Relief of Low Back Labor Pain by Using Intracutaneous Injections of Sterile Water: A Randomized Clinical Trial

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Objective: *To study the effectiveness of intracutaneous injections of sterile water in relieving low back pain during labor in Thai women.*
Study design: *Randomized controlled trial*
Setting: *Department of Obstetrics and Gynecology, Taksin Hospital, Bangkok*
Material and Method: *Fitfy pregnant women at term, requiring pain relief for severe low back pain during the first stage of labor. The women were randomized to receive either 4 intracutaneous injections of 0.1 mL sterile water (n = 25) or isotonic saline as placebo (n = 25).*
Main outcome measures: *Pain scores measured by visual analogue scale.*
Results: *Mean pain scores were significantly lower among the treatment group compared to the placebo group at 30 minutes, 1 and 2 hours after injections (p = 0.018, 0.046, and 0.027 respectively). Mean pain reduction were significantly greater in the treatment group compared to the placebo group at 30 minutes, 1 and 2 hours after injections (p < 0.001). There was no difference between the two groups with regard to time to delivery and rate of instrumental and cesarean delivery.*
Conclusion: *The intracutaneous injections of sterile water was found to be an effective treatment against lower back pain during the first stage of labor.*

Keywords: *Labor pain, Intracutaneous injection, Sterile water*

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During labor and delivery, pain occurs at different locations, intensity, and quality for each woman. In addition, experience of pain changes throughout the delivery process. Most women in the first stage of labor feel pain predominantly in the lower abdomen, whereas others experience severe low back pain. In approximately 30% of the cases, the pain is continuous and annoying[1]. The uterine cervix and corpus are supplied by afferent neurons ending in the dorsal horns of spinal segments T10-L1[2,3]. Since cutaneous afferents from the lower back coverage to the dorsal horns in the same segments, there is anatomical support for the assumption that low back pain in labor is referred pain.

Based on the gate-control theory[4] various attempts have been made to relieve labor pain by treating dermatomes having the same nerve innervation with acupuncture[5] or Transcutaneous Electrical Nerve Stimulation (TENS)[6] with varying results[7-11]. Previous studies on cutaneous injections of sterile water have been shown to relieve pain following chronic myofascial pain and whiplash injuries[12-14]. Pain from visceral organs projected to a skin area, such as pain from ureteric stones or labor pain has also been treated effectively by sterile water injections. The sterile injection method is simple to use and can be used on women in labor who frequently suffer from back pain. It has been used in many countries such as the Scandinavian countries. However, there has not been a study of the analgesic effect of intracutaneous sterile water blocks in Thai women.

The aim of the present study was to determine the effectiveness of intracutaneous injections of sterile water in relieving low back pain during labor in Thai women.

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Material and Method

A randomized double-blind clinical trail was conducted. The present study comprises of 50 pregnant women at 37-42 weeks of gestation who were admitted to the labor room of the Taksin Hospital, Bangkok. To qualify for entry into the trial, they had to be in the active phase of first stage of labor and required pain relief of severe low back pain measured by visual analogue scale (VAS) of ≥ 7, and did not receive any analgesics within the last 3 hours. All gave informed consent to be included in the present study and the protocol was accepted by the Ethics Committee of the institution. The women were randomized into two groups. The first group (Treatment group) received four intracutaneous injections of sterile water in the lumbo-sacral region (Michaelis' rhomboid) at the positions shown in Fig. 1. The other group (Placebo group) received intracutaneous injections of isotonic saline in the same region. In both groups, a 1 mL plastic syringe with a thin needle (0.33 x 13 millimeters) was used. The volume of each injection was 0.1 mL. The injections of sterile water gave a sharp local pain sensation lasting for about 20 seconds while intracutaneous injections of isotonic saline were almost painless. In order to blunt the difference in pain sensation between the two treatments, the injections were given during a contraction. These injections were given by the investigator who did not take part either in the patient's care or in the pain assessment. The attending physicians and nurses were unaware of the type of treatment each patient received. The attending nurse was asked to record the clinical data, including the need for other analgesic therapy during labor. In addition, the patient was asked to fill in an ungraded horizontal 100 mm. visual analogue scale (VAS) at 30, 60, and 120 minutes after the treatment. The scale ranged from "no pain" to "unbearable pain". Apart from the blocks, the women were treated according to the usual principles of the institution.

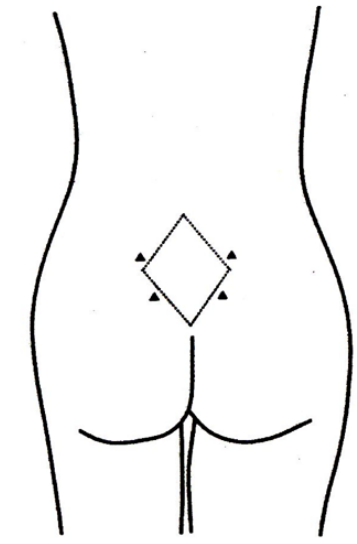

Fig 1. Michaelis' rhomboid and sites for injections

Descriptive statistics including mean, standard deviation, number, and percentage were used to describe various baseline characteristics. Comparisons between groups were made using Student's t test and Chi square test or Fishers' exact test as appropriate. A p-value of < 0.05 was considered statistically significant.

Results

Fifty women were enrolled in the present study. The women in the two groups were similar with regard to age, parity, gestational age and other clinical data (Table 1).

Table 2 shows comparison of pain scores during labor between the two groups. Because some women gave birth shortly after being included in the present study, they were excluded from the analyses at 1 and 2 hours.

The mean pain scores were reduced after treatment in both groups, but the difference was more pronounced in the group treated with intracutaneous injections of sterile water than in the placebo group. Mean pain scores were significantly lower among treatment compared to the placebo group at 30 minutes, 1 and 2 hours after injections ($p = 0.018$, 0.046, and 0.027 respectively). Mean pain reduction were significantly greater in the treatment group compared to the placebo group at 30 minutes, 1 and 2 hours after injections ($p < 0.001$). No patients required Pethidine during labor in both groups.

Table 3 shows data on delivery of the women enrolled in the present study. Duration between injections and delivery were comparable between the two groups. The rate of vacuum extraction and cesarean delivery were also comparable.

Discussion

The present study demonstrated an analgesic effect of treatment with intracutaneous injections of sterile water on low back pain during the first stage of labor. Significant pain reduction was observed as early as 30 minutes after injections and sustained for 2 hours. However, the placebo group with injections of

Table 1. Baseline demographic and clinical data

Characteristics	Treatment group (N = 25)	Placebo group (N = 25)	p-value
Mean age ± SD (years)	25.0 ± 4.5	24.8 ± 4.8	0.703
Primipara	16 (64.0%)	16 (64.0%)	1.000
Mean gestational age ± SD (weeks)	38.9 ± 1.2	39.0 ± 1.0	0.502
Mean cervical dilatation ± SD (cm)	4.4 ± 0.9	4.1 ± 1.0	0.836
Ruptured of membranes	18 (72%)	17 (68%)	0.758

Table 2. Mean pain scores and pain scores reduction between the 2 groups

Mean pain scores	Treatmentgroup	Placebogroup	p-value
Mean pain scores before injections ± SD	86.5 ± 12.5	89.2 ± 11.0	0.118
Mean pain scores 30 min after injections ± SD	31.4 ± 17.4	70.6 ± 27.2	0.018
Mean pain scores 1 hr after injections ± SD	14.9 ± 13.7 (n = 15)	73.2 ± 22.3 (n = 14)	0.046
Mean pain scores 2 hr after injections ± SD	17.0 ± 16.5 (n = 6)	72.2 ± 26.2 (n = 9)	0.027
Pain score reduction 30 min after injections ± SD	55.1 ± 20.9	18.6 ± 26.3	<0.001
Pain score reduction 1 hr after injections ± SD	69.2 ± 17.6	16.1 ± 17.1	<0.001
Pain score reduction 2 hr after injections ± SD	65.2 ± 13.5	16.8 ± 16.5	<0.001

Table 3. Clinical data on delivery after treatment

	Treatment group (N = 25)	Placebo group (N = 25)	p-value
Mean duration between treatment and delivery ± SD (hours)	1.9 ± 2.2	1.8 ± 1.7	0.853
Vacuum extraction	3 (12%)	0	0.235
Cesarean section	0	3 (12%)	0.235

isotonic saline solution also showed some analgesic effect with similar trend. This is in accordance with earlier observations during pain studies in which placebo treatments have shown a considerable analgesic potency[15-16].

It seems obvious that the sterile water papules cause distension in the skin, thereby stimulation nociceptors and mechanoreceptors, producing a sharp pain of short duration. A hyperemic zone is seen around the papule for some hours after the injections, demonstrating a prolonged irritation in the cutis, but causing no manifest discomfort for the subject.

In the clinically controlled double-blind study by Bengtsson[17], acute ureteric colic was treated by injecting four papules of sterile water over the cutaneous area where projected pain from the kidney and the upper urinary tract was felt. Papules of isotonic saline solution were used as placebo. A significantly better effect was demonstrated using sterile water than with isotonic saline solution where no pain was felt at the site of injection. The stimulation of nociceptors seems to be an important factor for the treatment to be effective.

The injections were administered in the area of Michaelis' rhomboid (Fig. 1) which is the area that pain from uterine contractions is experienced. Visceral pain from the uterine cervix and corpus are anatomically projected to this area of the skin, which supports the assumption that the low back pain is a referred pain[2,3]. One might speculate that the stimulation of the skin during administration of sterile water papules gives rise to a similar gate control effect and/or a stimulation of the endogenous opioid system as TENS and acupuncture do. Acupuncture for analgesic purposes can be applied to specific traditional points following meridians. These points are often located far from the

painful area. However, needling at sites segmentally related to the painful site may be equally or even more effective. The intracutaneous injections of sterile water may act as a long lasting segmental acupuncture. The action of acupuncture and TENS is supposed to work through at least two different mechanisms. Firstly, a stimulation of fast conducting A fibers with afferent interneurones in the substantia gelatinosa, producing pain inhibition as described in the 'gate control theory'[4]. Secondly, in some studies, acupuncture and electro-acupuncture have been shown to raise the β-endorphic levels in the Cerebro-Spinal Fluid (CSF) concomitantly with pain relief[18]. It is stated that the β-endorphins act as endogenous pain modulators. Furthermore, acupuncture[19] and TENS-produced[20] analgesia can be reversed by naloxone, an agent able to antagonize endogenous opioid action.

However, in the present study, no attempts were made to define the mechanisms of action more exactly. In order to investigate if the treatment with sterile water papules acts through activation of the endorphic system, samples of β-endorphin would have to be taken from the CSF. Another possibility would have been to try to antagonize the analgesic effect by using naloxone[19]. However, placebo treatment has also been shown to be antagonized by naloxone[21], supporting the theory that placebo treatment is partly mediated by endogenous opioids. Therefore, even in the treatment group, there may be some elevation of β-endorphins due to the placebo effect that naloxone will antagonize with resultant reduction in analgesia, even if the analgesia in the treatment group is due to some other mechanism.

However, inhibition of pain is not restricted to one specific segment, which suggests a more non-specific modulation of pain than the gate control mechanism. Intense stimulation of a skin surface by water injections as well as by acupuncture and TENS may lead to a condition called 'hyperstimulation' or 'counterirritation'. This phenomenon was described by Melzack[22] and may be effective if the stimulation is given near or far from the painful site. A similar phenomenon was described by Le Bars et al[23] as 'diffuse noxious inhibitory control'. The reduced sensation of pain is assumed to be achieved by inhibiting multireceptive neurons to the brain[24]. However, the mechanism of this analgesic effect of treatment with intracutaneous injections of sterile water cannot be clearly understood.

Epidural analgesia is the most potent method for women in labor in need of effective analgesia[25], but it is available as a fulltime service in only a few centers. Intramuscular administration of narcotics can also reduce the pain of labor but this method is limited by negative side effects such as maternal drowsiness, nausea and vomiting as well as neonatal respiratory depression[26, 27]. Because of the risk of losing control or potential negative effects on the baby, many women do not want pain relief with narcotic drugs. Sterile water injections may be an alternative for these women. It seems to be an efficient and simple method for antagonizing parturition low back pain. The patient's midwife can easily administer it and no side effects have been observed other than a burning pain lasting for a few seconds.

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การบรรเทาอาการปวดหลังขณะเจ็บครรภ์คลอดด้วยการฉีดน้ำกลั่นเข้าในชั้นผิวหนัง โดยการทดลองแบบสุ่ม

เพียงจิตต์ วิรัชพงศานนท์

วัตถุประสงค์*: เพื่อศึกษาประสิทธิผลของการฉีดน้ำกลั่นเข้าในชั้นผิวหนังในการบรรเทาอาการปวดหลังขณะเจ็บครรภ์คลอดในสตรีไทย*

วัสดุและวิธีการ*: ทำการศึกษาในสตรีตั้งครรภ์ครบกำหนดจำนวน 50 ราย ที่มีอาการปวดหลังมากขณะเจ็บครรภ์คลอด โดยสตรีตั้งครรภ์จะถูกสุ่มออกเป็น 2 กลุ่ม เพื่อฉีดน้ำกลั่นหรือน้ำเกลือ (ยาหลอก)อย่างใดอย่างหนึ่งเข้าในชั้นผิวหนังทั้งหมด 4 จุด ประเมินอาการปวดหลังก่อนเริ่มฉีดสารน้ำ และหลังฉีดสารน้ำไปแล้ว 30 นาที 1 ชั่วโมง และ 2 ชั่วโมง*

ผลการศึกษา*: พบว่าคะแนนเฉลี่ยของอาการปวดหลังขณะเจ็บครรภ์คลอดในกลุ่มที่ได้รับการฉีดน้ำกลั่นลดลงอย่างมีนัยสำคัญทางสถิติเมื่อเทียบกับยาหลอกทั้งที่ 30 นาที 1 ชั่วโมง และ 2 ชั่วโมงหลังได้รับสารน้ำ ($p = 0.018, 0.046$ และ 0.027 ตามลำดับ) โดยคะแนนเฉลี่ยของอาการปวดหลังขณะเจ็บครรภ์คลอดที่ลดลงในกลุ่มที่ได้รับการฉีดน้ำกลั่นจะลดลงมากกว่าเมื่อเทียบกับยาหลอกทั้งที่ 30 นาที 1 ชั่วโมงและ 2 ชั่วโมงหลังได้รับสารน้ำ ($p < 0.001$) และไม่พบความแตกต่างระหว่าง 2 กลุ่มเมื่อพิจารณาถึงระยะเวลาศึกษาจนคลอด และอัตราการคลอดโดยใช้สูติศาสตร์หัตถการ*

สรุป*: การฉีดน้ำกลั่นเข้าในชั้นผิวหนัง เป็นวิธีที่สามารถบรรเทาอาการปวดหลังขณะเจ็บครรภ์คลอดในระยะที่หนึ่งของการคลอดได้อย่างมีประสิทธิภาพ*