Intradermal sterile water injection versus intramuscular pethidine injection for pain relief in first stage of labor

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Objectives
To compare the effectiveness and safety of intradermal sterile water injection versus pethidine to decrease labor pain.

Background
In this study, we tried to clarify the possible role of sterile water injection as alternative to pethidine for relieving labor pain.

Patients and methods
A randomized controlled clinical trial was carried out on 78 parturient women in active phase of first stage of labor. Patients were randomly assigned to either one of two groups: group A (intradermal sterile water injection group) received four intradermal injections of 0.5-ml sterile water in the lumbosacral region, and group B (pethidine group) received 1 mg/kg intramuscular pethidine. The primary outcome of this study included the effect of two techniques in relieving labor pain according to visual analog scale. The secondary outcome included labor duration and delivery mode.

Results
Intradermal sterile water injection had significantly higher pain scores immediately before injection ($P = 0.04$), significantly lower pain scores at 60 min after injection ($P = 0.009$), and nonsignificantly lower pain scores at 30 min ($P = 0.07$) and 90 min ($P = 0.12$) after injection. Sterile water injection had significantly lower maternal vomiting ($P < 0.001$) and drowsiness ($P < 0.001$). There was a nonsignificant difference in neonatal Apgar score after 1 min ($P = 0.07$) and significantly higher Apgar score after 5 min in group A ($P = 0.001$). There was significant shortness of duration of labor in pethidine group ($P = 0.042$). There was no significant difference regarding mode of delivery ($P = 0.455$).

Conclusion
Sterile water injection is considered to be effective, safe, inexpensive, and acceptable method for decreasing labor pain.

Keywords:
intradermal, labor pain, pethidine and sterile water

Introduction
Labor is a painful condition. Most women perceive labor pain and childbirth as most severe and agonizing event of a woman’s existence, especially nulliparous women [1]. Labor pain has different area, intensity, quality, and meaning, and the experience of the pain changes according to the delivery process, and approximately one-third of women in labor have severe low back pain [2].

Labor pain if not adequately controlled can lead to sympathetic activation that causes increase in cardiac output, blood pressure, and pulse rate of the mother and reduces uteroplacental blood flow by up to 25% [3].

Pain management in labor is one of the biggest maternity issues, with the majority of women using pharmacological forms of analgesia during childbirth. Pharmacological agents such as pethidine and other analgesics are used to effectively control labor pain [4].

Nonpharmacological methods include continuous labor-support baths, intradermal water blocks, acupuncture, massage, and transcutaneous electrical nerve stimulation [5].

Pethidine is the commonest opioid used in labor administered by intramuscular injection [6]; it acts mainly through the mu (\(\mu_1\) and \(\mu_2\)) opioid receptors by attaching to the nerve fibers in the spinal cord or brain. This works in a similar way to our body’s own natural ‘feel good’ hormones, known as endorphins [7].
However, the effectiveness of pain relief provided by pethidine has long been challenged [2]. Its shortcomings are more serious when set against known adverse effects including maternal sedation, nausea, and potential transfer across the placenta to the fetus [7].

Sterile water injected lateral to the lumbosacral spine is a simple approach to ameliorate the visceral pain of labor including that of back labor [8].

The cervix and corpus uteri are supplied by afferent neurons ending in the dorsal horn of spinal segment thoracic 10 (T10) and lumbar vertebrae 1 (L1). As cutaneous afferent from the lower back converge to the dorsal horns in the same segment, there is anatomical support for the lower back pain, being a referred pain [9]. Using gate control theory or counter irritation theory, stimulation of specific areas can relieve a referred pain. The mechanism has been described as activation of A-beta (Ab) mechanoreceptor fibers, which are faster than A-delta (Aδ) and C fibers and interneurons of lamina intravenous in spinal cord dorsal horn, in the so-called competitive inhibition [10].

Intradermal sterile water injection is associated with acute somatic pain that lasts for 30 s, but as the pain of the injections subsides, so does the visceral referred pain of the low back. The effect begins quickly and has been shown to be effective for 2–3 h, long after the acute pain of the injection has subsided [8].

The aim of this study is to compare the effectiveness, safety, and efficacy of intradermal sterile water injection versus intramuscular injection of pethidine to decrease pain in the first stage of labor.

Patients and methods
This randomized study was conducted at Menoufia University and Ashmon General Hospitals from March 2017 till February 2020.

This study included 78 parturient women in active phase of first stage of labor. An informed consent was obtained from each participant before being included in the study. The approval of research ethics committees of both Menoufia University and Ashmon General Hospitals was obtained before starting this study.

Inclusion criteria
The following were the inclusion criteria:
1. Age: from 20 to 35 years
2. Healthy parturient with singleton pregnancy at term (37–41 weeks)
3. Cephalic presentation
4. Spontaneous labor
5. Patient at the onset of active phase of first stage of labor.

Exclusion criteria
The following were the exclusion criteria:
1. Contraindication to pethidine: hypersensitivity to pethidine, severe respiratory depression, diabetic acidosis, severe renal impairment, severe asthma, supraventricular tachycardia, convulsive states, pheochromocytoma, severe hepatic impairment, acute alcoholism, patients taking monoamine oxidase inhibitors, or patients with high risk of paralytic illus,
2. Preterm labor
3. Patients who received analgesic less than 3 h before onset of labor
4. Previous cesarian section or other uterine surgery
5. Contraindication to vaginal delivery, for example, cephalopelvic disproportion, placenta previa, and genital herpes.

Women who met the inclusion criteria were invited to participate in this study and were adequately counseled, and their informed consent was obtained for their inclusion in the study.

After medical, surgical, drug, and obstetrical history is taken from all women, they had full physical and obstetrical examination and investigation that excluded medical disorders (liver and kidney function test, random blood sugar, urine analysis, and pelvi-abdominal ultrasound).

Patients were randomly assigned to either one of two groups according to random number table from text book. The developed allocation sequence was distributed in sequenced sealed envelopes, where each envelope contained a single assignment.

Intervention

Group A (intradermal sterile water injection group)
Patients of this group received four intradermal injections of 0.5 ml sterile water injection at the lumbosacral region after cleaning it by alcohol, in the sitting position. Two injections was given each at the posterior superior iliac spines on both sides (the posterior superior iliac spines are palpated by feeling the bony prominences just lateral to the sacrum) and the second injection at 1–2 cm medial, and 2–3 cm inferior to the first point on both sides using an insulin
needle. These points overlie the area called Michaelis’ rhomboid.

**Group B (pethidine group)**

Patients of this group received 1 mg/kg intramuscular pethidine, maximum dose 150 mg; its effect usually appears after 30 min.

The following parameters were assessed:

- **Pain assessment:** pain was assessed with a linear 10-cm visual analog scale, with 0 representing no pain and 10 being the worst (imaginable) pain, after 30, 60, and 90 min. The primary outcome of this study included the effect of two techniques in relieving labor pain. The secondary outcome included duration of the first stage of labor, delivery mode, or the need for analgesia.

In case of nonadequacy of the new maneuver in control of labor pain, another modification not be sought.

**Sample size calculation**

Concerning the issue of sample size calculation, we had revised previous reports by Koyucu and colleagues, and Faied and colleagues. Based on these research reports, we assumed that our ‘interventional technique,’ intracutaneous sterile water injection, would yield a 50% of pain reduction versus 19% of its counterpart pethidine in the control group.

Accordingly, a total sample size of 70 parturient women would be required to be included in this study at a study power of 80% with alpha error of 5%.

**Statistical analysis**

Data were collected and analyzed using Statistical Package for Social Science program (version 20; SPSS Inc., Chicago, Illinois, USA). Numerical variables reported as mean ± SD and qualitative variables reported as frequency and frequency percent. Suitable statistical tests such as Fisher exact test, χ², and t test were used according to data type, and P value showed significant difference if less than or equal to 0.05.

**Results**

Regarding sociodemographic, obstetric, and labor characteristics of the study participants, there was no statistically significant difference between the studied groups regarding maternal age (P = 0.11), weight (P = 0.11), gravidity (P = 0.16), parity (P = 0.56), gestational age (P = 0.62), and cervical dilatation (P = 0.03). There was significant shortness of duration of labor in the pethidine group (P = 0.042) (Table 1).

Intradermal sterile water injection had significantly higher pain scores than pethidine immediately before injection (P = 0.04), significantly lower pain scores at 60 min after injection (P = 0.009), and nonsignificantly lower pain scores at 30 min (P = 0.07) and 90 min (P = 0.12) after injection (Table 2).

Intradermal sterile water injection had significantly lower maternal vomiting (P < 0.001) and drowsiness (P < 0.001) (Table 3).

There was no significant difference in neonatal Apgar score after 1 min (P = 0.07), but there was significant higher Apgar score after 5 min in group A (P = 0.001) (Table 4).

There was no significant difference regarding mode of delivery (P = 0.455) (Table 5 and Fig. 1).

**Discussion**

Labor pain is one of the most significant pain experienced by women. Uterine muscle hypoxia, lactic acidosis, distension of the lower uterine segment, stretching of ligaments, and pressure on the bony pelvis may all contribute to the pain experienced in the first stage of labor [11]. Many methods have been used to make labor smooth and pain free. Many are effective, but none have been proved to be free from adverse effects. Regional anesthesia methods (epidural, spinal, or epidural–spinal combination) are considered the most popular and most effective methods for addressing labor.

![Four points for intradermal injections of sterile water.](http://www.mmj.eg.net)
IDSWI vs. IMPI for pain relief of labor

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However, they have disadvantages, such as causing immobilization of the mother and leading to a prolonged and instrumental labor [13]. The use of narcotics is also efficient in most cases but is limited by negative adverse effects, namely, maternal nausea, vomiting, dizziness, and drowsiness, as well as neonatal respiratory depression [14].

Intradermal 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 contraindicated [15].

Regarding the primary outcome of our study, our result showed that intradermal sterile water group has significant lower pain score than pethidine group at 60 min. This result is not consistent with that of Elbohoty [16], who studied 50 low-risk laboring primiparous women. This was evident by the nonsignificant lower pain scores after 60 min from administration. This might be owing to that labor pain has different quality and meaning for each woman, and the experience of the pain changes throughout the delivery process, so the pain can be simply defined as a subjective experience.

Regarding the secondary outcome, the present study found that there was statistically nonsignificant difference between the studied groups regarding mode of delivery. This is in agreement with Elbohoty [16] who found that 12% had cesarean section and 88% had...
vaginal delivery in the intradermal sterile water group compared with 20% cesarean section and 80% vaginal in the pethidine group ($P = 0.70$).

Moreover, the results of the current study demonstrated the safety of intracutaneous sterile water administration, where no maternal or fetal adverse effects or complications were reported. The only undesirable point in sterile water injection noticed in this study was the localized pain that develop immediately after injection owing to its local irritation because of the difference of osmolarity between tissues and water. This agrees with Elbohoty [16]. On the contrary, pethidine group in our study showed significant maternal adverse effects in the form of drowsiness and vomiting, which also agreed with Elbohoty [16].

Our study found that there is nonsignificant difference between both groups regarding neonatal Apgar score after 1 min. This disagrees with Elbohoty [16], who evaluate neonatal Apgar after 1 min and found significant differences in neonatal Apgar score, which decrease in pethidine group after 1 min, with mean of 5 for intradermal sterile water group compared with 3 for pethidine group ($P$ value after 1 min $< 0.001$). This may owing to our study being conducted in women whose cervical dilatation was 3–5 cm compared with 3–7 cm in their results, but our result agreed with their result regarding Apgar score after 5 min ($P$ value after 1 min $< 0.001$).

Many previous studies have also showed the effectiveness of sterile water injection in relieving pain during labor but in comparison with placebo and agreed with us regarding the mean decrease in pain score.

The study by Koyucu et al. [17] was performed on 168 women ($n = 84, 4 \times 0.1$ ml of sterile water) and control groups ($n = 84, 4 \times 0.1$ ml of dry injection). It was observed that the mean pain score after 30 min was lower than the baseline score of 86 ($48 \pm 6.66$ vs. 31.66).

Moreover, the study by Fouly et al. [18] was performed on 73 women and reported that the mean pain score after 30 and 90 min was lower than the baseline ($6.43 \pm 0.96$ and $5.76 \pm 0.70$ vs. $9.35 \pm 0.79$).

Our study also agreed with Sharma and Rupa [15] regarding significant difference that found between visual analog scale immediately before intervention and after 90 min after intradermal injections. This study was performed on 100 pregnant patients admitted to the labor room, who were divided into sterile water group ($n = 50, 4 \times 0.5$ ml of sterile water) and pethidine group ($n = 50, 30$ mg intramuscular pentazocine injection).

### Conclusions
Intracutaneous injections of sterile water was superior than intramuscular pethidine regarding visual analog scale score, and women who were managed by intracutaneous injections of sterile water had lower adverse effects than those who were managed by intramuscular pethidine.

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Nil.

### Conflicts of interest
There are no conflicts of interest.

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