Intracutaneous Sterile Water Injections for Relief of Back Pain during Labor

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Abstract

Objective: To re-evaluate the role of intracutaneous sterile water injections as a method of back pain relief during labor compared to placebo.

Patients and Methods: Randomized, double-blinded, placebo-controlled trial, where sixty laboring patients were randomly allocated into one of two groups. Group I (40 patients) received four injections of sterile water while group II (20 patients) received four injections of normal saline as a placebo intracutaneously to Michaelis’ rhomboid during active first stage of labor. Primary outcome was back pain scores according to visual analogue scale immediately before then 10, 45 and 90 minutes after the injections. Secondary outcomes were occurrence of fetal or maternal complications, requesting further analgesia, and acceptance of the technique by the participants for future labors.

Results: Pain scores were similar between both groups at time of injections but significantly lower at 10, 45 and 90 minutes in group I compared to group II, with maximal difference at 10 minutes following injections. Also, participants requesting more pain relief were more among group II with a statistically significant difference. Moreover, significantly more participants of group I accepted this technique to be used in their future labors. No side effects or complications were reported throughout the study.

Conclusions: Intracutaneous sterile water injection appeared to be a safe, effective, inexpensive and acceptable method of back pain relief during labor.

Key Words: Intracutaneous – Labor pain – Sterile water.

Introduction

PAIN perception is variable between individuals and is affected by cultural, personal and educational factors where some people view pain mastering as a self-actualizing experience, while others, seem to accept it as an inevitable part of life [1]. The American College of Obstetricians and Gynecologists (ACOG) in their committee opinion on pain relief during labor, stated that “there is no other circumstance where it is considered acceptable for a person to experience untreated severe pain, amenable to safe intervention, while under a physician’s care” and acknowledged that maternal request is a sufficient reason for pain relief during labor [2]. Epidural analgesia using opiates seems to be the most potent method for pain control in labor [3]. The use of narcotics is also efficient in most cases but is limited by negative side effects namely; maternal nausea, vomiting and drowsiness as well as neonatal respiratory depression [4]. Non-pharmacological methods have been tried in the form of attention, focusing hypnosis and biofeedback as well as techniques based on the gate-control theory as acupuncture, Trans-cutaneous Electrical Nerve Stimulation (TENS), counter-pressure, abdominal decompression, touch, massage and aroma therapy with varying results while intracutaneous sterile water injection has been used in the last decade for relieving pain in many conditions as renal colics, chronic myofascial pain syndromes [5].

Intracutaneous injections of sterile water in the back skin is a simple and cheap method to provide a medication-free option to laboring women who want to either delay or avoid the use of epidural analgesia or when epidurals are not available or contra-indicated [6].

The aim of this study was to re-evaluate the effect and safety of intracutaneous sterile water injection in relieving lower back pain during the first stage of labor in comparison with saline injection in the same site and with the same maneuver as a placebo.

Patients and Methods

This multi-centre randomized placebo-controlled trial was conducted at the labor and delivery
Participants were blinded towards nature of the procedure after explaining the nature, purpose and safety aspects of the study. Women were considered eligible to participate if they were 20-35 years old, pregnant at 37-42 weeks with a parity of not more than 3, singleton pregnancy with a vertex presentation and being at the onset of active phase of first stage of labor with cervical dilatation of 3-5 cm and effacement > 50% and complaining of low back pain. Exclusion criteria were antepartum hemorrhage, placenta previa, prior uterine scar, cephalo-pelvic disproportion, use of labor-inducing agents, contraindications for vaginal delivery, non-reassuring fetal status, prior cervical surgery, any observable spinal lesions, known neurological conditions, women with suspicion or presence of dermatological pathology interfering with injections and women already received any forms of analgesia prior to the study.

Eligible participants were randomly assigned to Group I or Group II. Randomization was achieved using a computer-generated sequence using Research Randomizer (www.randomizer.org) and kept in a secure box and the participants were assigned to the groups using sequentially-numbered and sealed opaque envelopes containing injection sets (sterile water or normal saline) with the same number of the envelope on the injection set. The participants were blinded towards nature of the injection they are receiving and the person involved in the data analysis wasn't aware of the assignment. Participants assigned to Group I, received four intracutaneous injections of 0.1 ml sterile water while women assigned to Group II received four intracutaneous injections of 0.1 ml normal saline (0.9% sodium chloride). A small tuberculin syringe with a 25-gauge needle was used for injecting into Michaelis' rhomboid (four locations on the lumbo-sacral region, two points over each posterior superior iliac spine (PSIS) and two points 3 cm below and 1 cm medial to the PSIS) [5], with the woman lying on her side, leaning forwards over the bed, sitting sideways or facing the back of a chair.

All participants were managed according to the local intrapartum protocol and received proper monitoring and supportive care and a partogram was used to document the progress of labor. Artificial rupture of fetal membranes (ARM) was considered in women with intact membranes and poor progress of labor (cervical dilatation <1 cm/hour). Oxytocin infusion, if needed, was started two hours after ARM, with a low dose titration method with starting dose of 2mU/minute and increments of 2mU/minute every 15 minutes till obtaining adequate uterine contractions or reaching the maximum dose (32mU/minute). Interpretation of Intrapartum fetal heart rate pattern and uterine contractions were interpreted according to ACOG guidelines [7,8].

Demographic data involving age, body mass index (BMI), parity, and gestational age were recorded. Other data included base line cervical dilatation, need for oxytocin augmentation, injection to delivery interval and mode of delivery.

Subjects reported pain intensity on a 10-cm visual analogue scale (VAS) bounded by 0 “no pain” and 10 “the worst pain”, and VAS pain score was measured as primary outcome immediately before injection and at 10 min, 45 min and 90 min after injection.

Secondary outcomes included percentage of women requesting further analgesia, the presence of maternal, fetal or neonatal adverse events and whether the patient would accept this technique in her future labor or not using face to face questionnaire after delivery. Participants who requested more analgesia before 90 minutes have elapsed from injections, were excluded from the study analysis (3 patients of sterile water group and 10 patients of placebo group).

Sample size was calculated using G* Power software version 3.17 for sample size calculation (*Heinrich Heine Universitat; Dusseldorf; Germany). Based on data from a previous study [9], it was estimated that a sample size of 33 cases for study group and 20 cases for control group, would produce a statistically acceptable figure setting the a-error probability at 0.05, power (1-β error probability) at 0.99%, and effective sample size (w) at 0.50. The sample size was increased by 10 patients in each group to compensate for post-randomization exclusions of patients requesting further analgesia within 90 minutes of injections. Therefore, the total sample size was opted to be 73 cases, 43 cases and 30 controls. Data were collected, tabulated then statistically analyzed using the Statistical Package for Social Sciences (SPSS) computer software version 15 and using Student’s t-test for numeric parametric data and Mann-Whitney U test for numeric non-parametric data where quantitative variables were described as mean and standard deviation (SD) versus median and interquartile range.
(IQR) as appropriate while qualitative variables were described as number and percentage (%).

**Results**

The study statistical analysis included 60 women. Table (1) illustrates that there were no statistically significant differences between both groups regarding demographic data.

Difference wasn't statistically significant between both groups regarding VAS at time of injection, while post-treatment VAS scores showed a drop in mean VAS scores with maximal drop at 90 minutes of treatment among both groups with significantly more pain relief among group I at 10, 45 and 90 minutes after injection [(Table 2), Fig. (2)]. Moreover, 18 women (45%) of group I and 19 women (95%) of group II requested further pain relief where this difference was a statistically significant.

Table (3) shows a non-significant difference between both groups regarding cervical dilatation at time of injection, use of oxytocin augmentation, injection to delivery interval, distribution of modes of delivery, and neonatal birth weight.

Thirty women of group I (75%) accepted this technique to be used in their future pregnancies while only 7 women (35%) of group II accepted this with a statistically significant difference (p<0.0001).

No maternal, fetal or neonatal side effects or complications reported throughout the study.

**Table (1): Comparison between both groups as regards demographic characteristics.**

<table>
<thead>
<tr>
<th>Studied parameters</th>
<th>Group I (sterile water)</th>
<th>Group II (placebo)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age (years)</td>
<td>25.4±3.0</td>
<td>26.7±3.0</td>
<td>0.119</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>24.73±2.56</td>
<td>25.42±1.94</td>
<td>0.293</td>
</tr>
<tr>
<td>Gestational age (weeks)</td>
<td>38±1.3</td>
<td>38±1.2</td>
<td>0.567</td>
</tr>
<tr>
<td>Primiparity</td>
<td>23 (57.5%)</td>
<td>9 (45%)</td>
<td>0.090</td>
</tr>
</tbody>
</table>

BMI Body mass index [calculated as weight (kg) divided by squared height (m²)].
Kg Kilograms.
m² Square meters.
Analysis using independent student’s t-test or Chi square test as appropriate.
Data are presented as mean ± standard deviation or number (percentage) as appropriate.

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![Fig. (1): Participants’ flow diagram showing process of enrollment, allocation and analysis.](image-url)
Table (2): Comparison between both groups as regards VAS scores and further analgesia.

<table>
<thead>
<tr>
<th>Studied parameters</th>
<th>Studied groups</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group I (sterile water) (n=40)</td>
<td>Group II (Placebo) (n=20)</td>
</tr>
<tr>
<td>Initial VAS</td>
<td>8.75±0.93</td>
<td>9.55±0.68</td>
</tr>
<tr>
<td>VAS after 10 minutes</td>
<td>6.90±1.40</td>
<td>8.05±0.75</td>
</tr>
<tr>
<td>VAS after 45 minutes</td>
<td>5.00±1.70</td>
<td>7.05±1.10</td>
</tr>
<tr>
<td>VAS after 90 minutes</td>
<td>3.07±1.10</td>
<td>5.95±0.60</td>
</tr>
<tr>
<td>Reduction in VAS at 90 minutes</td>
<td>5.06±1.32</td>
<td>4.12±0.91</td>
</tr>
<tr>
<td>Request for further analgesia</td>
<td>18 (45%)</td>
<td>19 (95%)</td>
</tr>
</tbody>
</table>

VAS: Visual analogue scale.
Analysis using independent student’s t-test or Chi square test as appropriate.
Data are presented as mean ± standard deviation or number (percentage) as appropriate.
‡: Indicates statistical significance.

Table (3): Comparison between both groups as regards intrapartum events.

<table>
<thead>
<tr>
<th>Studied parameters</th>
<th>Studied groups</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group I (sterile water) (n=40)</td>
<td>Group II (Placebo) (n=20)</td>
</tr>
<tr>
<td>Cervical dilatation at injection (cm)</td>
<td>4 (3-5)</td>
<td>4 (3-5)</td>
</tr>
<tr>
<td>Oxytocin augmentation interval (hours)</td>
<td>25 (62.5%)</td>
<td>13 (65%)</td>
</tr>
<tr>
<td>Normal vaginal delivery</td>
<td>5.34±0.98</td>
<td>5.11±0.75</td>
</tr>
<tr>
<td>Instrumental delivery</td>
<td>3 (3.75%)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>Cesarean delivery</td>
<td>5 (12.5%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Neonatal birth weight (grams)</td>
<td>3211±314</td>
<td>3117±270</td>
</tr>
</tbody>
</table>

Cm: Centimeters.
Analysis using independent student’s t-test, Chi square test or Mann Whitney U test as appropriate.
Data are presented as mean ± standard deviation, number (percentage) or median (interquartile range) as appropriate.

Table (4): Summary of previous trials comparing sterile water injection to placebo for back pain relief during labor.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Study type</th>
<th>Sample size</th>
<th>Intervention</th>
<th>Assessment method</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Ader et al., 1990.</td>
<td>RCT</td>
<td>45</td>
<td>4 Intracutaneous sterile water vs subcutaneous normal saline.</td>
<td>VAS</td>
<td>VAS score more reduced in sterile water group at 10, 45 and 90 minutes.</td>
</tr>
<tr>
<td>- Trolle et al., 1991.</td>
<td>RCT</td>
<td>272</td>
<td>4 Intracutaneous sterile water vs normal saline.</td>
<td>VAS</td>
<td>VAS score more reduced in sterile water group at one hour and two hours.</td>
</tr>
<tr>
<td>- Martensson and Wallin, 1999.</td>
<td>RCT</td>
<td>99</td>
<td>4 Intracutaneous 0.1ml sterile water vs subcutaneous 0.5ml sterile water vs placebo.</td>
<td>VAS</td>
<td>VAS score more reduced in both sterile water groups at 10 and 45 minutes.</td>
</tr>
<tr>
<td>- Bahasadri et al., 2006.</td>
<td>RCT</td>
<td>100</td>
<td>Subcutaneous single injection of 0.5ml sterile water vs normal saline.</td>
<td>FRS</td>
<td>FRS score more reduced in both sterile water groups at 10 and 45 minutes.</td>
</tr>
<tr>
<td>- Wiruchpongsan, 2006.</td>
<td>RCT</td>
<td>50</td>
<td>4 Intracutaneous injections of 0.1mL sterile water vs isotonic saline.</td>
<td>VAS</td>
<td>VAS score more reduced in sterile water group at 30, 60 and 120 minutes.</td>
</tr>
<tr>
<td>- Saxena et al., 2009.</td>
<td>RCT</td>
<td>100</td>
<td>4 Intracutaneous injections of 0.5ml sterile water vs normal saline.</td>
<td>VAS</td>
<td>VAS score more reduced in sterile water group at 10, 45 and 90 minutes.</td>
</tr>
<tr>
<td>- Kushtagi and Bhanu, 2009.</td>
<td>RCT</td>
<td>100</td>
<td>4 Subcutaneous sterile water vs isotonic saline.</td>
<td>VAS</td>
<td>VAS score more reduced in sterile water group at 10 and 45 minutes.</td>
</tr>
</tbody>
</table>

RCT: Randomised controlled trial.
VAS: Visual analogue scale.
FRS: Faces rating scale.

**Fig. (2): Comparison between both groups regarding pain scores over time as assessed by visual analogue scale.**

**Discussion**

Although the potential role of intracutaneous sterile water injection as a pain relief measure to reduce back pains in labor has been investigated in previous trials, most of these trials had unclear labor management protocols with heterogeneous interventions, and also weren’t able to assess patient’s satisfaction. Moreover, systematic reviews have shown different outcomes with some supporting the evidence of its efficacy [13,14] while others found a little robust evidence and recommended further research in this aspect [15].

Although epidural analgesia is currently the gold standard for pain relief in labor, it is associated with an increase in pyrexia and hypotension during labor and the risk of long term backache and neu-
rological symptoms and also can adversely affect the mobility of the laboring woman, as well as affecting the reflex desire to push and hence increase the incidence of assisted vaginal deliveries. Nevertheless, paracervical block has a limited duration of action and carries the risk of fetal injury, while pudendal block provides no relief from the pain of contractions, there is often little systemic absorption, and large doses of anesthetic that may be required may lead to local anesthetic toxicity, and there is also a chance for hematoma or abscess formation [16]. Sterile water injection has been compared to other non-pharmacological methods in few studies and it has showed the best efficacy in pain relief [17-20] and a systematic review by Huntley et al., showed no evidence for alternative and complementary medicine for pain relief in labor except for intracutaneous sterile water injection [21].

Sterile water injections are supposed to interrupt pain pathway with Trolle et al., first suggesting the area of Michaelis’ Rhomboid to be the site for injections, being the area where laboring women acutely feel back pains. Also, injections need to be multiple to stimulate the skin area of the back which is supplied by the cutaneous branches of T10-L1 spinal segments [11] and this stimulates the surrounding nociceptors by raising a small bleb and causing a local irritation. The analgesia effect is presumed to be because of gate control at the spinal level or stimulation of endogenous opioid system [12] but the exact mechanism is not yet fully understood.

The results of the current study showed that intracutaneous injections of sterile water have a significantly greater effect on low back pain as compared to placebo and this effect lasts for, at least, 90 minutes. This was evident by the significant lower pain scores after 10, 45 and 90 minutes from administration. Many previous studies have also showed the effectiveness of sterile water injection in relief of pain during labor in comparison to placebo (Table 4). Also the results of the current study demonstrate safety of intracutaneous sterile water administration as no maternal or fetal side effects or complications were reported and this is unlike negative effects associated with the use of other methods as epidural analgesia and narcotics reported in previous studies [5,10,22,23]. Also, the technique didn't affect labor progress or show any adverse effects apart from the needle prick felt by the patient which was reported in few previous studies [5,10], which is presumed to be due to local irritation of nerves as a result of the difference of osmolality from body fluids [24].

At time of administration, the mean VAS pain score was similar between sterile water group and placebo group (8.75 ± 0.93 and 9.55 ± 0.68, respectively) while sterile water showed to be more effective in relieving pain with mean VAS score of 6.90 ± 1.40, 5.00 ± 1.70 and 3.07 ± 1.10 after 10, 45 and 90 minutes of injection respectively compared to 8.05 ± 0.75, 7.05 ± 1.10 and 5.95 ± 0.60 for placebo which agreed with Wiurchspognan [9] and Märtensson et al., [8]. Moreover, the mean VAS score decreased by time and was reduced to its minimal levels after 90 minutes, which agrees with Wiurchspognan but disagrees with Martensson et al., who found a fading effect and elevation of pain scores at 90 minutes and this conflict may be secondary to choosing subcutaneous rather than intracutaneous route for injections which allows quicker absorption and hence fading of local gate control effect.

The current study showed that the analgesic effect of saline was significantly less than sterile water after 10, 45 and 90 minutes, probably as explained by Kushtagi and Bhanu [25], because sterile salt-free water provides both osmotic stimulation and distension of the firm cutaneous layers, while saline injections fail to produce osmotic or physical distension. Interestingly,Wiruchspognan [9] has noticed a more significant reduction in pain scores after saline injection which was maximal after 30 minutes and may be due to different amount and route of administration.

The current study showed that analgesic effect of saline, although used as a placebo, increased by 90 minutes after injection, which was also concluded by Bahasadri et al., [26], while Kushtagi and Bhanu [25] haven't noticed such an effect after using only single injection of saline subcutaneously and because of the fact that they assessed pain only for 45 minutes after injection.

Visual analogue scale has been shown to have high validity and reliability in pain quantification and was the measuring tool used by all studies except by Bahasadri et al., [26], who thought that VAS is difficult to explain to patients with varying degrees of education especially when they are in pain and alternatively, they used the Faces Rating Scale (FRS) for its ease of understanding.

Different ways of testing sterile water injections have been tried as all studies used the intracutaneous route of administration except two studies [25,26] which used subcutaneous route. The two routes were compared in two studies [5,27] and no statistical difference was found regarding injection site pain. Also Bahasadri et al., [26] used subcuta-
neous injections at the most painful point over the sacrum as a single injection point subcutaneously which has obviously showed less injection site pains but with less reduction of pain than the current study.

In a study by Lee et al., to compare four injections to a single injection, they found that the four injection technique was associated with increased level of analgesia at 30 minutes compared to the single injection, but with a greater injection pain [28].

In the current study, 30 women of sterile water group (75%) accepted this technique for future pregnancies while only 7 women (35%) of saline group accepted this with a statistically significant difference which illustrates that intracutaneous injection of sterile water has a satisfying effect on reducing the back pain of laboring woman, which agrees with some studies [5,10,11,29], while other studies [9,26] haven’t noticed such difference.

In summary, sterile water given intracutaneously seems to be an efficient and simple method for antagonizing low back pain during labor especially in low-resource settings. It provides a strong effect lasting for up to 90 minutes, and may be repeated with neither systemic nor fetal/neonatal side effects. Moreover, it has a short lag time between requesting pain relief and obtaining it, doesn’t affect the state of consciousness, and can decrease the need for epidural analgesia. Also, it doesn’t limit ability to move about, does not interfere with labor progress or ability to push and can be done at home births and in out-of-hospital birth centers by a nurse or midwife without a need for an anesthesiologist. Also, it doesn’t interfere with hemodynamics and so has no undesired effect on the fetus. Also, unlike narcotics, it doesn’t lead to vomiting or neonatal depression and it doesn’t cause drowsiness and nausea which nitrous oxide does.

Sterile water injection has been found to decrease Caesarean delivery rate in a systematic review of 8 RCT’s [31]. Currently we are awaiting the outcome of ICARIS (Impact on Caesarean section Rates following Injections of Sterile water) multicenter trial to validate the effect on the incidence of Caesarean section among laboring women [32].

Recently, Ibáñez-Gil et al., used a questionnaire to investigate knowledge of obstetricians and midwives regarding this technique and found that those with less working experience used the technique most often compared to the group with more working experience with a general lack of knowledge regarding this technique [30], hence the current study and future research are needed to raise the confidence of health professionals in the technique and increase its scale of use in modern obstetrics.

The current study applied continuous 10cm scale for assessing pain rather than conventional VAS with categorical scoring, which may be more accurate in assessing degree of pain. Also it applied the technique of sterile water injection to a new population in two teaching hospitals in Egypt where the technique hasn’t been incorporated to practice and it showed satisfactory outcome and a high acceptance rate which can decrease costs of pain relief in such low-resource hospitals.

Future studies are needed to find out whether the injections need to be repeated in longer durations of labor and how frequent should be done. Also, new studies are required to assess its role in latent phase of labor.

**Conflict of interest statement:** There is no conflict of interest or commercial obligations associated with this article.

**References**


الملخص العربي

الهدف: إعادة تقييم دور حقن الماء العمق داخل الجلد كوسيلة من وسائل تخفيف آلام الظهر أثناء الولادة مقارنة مع العلاج الوعي.

الممرضين والوسائل: دراسة عشوائية، مزدوجة التعمية، حيث تم تقسيم ستين من المرضى بشكل عشوائي إلى مجموعتين. المجموعة الأولى (10 مريضة) تلقى أربع حقن للما العمق في حين تلقى المجموعة الثانية (20 مريضة) أربع حقن من محول الملح العادي التركيز داخل الجلد في منطقة أسفل الظهر خلال المرحلة الأولى من الولادة وكان المتغير الأساسي الذي تم قياسه هو درجة الألم وفقًا لقياس التفاعلي البصري مباشرة قبل الحقن، ثم بعد 10 و4 و9 دقائق بعد الحقن. وكانت التغييرات الثانوية في حدوث مضاعفات للجنين أو للأم، طلب المزيد من مسكات الألم، ونسبة هذه الوسيلة من قبل المرضى لاستخدامها في المستقبل.

النتائج: كانت معدلات الأم متماثلة بين المجموعتين في وقت الحقن ولكن أقل في المجموعة الأولى عند 10 و9 و4 و9 دقائق بعد الحقن مقارنة بالمجموعة الثانية وكان الفرق ذو دلالة إحصائية، ووجد أقصى فارق بين المجموعتين بعد 10 دقائق من الحقن. كذلك فإن عدد المرضى اللاتي احتقاباً المريحة من مسكات الألم أكثر بين المجموعة الثانية مع وجود فرق دال إحصائيًا. وعلاوة على ذلك، فإن عدد المرضى اللاتي قبئين هذه الوسيلة لاستخدامها في المستقبل كانوا أكثر داخل المجموعة الأولى. لم ينتج أي آثار جانبية أو مضاعفات طوال فترة الدراسة.

الاستنتاجات: حقن الماء العمق داخل الجلد يبدو كطريقة أمنة وفعالة وغير مكلفة وكذلك مقبولة لتخفيف آلام الظهر أثناء الولادة.