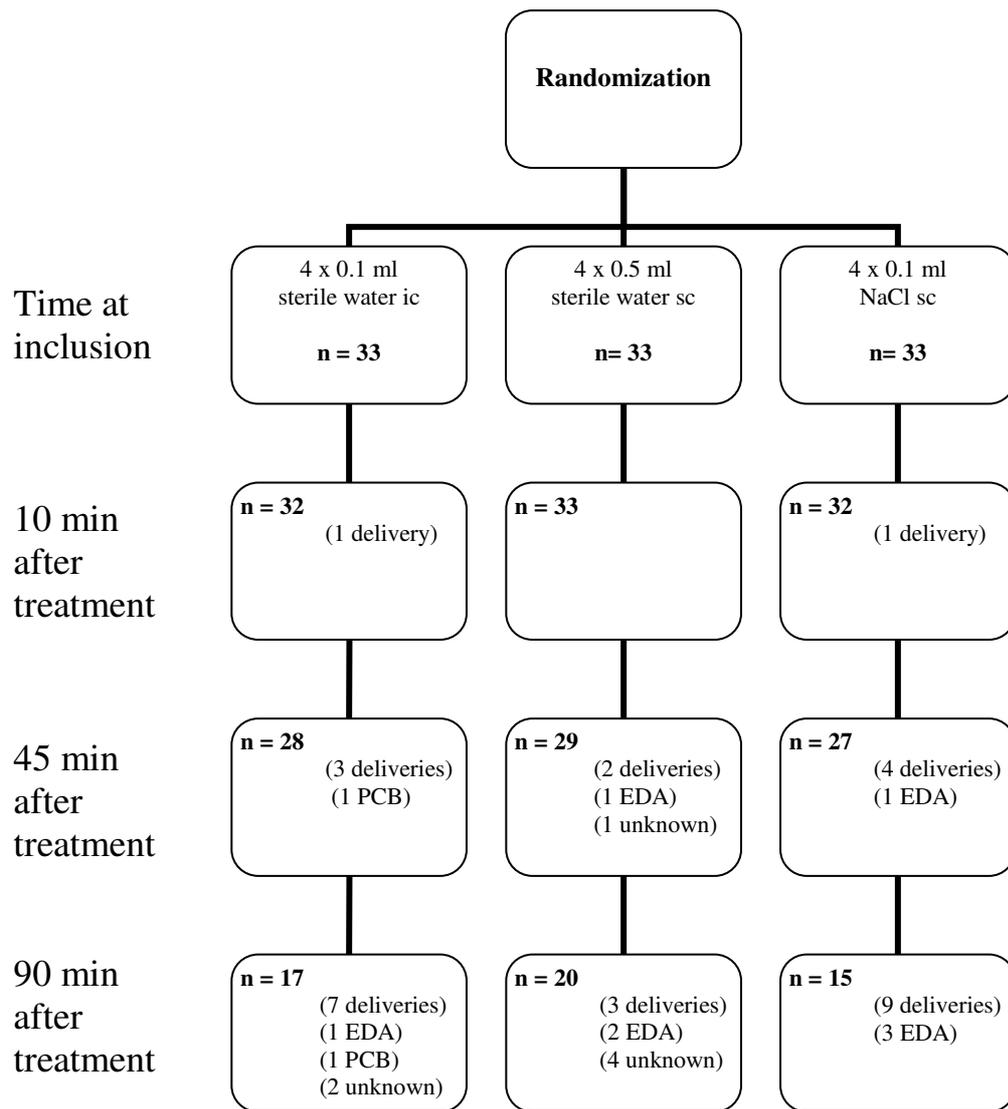


Figure 3. Flow of women's participation throughout the trial in Paper I.

Criteria for inclusion:

- » Gestational week 37-42
- » First stage of labour
- » Requires pain relief for lumbar pain

Criteria for exclusion:

- » Use of opiates up to three hours prior to the trial
- » Paracervical block
- » Epidural analgesia

Procedure

The first group was given 4 x 0.1 ml sterile water intracutaneously, the second group was given 4 x 0.5 ml sterile water subcutaneously and the third group was given 4 x 0.1 ml isotonic saline (NaCl) subcutaneously (placebo group). All injections were administered in the lumbar region (Figure 4) during a contraction while the woman was inhaled entonox. A 1-ml syringe (Codan Medical, Denmark) and a short thin needle (0.4 x 19 mm, Becton Dickinson, Ireland) were used for all injections.

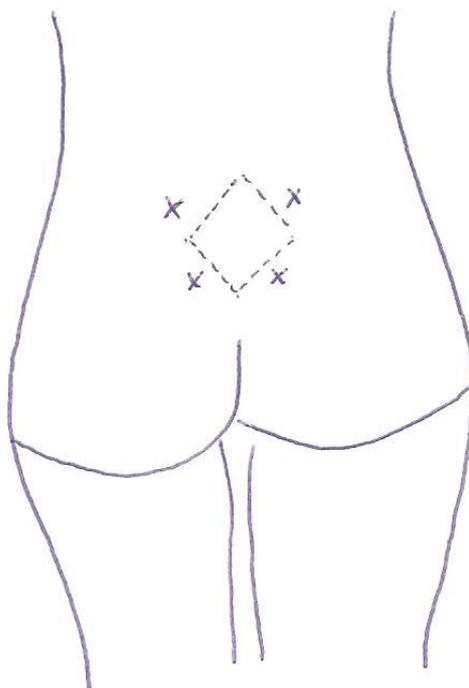


Figure 4. The placement of sterile water injections in Paper I.

Only the midwife administering the treatment knew to which group the woman was randomized. This particular midwife did not participate in the woman's care in any other way nor did she participate in registering the woman's scoring of her labour pain. The woman's delivery midwife was not present in the delivery room during the injections, and did thus not know to which group the woman was randomized. The pain level was measured by a visual analogue scale (VAS) immediately before and 10, 45 and 90 minutes after treatment. After delivery the woman was asked to answer some questions about the treatment effect. The delivery midwife was also asked to give her opinion on the treatment effect.

Paper II

The study was a prospective randomized controlled trial with a cross-over design in which all participants were given both intracutaneous and subcutaneous injections. The women were recruited among employees at the Departments of Obstetrics and Gynaecology at Mölndal Hospital and the Kärnshuset Hospital in Skövde and students at the Department of Health Sciences at the University of Skövde. General information about the study was given to the hospital staff at ordinary staff meetings. At the university, three special meetings were arranged in order to provide the students with information about the study.

The women were randomized by computer to one of two groups (Table 4). The individual envelopes with the randomization results were kept in sealed outer envelopes at the delivery ward at Mölndal Hospital and at the Department of Health Sciences at the University of Skövde.

RANDOMIZATION							
Group 1				Group 2			
<i>First day</i>				<i>First day</i>			
0 min	1.5 min	10 min	11.5 min	0 min	1.5 min	10 min	11.5 min
0.1 ml sterile water ic	VAS	0.5 ml sterile water sc	VAS	0.5 ml sterile water sc	VAS	0.1 ml sterile water ic	VAS
<i>Second day</i>				<i>Second day</i>			
0 min	1.5 min	10 min	11.5 min	0 min	1.5 min	10 min	11.5 min
0.5 ml sterile water sc	VAS	0.1 ml sterile water ic	VAS	0.1 ml sterile water ic	VAS	0.5 ml sterile water sc	VAS

Criteria for inclusion:

- » Healthy women
- » Non-pregnant
- » Aged 18-45 years
- » No pain condition at time of the trial

Procedure

The trial was performed on two occasions with a three- to six-day interval. On the first day, the women were given two injections with a 10-minute interval. Group one was first given 0.1 ml sterile water intracutaneously, followed by a second subcutaneous injection of 0.5 ml sterile water. Group two was first given 0.5 ml sterile water subcutaneously, followed by a second intracutaneous injection of 0.1

ml sterile water. During the second day, the injections were administered in reverse order in both groups (Table 4). A 1-ml syringe (Codan Medical, Denmark) and a short thin needle (0.4 x 19 mm, Becton Dickinson, Ireland) were used for all injections. All injections were administered by two midwives experienced in administering injections of this kind. The women were not aware of the type of injection they received during the trial. The injection pain level was measured by VAS 90 seconds after all injections.

Paper III

Twelve hundred questionnaires were sent out to all 51 delivery units in Sweden. Before the main study, a test version of the questionnaires was tried out among twenty midwives. Critical points of view on the design were discussed and some minor modifications were made before the final version was sent to the delivery units.

Criteria for inclusion:

- » Midwife
- » Working in the delivery ward at time of trial
- » Successful formal acupuncture training

Procedure

Personal contact was taken with the head midwife or equivalent at all delivery units for verbal information before and during data collection. Two reminders were sent out. Questionnaires were distributed by mail to the head midwives at the delivery units. In an enclosed letter the head midwives were asked to inform the ward midwives about the survey. The questionnaires were handled anonymously and returned in prepaid envelopes.

Paper IV

The study design was a prospective randomized controlled trial. Women in labour were randomized to one of two treatments; acupuncture or sterile water injections. It was impossible to blind this trial due to the two method's different characteristics. Randomization was accomplished by computer and the individual envelopes with the randomization results were kept in sealed outer envelopes in the delivery ward. The envelopes were kept in two groups, one for primiparas and one for multiparas and were opened by the midwife just before the treatment. Block randomization in groups of ten was used in order to balance the participants in the different groups. Prior to the trial the acupuncture points were chosen both from recommendations in the literature and in cooperation with the midwives, the latter in an attempt to imitate normal clinical practice.

Criteria for inclusion:

- » Gestational weeks 37-42
- » Spontaneous onset of labour
- » Requires pain relief

Criteria for exclusion:

- » Use of opioid analgesic, acupuncture, (TENS) or sterile water injections within 10 hours prior to the trial
- » Paracervical block
- » Intrathecal analgesia
- » Epidural analgesia
- » Augmentation of labour

Procedure

In the acupuncture group all women were given acupuncture at GV20, LI4 and SP6. Local acupuncture points were selected individually, depending on where the woman felt the pain; the midwives could choose four to seven points among BL23-28, BL54, EX19, GB25-29 and KI11 (Figure 5). A total of 12-19 needles could be administered. The needles (Hegu AB, Landsbro, Sweden) were made of stainless steel (0.30 x 30 or 0.35 x 50 mm). After insertion the needles were all stimulated to evoke needle sensation (De Qi), left in situ for 40 minutes and stimulated manually as described above every 10 minutes. The treatment could be repeated if necessary.

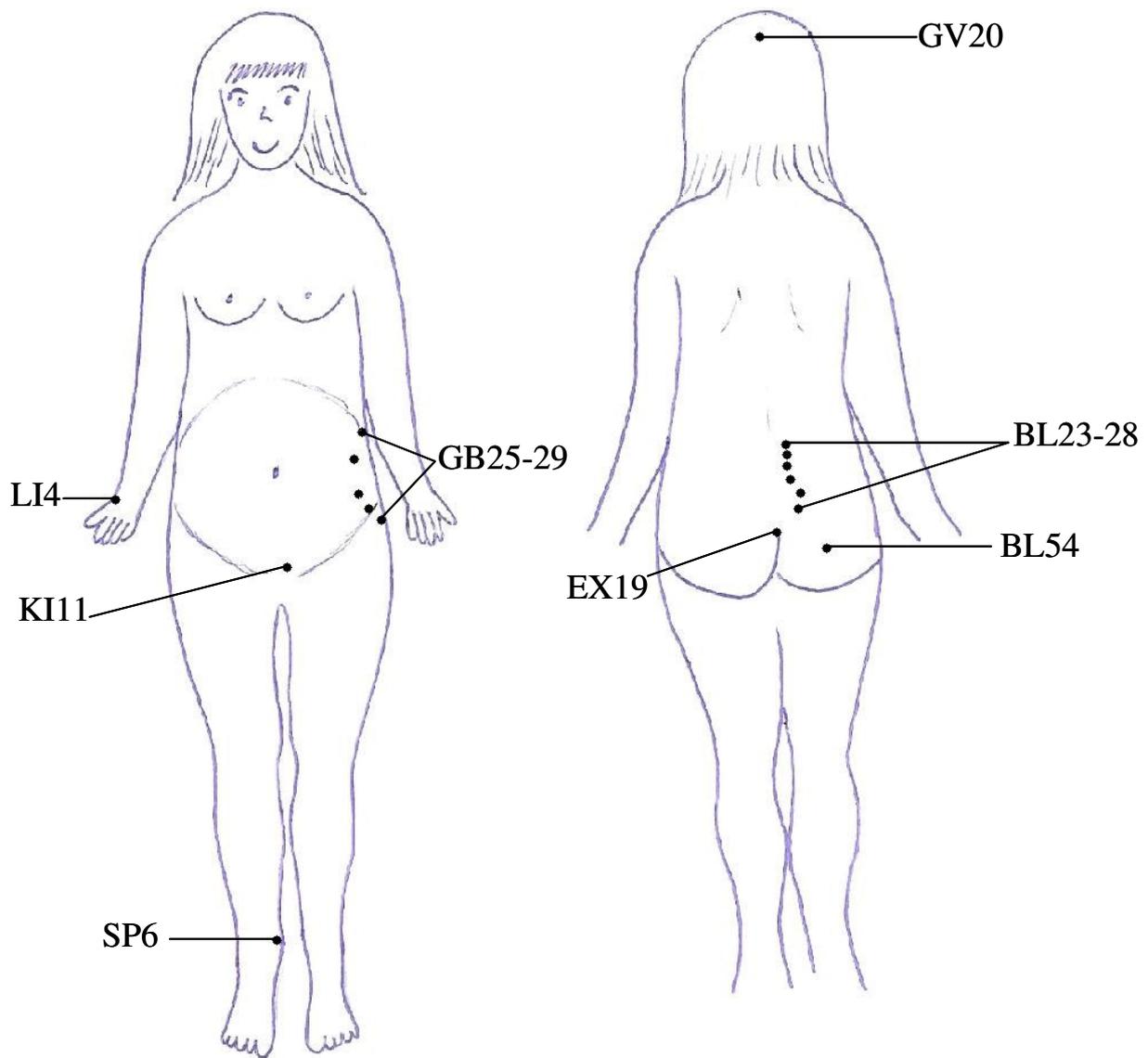


Figure 5. The acupuncture points used in Paper IV.

The other group was given 4-8 injections of 0.5 ml sterile water subcutaneously. The injections were administered where the pain was perceived (Figure 6), and could be repeated if necessary. The injections were administered during a contraction and the woman could, if she wanted, breath entonox during the treatment. A 2-ml plastic syringe (BIBRAUN Omnifix®) with a thin needle (BIBRAUN Omnifix® 0.4 x 20 mm) was used.

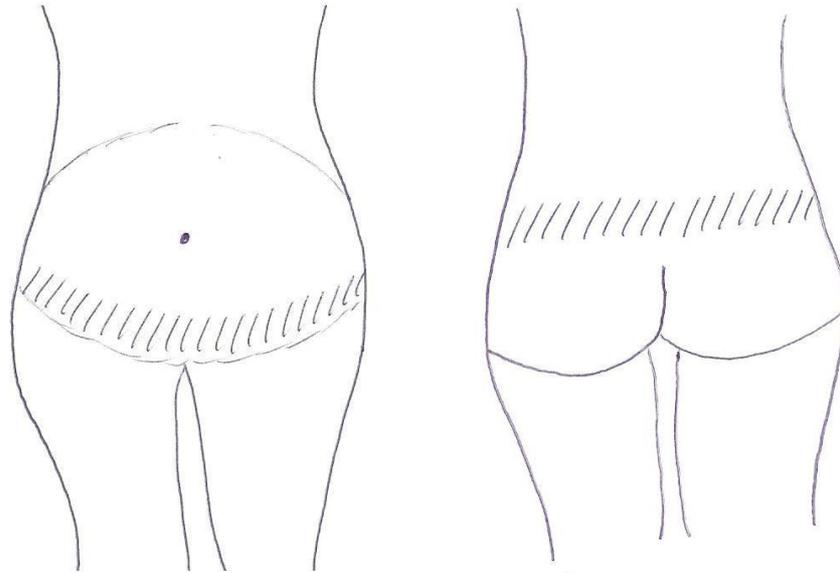


Figure 6. The location of sterile water injections in Paper IV.

The treatment was given by the woman's delivery midwife in both groups. Another midwife was responsible for the assessment of pain and degree of relaxation on a VAS immediately before and 30, 60, 90, 120, 150 and 180 minutes after treatment. After delivery the woman was asked to answer some questions about the treatment effect. The delivery midwife was also asked to give her opinion of the treatment effect.

Assessment instrument

Visual Analogue Scale (VAS)

A VAS is a 10-cm long vertical or horizontal line with the suggested end points *no pain* and *severe pain*. The pain experience is measured by the person marking the appropriate point on the line (110). VAS has been shown to be sensitive for pain intensity (111-113) and most individuals have no difficulties using it (111, 114). VAS has also been used to measure relaxation in some studies (81, 83, 115). The instrument is quick and easy to use and its simplicity makes it suitable during childbirth when the woman has a short time between the contractions to rank pain and relaxation.

When measuring labour pain (Papers I and IV) and injection pain (Paper II) a 10-cm horizontal ungraded VAS, with the endpoints *no pain* (ingen smärta) on the left and *worst conceivable pain* (värsta tänkbara smärta) on the right was used. Scores

were given in mm. When measuring the degree of relaxation (Paper IV) a 10-cm horizontal ungraded VAS, with the endpoints *totally relaxed* (helt avslappnad) on the left and *very tense* (mycket spänd) on the right, was used. Scores were given in mm.

Questions

The women in Papers I and IV were asked after delivery rate effect and if they would consider the respective treatment during a possible future delivery. They were also asked to motivate their answers. The delivery midwives were asked for their opinions regarding the treatment effect (Papers I and IV).

Questionnaire

In Paper III a questionnaire was sent out to midwives with acupuncture training in all delivery units in Sweden. All questions were constructed with given alternative answers, with the possibility to comment on some of the answers. The following areas were in focus: delivery ward experience; education (in addition to midwifery education and acupuncture training); when to use acupuncture and sterile water injections, respectively; how to administer sterile water injections; how to use acupuncture; knowledge of general recommendations concerning the methods and; finally, the basis for the information about the methods given to the woman and her partner. The questionnaires contain a total of 34 questions and can be viewed at: <http://www.his.se/templates/vanligwebbsida2.aspx?id=13580>.

Statistical analysis

Paper I

The sample size was estimated in accordance with our earlier experience of a similar study, in which a sample size of 45 women divided into two groups was sufficient to yield a highly significant difference in pain scores between active treatment and placebo (70). Continuous data were analyzed with a nonparametric test (Mann-Whitney *U* test) and data were presented as median [25th, 75th centiles]. Categorical data were analyzed with the Chi-square test. *P* values <0.05 indicated a significant difference. Odds ratio (OR) and 95 % confidence intervals (95 % CI) were calculated for categorical data.

Paper II

In order to detect a difference of ten mm on a VAS with a power of 85 %, at a 5 % significance level, the sample size would have to be 90 women. Our sample

consisting of 100 women is thus adequate. Means of the two rankings of pain during the intracutaneous and subcutaneous injections, respectively, were calculated for each subject and for each trial day. A general linear model for repeated measures was applied. Statistical significance tests were performed against the null hypothesis that there would be no difference in perceived pain between intracutaneous and subcutaneous injections.

Paper III

Descriptive statistics, including frequencies, mean \pm standard deviation, median [25th 75th centiles] and percentages, were used. The sign test was applied for pair comparisons between acupuncture and sterile water injections with respect to the estimated proportions of pregnant women who were familiar with the methods. The same test was also used for comparison of the probabilities that an item was among the three most important for one treatment only. Two-tailed tests were used.

Paper IV

We assumed that there would be a difference of 15 mm in the change in the VAS pain score after treatment, compared to pre-treatment, between the groups. The estimated standard deviation of the change was 30 mm in an earlier study. To achieve 80 % power at the 5 % significance level in a two-tailed test, 64 women in each group was sufficient. Continuous variables were compared by use of a nonparametric test, Fisher's Permutation Test (116) and data were presented as mean \pm standard deviation, median, [25th, 75th centiles], n and per cent. Categorical variables were analyzed with Fisher's exact test and the chi square test and data were presented as mean \pm standard deviation, n and per cent. Pitman's test was used to test the correlation between age and pain/relaxation respectively. In order to eliminate the influence of age, Mantel's test (116, 117) was applied for the primary comparison of maximum pain after treatment during the study period compared to pain before treatment in the two groups. Two-tailed tests at the significance level 0.05 were used.

Ethical approval

The studies in this thesis were approved by the Ethics Committee at Göteborg University (Paper I, Dnr: 460-93), (Paper II, Dnr: 262-96) and by the Research Ethics Committee of the Medical Faculty at the University of Göteborg (Paper III, Dnr: 383-04), (Paper IV, Dnr: Ö 476-03).

RESULTS

Paper I

The study comprised 99 pregnant women who chose to give birth at the delivery ward at Mölndal Hospital. We found that the VAS pain score was significantly lower in both treatment groups 10 minutes after treatment, compared with the placebo group ($p=0.001$). The difference remained 45 minutes ($p=0.005$), but not 90 minutes ($p=>0.05$), after treatment (Figure 7).

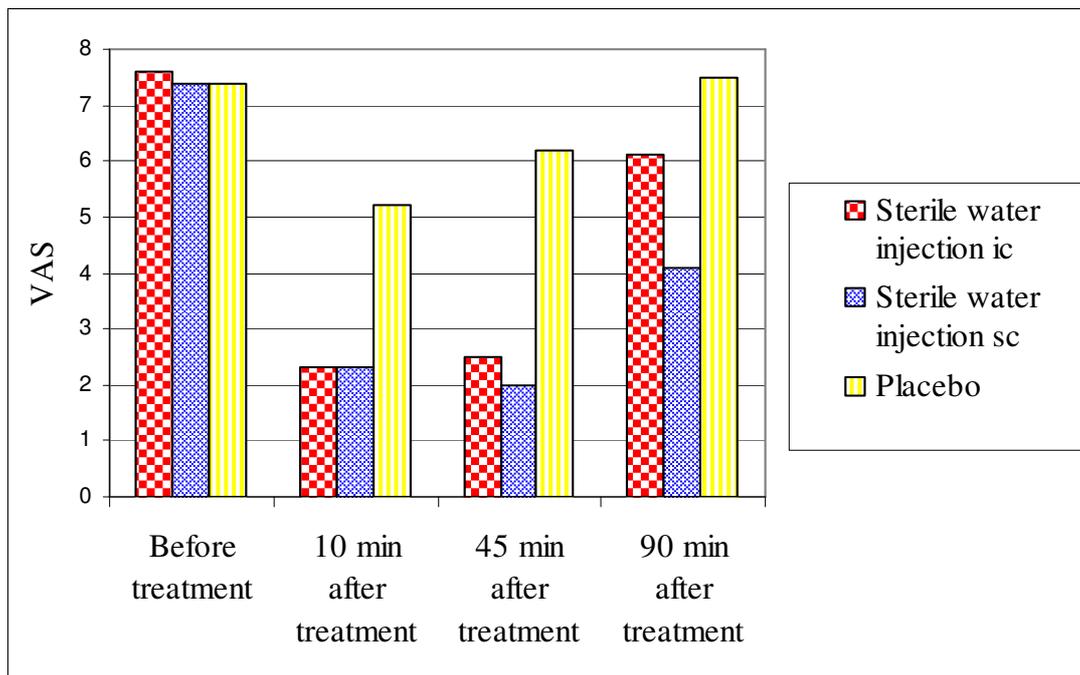


Figure 7. Median pain scores before and after treatment.

The midwives responsible for the parturients assessed the pain relief effect as significantly higher in the treatment groups than in the placebo group ($p<0.001$). No significant difference between the two treatment groups was registered. The women's willingness to use the method in a possible future delivery was higher in both treatment groups, compared with the placebo group ($p<0.001$).

Paper II

The study comprised 100 healthy women (50 nursing students, 34 midwives, 13 nursing assistants and 3 obstetricians), all of whom completed the two-day trial. We found that subcutaneous injections were still perceived as less painful than

intracutaneous injections after trial, day and injection location were taken into consideration (mean 60.8 vs 41.3, $p < 0.001$). Four women did not experience any difference between the injection pain of the two techniques. Twelve women experienced the subcutaneous injection as the most painful and 84 women experienced the intracutaneous injection as the most painful (Figure 8).

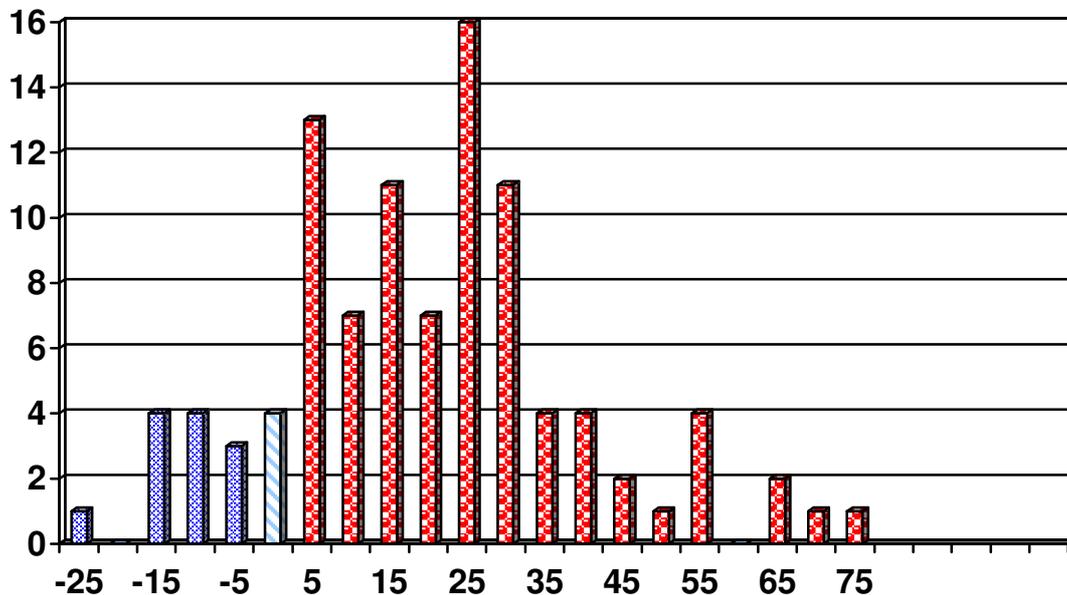


Figure 8. Distribution of differences in pain rankings for intracutaneous and subcutaneous injections. A negative value signifies more pain after subcutaneous injection, a positive value signifies less pain after subcutaneous injection, 0 indicates no difference.

Furthermore, the women experienced the injections administered on the first day as more painful than those administered on the second day (mean 53.7 vs 48.5, $p < 0.001$).

Paper III

Nine hundred and sixty midwives fulfilled the inclusion criteria and had the opportunity to respond. We received answers from 565 (59 %) midwives; demographic data for the participants are shown in Table 5.

Table 5. Demographic data for the study participants (n=565). Values are given as n, mean±SD.

Demographic Data	n	Mean	SD
Age (years)	560	46.93	7.96
Hours of duty (percent of full time)	558	84.15	17.17
Midwifery experience (years)	565	17.62	9.84
Experience of maternity care (years)	554	15.56	9.59
Acupuncture experience (years)	531	7.22	3.95

All hospitals in Sweden were represented and the response rate varied from 18 % to 100 % (Figure 9).

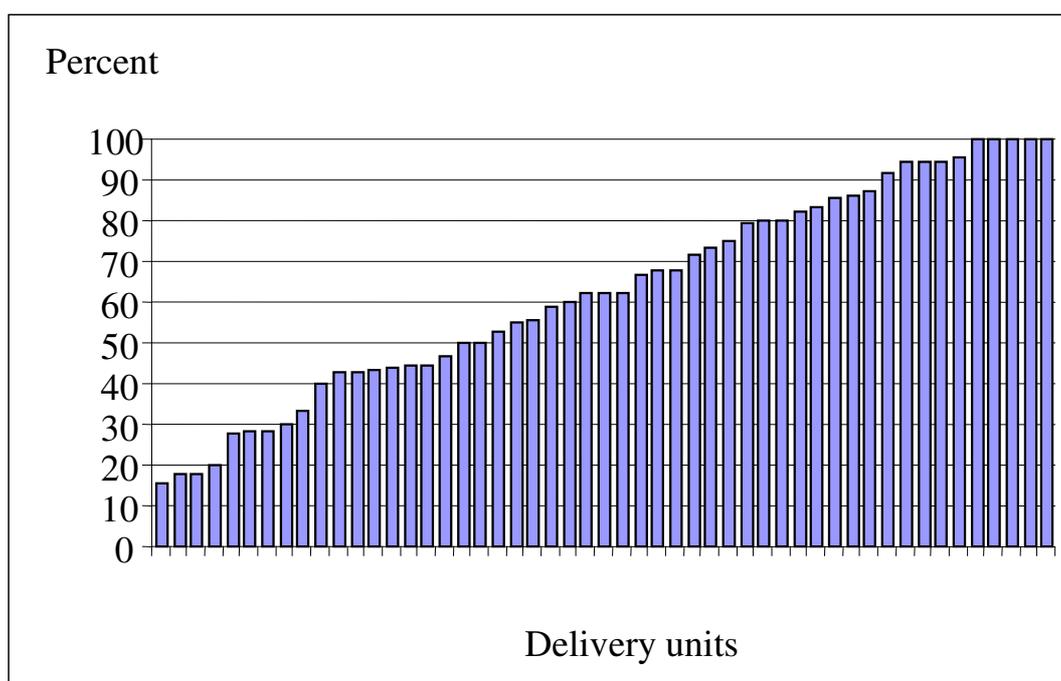


Figure 9. Response rate for all 51 hospitals.

Both methods were used in all maternity wards. The midwives' estimated frequency of acupuncture administration was much higher than that of sterile water injections, 25 % versus 2 % (median).

Relaxation

Three hundred and twenty-nine (68 %) midwives chose acupuncture as their first choice for relaxation. Other relaxation methods were bath, shower, psycho-

prophylaxis, warm towels and pillows (152, 31.2 %). Just 4 (0.8 %) midwives reported sterile water injections as their first choice for relaxation.

Pain relief

When the midwives would choose sterile water injections for themselves for a possible future delivery, they chose a combination of both methods more often than only sterile water injections for the women in labour in their care. This is the pattern for all three pain locations. When midwives chose acupuncture for themselves for a possible future delivery, they chose a combination of both methods less often for abdominal pain and inguinal pain, but more often for back pain, for the women in their care.

Administration routines for acupuncture and sterile water injections, respectively

During acupuncture, stimulation of the needles after insertion was undertaken regularly by 392 (72 %), never by 107 (19.6 %) and sometimes by 30 (5.5 %) midwives and 16 (2.9 %) midwives stimulated just when they applied the needles. Treatment duration was between 5 and 350 minutes (median 45 minutes). When sterile water injections were used, it was most common (412, 88.1 %) to administer the injections intracutaneously. Only 46 midwives (9.8%) gave the injections subcutaneously and 10 (2.1 %) used both injection techniques.

Paper IV

A total of 451 pregnant women who chose to give birth at the delivery ward at Kärnsjukhuset Hospital in Skövde were asked to participate in the study. One hundred and fifty-six women (35 %) accepted to participate. The known reasons for not participating in the study are shown in Figure 10.

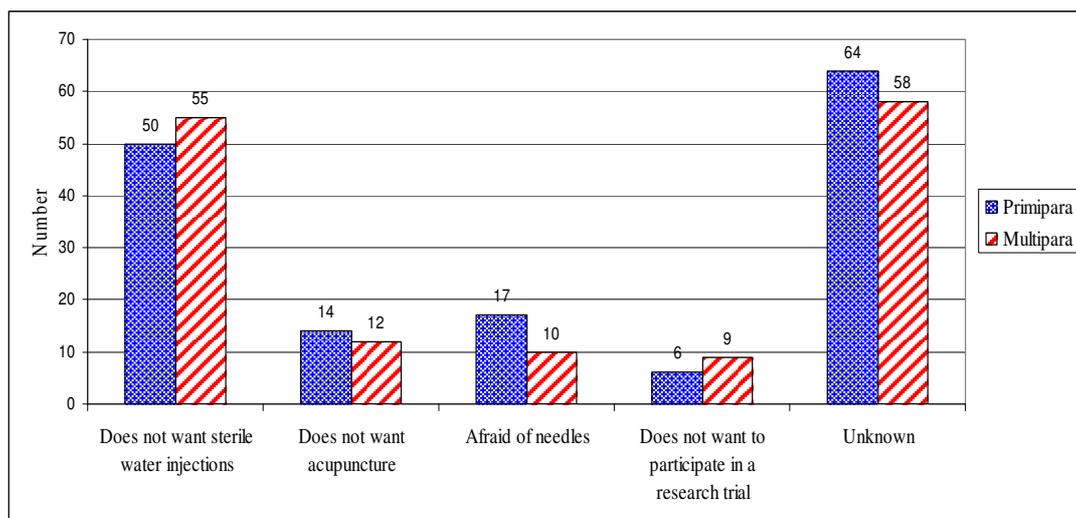


Figure 10. Known reasons for declining to participate in the study, (n = 295).

After randomization the dropout rates were quite similar in the two groups', 16 in the acupuncture group and 12 in the sterile water injection group. A total of 128 women completed the study (Table 6).

Table 6. Flow chart of women's participation throughout the trial (n = 128)

<i>Acupuncture (n=62)</i>	<i>Dropout</i>	<i>Sterile water injections (n=66)</i>	<i>Dropout</i>
<i>30 min after treatment (n=62)</i>	Delivery (n=5) Epidural analgesia (n=1)	<i>30 min after treatment (n=66)</i>	Delivery (n=6) Acupuncture (n=1) Epidural analgesia (n=2)
<i>60 min after treatment (n=56)</i>	Delivery (n=8) Sterile water injections (n=2) Epidural analgesia (n=4) Paracervical nerve block (n=1)	<i>60 min after treatment (n=57)</i>	Delivery (n=4) Acupuncture (n=1) Epidural analgesia (n=6) Paracervical nerve block (n=1)
<i>90 min after treatment (n=41)</i>	Delivery (n=3) Epidural analgesia (n=4)	<i>90 min after treatment (n=45)</i>	Delivery (n=6) Epidural analgesia (n=1)
<i>120 min after treatment (n=34)</i>	Delivery (n=6) Sterile water injections (n=1) Epidural analgesia (n=5)	<i>120 min after treatment (n=38)</i>	Delivery (n=3) Acupuncture (n=1) Epidural analgesia (n=7)
<i>150 min after treatment (n=22)</i>	Delivery (n=1) Epidural analgesia (n=3) Paracervical nerve block (n=1)	<i>150 min after treatment (n=27)</i>	Delivery (n=1) Epidural analgesia (n=2)
<i>180 min after treatment (n=17)</i>		<i>180 min after treatment (n=24)</i>	

We found that women given sterile water injections experienced significantly less pain ($p<0.001$) and a higher degree of relaxation ($p<0.001$) than women given acupuncture. The differences at defined timepoints are shown in Figure 11.

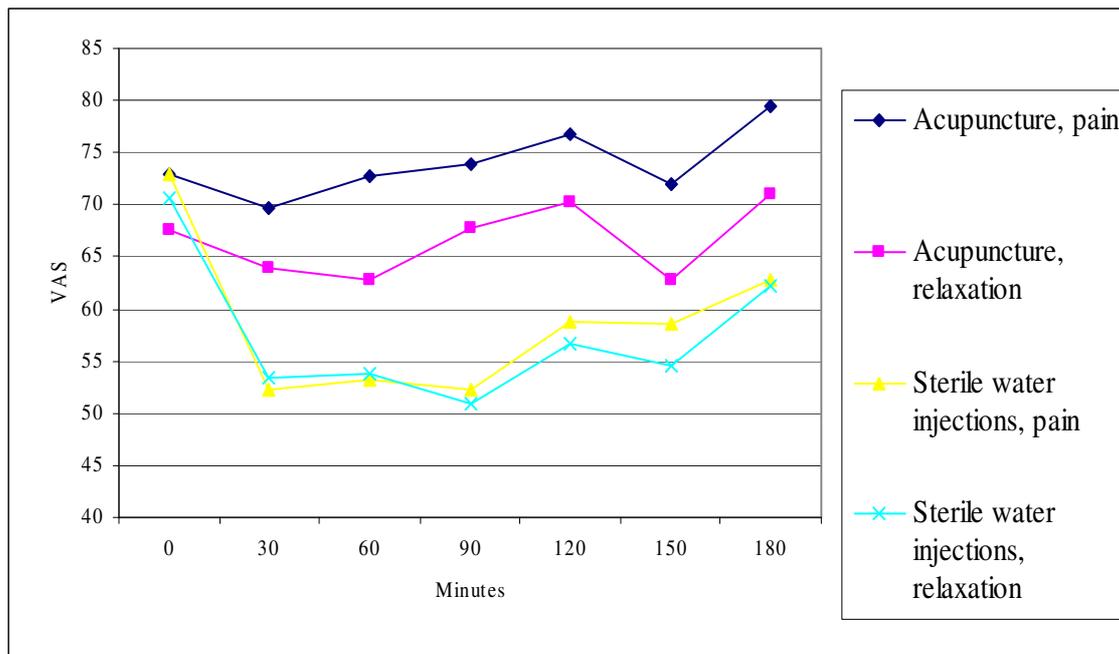


Figure 11. Changes in pain and degree of relaxation in sterile water injections and acupuncture groups at different timepoints. Dropout at different timepoints is shown in Table 6.

Both women's and midwives' preconceptions about the pain relief effect favoured sterile water injections ($p < 0.001$). The degree of relaxation was significantly higher in the sterile water group, compared with the acupuncture group ($p < 0.02$). There were no significant differences between the two groups regarding the use of additional pain relief after treatment.

Seventy-one percent of the women in the sterile water injections group and 59 % in the acupuncture group stated that they would use the same pain relief method in a possible future delivery. This difference was not statistically significant.

DISCUSSION

Results

The most interesting result in this thesis is that sterile water injections provide more pain relief and a higher degree of relaxation during childbirth than acupuncture. A survey of the literature indicates that sterile water injections are a good alternative, particularly for low back pain during labour (70-75). The designs of these studies are quite similar to each other and the results are concordant.

Previous studies regarding acupuncture and labour pain relief are not as concordant as those on sterile water injections (80-83). In a systematic review by Smith et al. (118) it was stated that acupuncture may help relieve pain during labour but that more research is needed. Ramerö et al. (81) found that acupuncture gave a higher degree of relaxation than was experienced by the control group; on the other hand, Ziaei and Hajipour (83) did not make a similar finding in their study. This relaxation issue has never been elucidated concerning sterile water injections but when the two methods were compared in Paper IV we found that sterile water injections created a higher degree of relaxation than acupuncture. However, it is difficult to distinguish between pain and relaxation. If the pain is decreased, it will probably also influence the level of relaxation and probably vice versa. As reported in Paper IV changes in VAS scores over time for pain and relaxation were quite similar (Figure 11).

Previous studies have mostly focused on sterile water injections in connection with lower back pain (70, 72-75). The reductions in VAS scores in these studies are quite similar to each other and to the results in Paper I, but differ from the results regarding sterile water injections in Paper IV, in which labour pain was treated independently of pain location. However, Dahl and Aarnes (71) also found better relief of back pain than of lower abdominal pain. It is relevant to question if these injections are particularly effective in cases of low back pain. The mechanisms of action of sterile water injections are not fully understood but are most likely either a combination of pain inhibition on both the segmental (20) and central (84) levels and/or based on counterirritation according to DNIC concept (22, 85). From this perspective there should be no difference if the injections are administered for back, hip or lower abdominal pain. However, no studies with the specific aim of elucidating the mechanisms of action of sterile water injections have been carried out. We therefore agree with Simkin and Bolding (119) that more research is required in order to obtain more knowledge on the effects of repeated injections, varying locations and mode of action.

Although it is difficult to compare results from different studies, we noted that pain relief in the Skilnand study (82) seems to be better, compared to the results in the acupuncture group in Paper IV. One difference between these two studies is the number of midwives involved. Only six midwives administered treatment in the Skilnand study (82) while 40 midwives were involved in the study reported in Paper IV. Perhaps the midwives in the Skilnand study (82) were more skilled and experienced in the acupuncture technique because they administered it so often. In Paper III, a wide range in midwives' own stated use of acupuncture for labour pain was found; the situation in the delivery ward in which we collected data for Paper IV was probably similar. This might have influenced the results of the treatment. We decided to permit all midwives with acupuncture training to administer acupuncture because this reflects current clinical practice. However, if acupuncture is a method that requires so much clinical skill, perhaps all midwives should not be permitted to administer this treatment.

Experimental studies indicate that the number of stimulations to reach De Qi, during acupuncture treatment, is important (88). In Paper IV, the instructions were clear: the needles were left in place for 40 minutes and stimulated every 10 minutes, according to clinical routine. Another option is to stimulate enough to reach De Qi at insertion and then to tape the needles and leave them in place without further stimulation, sometimes for several hours (personal communication, Lilleba Anckers 2005-04-13). The frequency of stimulation to reach De Qi varies a lot in clinical practice. In Paper III it was found that 28 % of the respondent midwives did not stimulate the needles regularly during labour. However, we thought it more reasonable to stimulate often in the study, because labour pain is most often is severe.

Subcutaneous sterile water injections are very easy to administer. Once having learned this injection technique it is almost impossible to fail. The intracutaneous injection technique is a little bit more difficult. If the intended intracutaneous injection is administered too deep, it will automatically become subcutaneous. The results in Paper I and II indicate that the subcutaneous technique also provides good relief for low back pain, with less injection pain.

What VAS score change, i.e. what reduction in pain level, is meaningful for a woman in labour pain? When the women were included in these trials the median VAS score for pain was between 74-76 mm (Paper I) and 75 mm (Paper IV). According to Jensen et al. (120), this is a severe level of pain. Some studies have suggested that a VAS score reduction of less than 13-20 mm has no clinical value (121-123). Other studies suggest that a 33 % (120) or 31-48 % (124) reduction in VAS score required, but that it depends on the initial pain intensity. Kelly (125) found that meaningful reduction in VAS score did not differ with the pain intensity level. However, these results are from patients with trauma or postoperative pain.

There are, to our knowledge, no similar studies regarding labour pain. Most women expect childbirth to be painful and they know that it is almost impossible to have a totally painless labour (126, 127). Furthermore some women want to avoid powerful pharmacological methods because of their known or unknown negative side effects (128). Therefore, it is conceivable that a low reduction in VAS score, as in Paper IV, is sufficient for some women.

Epidural analgesia is the most powerful pain relief method available for labour pain (129-131). The epidural rate in Paper I harmonized with the rate at that ward during the period of the trial (56). In Paper IV, the epidural rate was higher (40 % in the acupuncture and 47 % in sterile water group) than the ordinary ward rate (31 %) while the trial was running, (personal communication Anne-Berit Fredriksson, 2006-04-10). One explanation might be that neither sterile water injections nor acupuncture are powerful enough as pain relief for most women in labour. The high epidural rate in Paper IV could possibly be attributed to some kind of selection bias. Women who choose to participate in the trial probably expect to need pain relief. On the other hand, this factor should have had the same effect in Paper I. One might question if there is something else that increased the epidural rate in Paper IV. For example, has the women's and/or the midwives' overall attitude to epidural analgesia changed during this period?

The rates of sterile water injections and acupuncture administration have changed over time; acupuncture is currently in more common use than sterile water injections (56). The reasons for this are unknown but the observed disadvantage of sterile water injections, i.e. the pain women experience in connection with administration (70, 71, 73-75) might be one explanation. This injection pain can be reduced if the injections are given subcutaneously (Paper II), with unaltered pain relief effect (Paper I). In Paper III, it was found that only 11.9 % of the respondents use the subcutaneous technique.

The results concerning pain during injection are from a study carried out among non-pregnant female volunteers (Paper II). It is relevant to question if the results would have been similar if women in labour had been included. Some data indicate that β -endorphin levels are increased during delivery (27-29) which might raise the baseline for pain tolerance. This may well be the case but it does not seem likely that this phenomenon alters the different responses to the two injection techniques. However, we tried to elucidate this during collection of data for Paper I but it was difficult for the women in labour to discriminate between labour pain and injection pain. The clinical routine was that the injections were given during a contraction while the women inhaled entonox. We thought that it would have been inappropriate to change this routine solely for the trial.

Even if several studies demonstrate that sterile water injections provide good pain relief for low back pain (70-75), acupuncture seems to be more common in clinical practice (Paper III). The midwives' estimation of the pregnant women's familiarity with these two methods favoured acupuncture (Paper III), which might explain the women's requesting acupuncture to a greater extent when pain relief is desired.

The results in Paper III indicate an interesting difference between the midwives' ranking of important items as a basis for information and recommendations about these two methods. Few midwives ranked scientific results as one of the three most important items. Furthermore, significantly more midwives ranked scientific results as more important in the case of acupuncture than when it came to sterile water injections. According to Sleep (132) and Bogdan-Lovis and Sousa (133), there is a gap between research and the midwives' clinical practice. Berggren (134) reported in her qualitative thesis that there are four different approaches to using results from midwifery research in clinical practice. A midwife with the "professional approach" expects to use research in practice, the "realistic approach" means that the midwife uses research in practice if she understands that the research is valuable but she requires further education. A midwife with the "personal approach" uses the research results if she is comfortable with them but her perception is that research interferes with practice and finally a midwife with the "considerate approach" considers that midwifery research confirms something she already knows through her own experience of clinical practice. It is relevant to assume that midwives have the same approach to research not classified as "midwifery research".

Both sterile water injections and acupuncture quickly became popular as pain relief methods when they were introduced in clinical practice in Sweden. The Swedish National Board of Health and Welfare (78) stated that there was a lack of knowledge regarding labour pain relief with acupuncture and requested more research in that area. It is interesting that acupuncture was used in clinical practice for so many years before a midwife started to evaluate the pain relief effect of this method (Table 7). In obstetrics acupuncture is used above all by midwives and it is thus their responsibility to evaluate the method.

Table 7. Implementation of sterile water injections (SWI) and acupuncture (ACU) as pain relief alternatives for labour pain in relation to scientific studies regarding the methods during the period 1985-2006.

SWI	1			1	1	2							1	1						
1985				1990					1995					2000	xxx				2005	
				ACU												2	1			1
1, 2	Number of scientific studies on sterile water injections																			
1, 2	Number of scientific studies on acupuncture																			
xxx	The Swedish National Board of Health and Welfare's – State Of The Art – Report on the management of normal delivery																			

In addition to good pain relief other factors, such as anxiety, support from the midwife and duration of labour, are also important for a woman's overall experience of the childbirth (55, 135). In order to understand a woman's need for pain relief during labour, it is important to pay attention to all dimensions- sensory, affective and cognitive- when recommending or choosing a pain relief method (109). This must be combined with considerable knowledge about the advantages and disadvantages of all pain relief methods and clinicians must thus constantly keep abreast of research in this area. It is probably a great challenge for the midwife to maintain the balance between these dimensions and demands but it is necessary to achieve the goal that the woman and her partner remember the childbirth experience as pleasurable and fulfilling as as possible.

Methodological considerations

The volume (0.5 ml) of the subcutaneous sterile water injections (Paper I) was based on results from an earlier study using subcutaneous sterile water injections for whiplash syndrome (136). NaCl was considered to be a placebo (Paper I), based on earlier comparisons between injections of sterile water and NaCl in which sterile water gave significantly stronger pain relief than NaCl (70, 74). In Paper IV we preferred to use the subcutaneous technique due to the positive results in earlier studies concerning pain relief (Paper I) and less injection pain (Paper II). In Paper I, the trial was blinded to the woman in labour, her partner and the delivery midwife. In Paper IV, it was impossible to blind the trial in any way due to the methods' different characteristics.

Pain experience during delivery is influenced by many different factors (10, 47) which means that each measured parameter is influenced by factors unknown to the researcher. The pain experience results from a physiological process combined with a subjective experience and it is impossible to identify which dimensions are being

assessed (137). It was impossible to control these confounding factors (Papers I, II and IV). It is, however, the total pain experience that is measured; it can also be expected to be influenced by the current clinical situation and by earlier experiences (138).

It is known that caregivers' conceivable enthusiasms regarding the treatments in a study might influence their patients to be more responsive to these treatments (139). When the injections in Paper I were given, the delivery midwife was not present in the room. Only the midwife who gave the injections was aware of the treatment group to which the woman was randomized. The pain was assessed by the delivery midwife. In Paper IV, the situation was the opposite. The delivery midwife gave the sterile water injections or acupuncture and another midwife assessed the level of pain and degree of relaxation. These routines minimized the possibility that the midwives' attitudes toward the two treatments might influence the women's assessment of the pain relief and relaxation effects.

Asking a number of questions in order to increase validity when using the VAS as the sole measuring instrument is valuable. This was done in Papers I and IV in which both the recently delivered women and the midwives were asked about the effect of the method. The answers to these questions are very subjective but may constitute an interesting comparison with the VAS results.

The reason for only including midwives with acupuncture training instead of all midwives in Paper III was our interest in finding out how they use these methods in clinical practice when they have access to both. The response rate is known to be a problem when sending out questionnaires (139, 140) and personal contact with the respondents has been shown to yield positive results (140). In this case, it was impossible to reach the respondents personally which means that we had to depend on the head midwives. We therefore contacted the head midwives personally several times during the data collection period in an attempt to reach potential respondents.

Ethical considerations

A woman in Sweden gives birth only a few times. This event is very special and unique and our goal is to support her throughout this process with minimal intervention. Requiring a woman to consider participation in a research trial will somehow disturb the process. When planning for a research trial such as those reported in Papers I and IV it is important to consider if there is another way to answer the research question. In these cases, we could not find another way to carry out these trials. Our judgement was that these comparisons must take place in a real clinical situation for the most reliable results. In Paper I, we discussed some ethical problems; the midwives found it difficult to ask the woman to participate when

they knew that she might be randomized to the placebo group. Therefore, we decided to ask female volunteers to participate in Paper II. However, it is also unethical to carry on with a treatment in clinical practice if knowledge of the treatment is incomplete.

Clinical implications

It might be relevant to question whether these methods are appropriate for obstetric care. There will probably always be women who, for various reasons, do not want traditional pharmacological pain relief in connection with delivery. Many women wish to participate actively in delivery and to have a sense of control without the effect of pharmaceuticals (128). At present, these women are recommended different methods which are not fully scientifically evaluated including sterile water injections and acupuncture.

Women in other parts of the world do not have access to the range of pain relief methods available in Sweden. There may be several reasons for this, e.g. a completely different attitude toward labour pain or an economical situation that make methods such as blockades, that place high demands on staff competence and ability to monitor the birthing woman, impossible. However, great care must be taken to avoid blood infection if sterile water injections or acupuncture are applied; only disposable materials should be used.

The staff at the Dr Jose Fabella Memorial Hospital in Manila, the Philippines, at with 32 000 deliveries annually, have shown great interest in the sterile water injection method because it is cheap and easy to use. The hospital uses disposable materials and the method could constitute a satisfactory alternative since the availability of all other pain relief methods is very limited (personal communication, R. Gonzales 2003-01-10). There are probably many similar hospitals all over the world at which simple and cheap pain relief alternatives for women in childbirth are needed; thus we all have a responsibility to continue to evaluate these methods.

GENERAL CONCLUSIONS

- » Women giving sterile water injections experience significantly less labour pain, compared to women given acupuncture.
- » Women given sterile water injections experience a significantly higher degree of relaxation in labour, compared to women given acupuncture.
- » Subcutaneous injections of sterile water like intracutaneous injections, provide good pain relief for low back pain during labour.
- » The subcutaneous injection technique is less painful than the intracutaneous technique when sterile water is administered.
- » The intracutaneous injection technique is more common than the subcutaneous technique when sterile water injections are administered for labour pain in clinical practice.
- » Sterile water injections are used exclusively for pain relief during labour.
- » Acupuncture is used for both pain relief and relaxation during labour.
- » Acupuncture is more commonly administered for all pain locations during labour, compared to sterile water injections.

AREAS FOR FURTHER RESEARCH

More research about these two methods is required, with a focus on their use for pain relief and relaxation during childbirth. Knowledge is still insufficient regarding when during labour it is appropriate to recommend acupuncture or sterile water injections. Might a combination of both methods perhaps yield more optimal pain relief and relaxation?

To our knowledge, there is no study with the primary aim of elucidating the mechanisms of action of sterile water injections. It would be interesting to know if changing the amount of sterile water and/or repeated injections could provide stronger and prolonged pain relief.

It would also be interesting to elucidate if acupuncture might possibly shorten the delivery and if the pain relief from acupuncture is better during the early stage of the first stage of labour?

Furthermore, it would be very valuable to elucidate if the midwives' routine and skill influence the pain and relaxation effects of acupuncture treatment and what kind of training programme is needed.

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