

ORIGINAL RESEARCH

Effect of subcutaneous sterile water injection at the lumbosacral region on labour back pain

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Received: July 8, 2015

Accepted: July 23, 2015

Online Published: July 29, 2015

DOI: 10.5430/jnep.v5n10p98

URL: <http://dx.doi.org/10.5430/jnep.v5n10p98>

ABSTRACT

Objective: This study aimed to evaluate the effect of subcutaneous sterile water injection at the lumbosacral region on labour back pain.

Methods: A quasi-experimental, pre/post test design was utilized to carry out this trial at the Labour and Delivery room, Mansoura University Hospital, Egypt. Sixty three primiparous in spontaneous active labour, indicated a low back pain ≥ 7 on numeric pain rating scale, and expected to have spontaneous vaginal delivery were included in this study as a one study group. Participants had received 4 subcutaneous sterile water injections of 0.1 ml at the lumbosacral region for once. Using three tools data were collected; the 1st was a structured interviewing questionnaire schedule to assess the participants basic characteristics, the 2nd was the numeric pain rating scale to evaluate the baseline pain intensity changes at ten minutes, one, two and three hours post injection, while the 3rd tool was the 5-points Likert scale for mother's satisfaction with the pain relief.

Results: The baseline pain score was 8 ± 0.8 . It was reduced by 2.5, 3.5, 4.5, and 5 points at 10 minutes, one, two, and three hours post injection respectively. Strong satisfaction with the used method for pain relief was reported by 87.3% of the mothers, while only 3.2% were dissatisfied.

Conclusions: It can be concluded that subcutaneous sterile water injection is an effective labour back pain relief method. This leading the investigators to recommend; raising the awareness of the labour and delivery nurses about this method in order to implement it in practice.

Key Words: Sterile water injections, Lumbosacral region, Labour back pain

1. INTRODUCTION

Labour pain is one of the most fearful events in a woman's life. Around 30% of laboring women experience low back pain. It is a referred pain where the original pain arises in the uterine body and cervix. Pain impulses are transmitted; via the spinal sensory nerves in tenth thoracic to first lumbar vertebrae, to the lumbosacral area, iliac crests, gluteal area, thighs, and lower back causing a back pain.^[1-3]

According to the gate-control theory of pain, a limited number of pain impulses can travel through the sensory nerve pathways to the brain at one time.^[4] Based on this theory, the researchers investigated the effect of distraction techniques on reducing or completely blocking the capacity of nerve pathways to transmit the pain impulses.^[5] One of these techniques is the injection of sterile water at the lumbosacral region. This technique is thought to act by closing down the spinal cord hypothetic gate, thus preventing the pain im-

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pulses to reach the brain, thereby, diminishing the perception of pain.^[6]

Sterile water injection has been shown to be more effective in alleviating lower back pain during labour compared to other methods. In a randomized clinical trial the pain levels were assessed in a group of Sweden parturient women assigned to receive either sterile water injections (n = 66) or to be subjected for acupuncture (n = 62). Such trial concluded that sterile water injections are associated with a statistically significant greater pain relief compared to the acupuncture.^[7] The same conclusion was given by other trials which compared the effect of sterile water injection with that of a normal saline on reducing the low back pain.^[8,9] Surprisingly, an Egyptian study compared the efficacy and safety of sterile water injections with intramuscular meperidine injection for relieving labour pain and found that the sterile water injections are superior to the meperidine in terms of the greater pain relief and the lower adverse effects. Thereby, the authors suggested that it can be safely practiced by the perinatal nurses.^[10]

Labour pain; specifically in the back is a great concern for both laboring woman and perinatal nurse; who is the long lasting person in the labour and delivery room. As the nurses are mostly overwhelmed with the large number of the parturients beside the lack of skills for other options of pain relieving; hence, sterile water injection seems to be a handy option for back pain relieving in developing countries, where it is less time consuming, effective, and requires skills within the realm of the nursing practice.

1.1 Significance of the study

As a protocol for labour pain management of the study setting, Pethidine 50-100 mg IM may be provided to the parturient woman who indicates severe intolerable labour pain. However, this is expensive, can not be available for all, may be associated with adverse maternal-fetal side effects and it may be inconvenient for those unwilling to receive a pharmacologic pain relive method. Among the various methods for alleviating labor pain, nursing options are limited due to lack of human resource, facilities, and expert staff especially in developing countries like Egypt. In view of these remarks, the present study aims to evaluate the effect of subcutaneous sterile water injection at the lumbosacral region on labour back pain, where it was not investigated previously at the study setting.

1.2 Aim of the study

This study aimed to evaluate the effect of subcutaneous sterile water injection at the lumbosacral region on labour back pain.

1.3 Study hypotheses

To achieve the aim of this study, two hypotheses were tested.

Hypothesis 1: Parturient women who receive subcutaneous sterile water injection at the lumbosacral region experience lesser back pain after injection than before injection.

Hypothesis 2: Parturient women who receive subcutaneous sterile water injection at the lumbosacral region exhibit high satisfaction with the back pain relief.

2. SUBJECTS AND METHODS

2.1 Research design

A quasi-experimental (pretest/posttest) design was utilized; where it seems to be superior to the use of a control or placebo group that may carry unethical issue by ignoring parturient woman's feeling of the back pain.

2.2 Study setting

This study was conducted at the Labour and Delivery unit of Obstetrics and Gynecology department, Mansoura University Hospital, Egypt.

2.3 Sampling

2.3.1 Inclusion criteria

A purposive sample of 63 parturient women was recruited when they fulfilled the following inclusion criteria:

- (1) Age from 20 to 35 years.
- (2) Have no contraindication for spontaneous vaginal delivery.
- (3) Primiparous with a singleton live fetus, in vertex presentation, at occipito anterior position, and at a gestation period between 37 and 40 weeks.
- (4) In spontaneous active labour with a cervical dilation of 4-7 cm.
- (5) Indicate a low back pain ≥ 7 on pain numeric rating scale at enrollment.

2.3.2 Sample size

The dependant variable in this study is the numeric rating scale for pain at pre/post sterile water injection during the active phase of labour. If the clinically relevant difference in the pain score between the pre and post injection is presumed to be 4 points and the standard deviation 8 based on data obtained from a study by Hosseini *et al.* (2010);^[11] and if two-sided significance level of 0.05 (or 5%) is to be used and the power should be 0.8 (or 80%), then by substitution of these data in the sample size formula of $n = 2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2 / \Delta^2$. Where: n is the number of patients in the study, $Z_{\alpha/2}$ is the value of the normal distribution which cuts off an upper tail probability of $\alpha/2$. (If $\alpha = 0.05$ then $Z_{\alpha/2} = 1.96$), Z_{β} is the value of the normal distribution which cuts off an upper tail

probability of β . (if $\beta = 0.2$, then $Z_\beta = .84$). σ is the presumed standard deviation of the outcome, Δ is the difference sought between the means of the pre/post injections we have: $2(8)^2(1.96 + 0.84)^2/(4)^2 = 62.72$. Hence, 63 participants are required in the current study.

2.3.3 Recruitment technique

All primigravida women who met the inclusive criteria were recruited consecutively; one by one until the assigned sample size is completed. The required sample size was recruited in three months: from April to June 2015.

2.4 Tools of data collection

To attain the aim of this study, three tools were used for data collection. These involved a structured interviewing questionnaire schedule, the numeric rating scale for pain, and the Likert scale for mother's satisfaction with the pain relief.

Tool I: A structured interviewing questionnaire schedule

It was developed and used by the researchers. It consists of two parts; the first part of the schedule presents the sociodemographic data and the general characteristics of the participants. Sociodemographic data were presented in terms of age, occupation and level of education and the general characteristics entail body weight and height to calculate the body mass index (BMI). While, Obstetric history and admission data, specifically vaginal examination finding (*e.g.*, cervical dilation, fetal position, and presentation) represented the second part of the schedule.

Tool II: Numeric rating scale for pain

Numeric rating scale for pain (NRS-pain) is a one-dimensional measure for pain intensity. It is a horizontal line segmented into 11 points; from 0 to 10, where 0 represents no pain, while 10 reflects the worst pain. It requires less than one minute to be completed. Each respondent was asked to indicate verbally a numeric value on the segmented line which best describes the pain intensity at a particular time. This score ranges from 0-10 and the higher score indicates the greater pain intensity.^[12]

Tool III: Mother's satisfaction Likert scale

Mother's satisfaction with the sterile water injections for the back pain relief was assessed by a one dimensional 5-points Likert scale. Total score ranges from 1 to 5. Score 1 means very unsatisfied, 2 unsatisfied, 3 refers to not very satisfied, 4 express that the mother is satisfied, while 5 means that she is very satisfied. Higher score indicates greater satisfaction with the used method for back pain relief.^[13]

Validity of the tools

The first tool was reviewed by a panel of 3 expertises in the maternity nursing specialty before using it to ensure its

validity and their comments were considered. Both, numeric pain rating scale and mother's satisfaction Likert scale have been validated and tested for their validity and reliability in previous literature.^[12,13]

2.5 Ethical considerations

An official approval was obtained from the head of Obstetrics and Gynecology Department of Mansoura University Hospital and ethical approval was granted from the Ethics Committee of the Nursing Faculty. All enrolled parturients gave their informed consents before enrollment. As well as, privacy was strictly maintained while giving the sterile water injections.

2.6 Pilot study

A pilot study was conducted on six parturients who were excluded from the study sample. It aimed at testing the clarity and completeness of the tools. Result of the pilot indicated that the statements of the tools were clear and comprehensive.

2.7 Research process

The investigators attended the labor and delivery unit twice weekly for three months. The required data were collected through three phases; specifically, initial assessment, implementation, and outcome evaluation.

2.7.1 Initial assessment phase

On admission, each woman was interviewed with the nursing investigator and history has been taken. Clinical assessment was done by the obstetrician on duty to identify those who are not eligible for participation (*e.g.*, cephalopelvic disproportion, antepartum hemorrhage, multiple pregnancies). Then, the aim of the study was clarified; informed consent was taken from each eligible woman. This phase took about 5-10 minutes to be completed.

2.7.2 Implementation phase

This phase entails injection of the sterile water by the nursing investigators. Primarily, the needed materials were prepared; including, one ampoule of sterile water (manufactured by: Egypt Otsuka Pharmaceutical Co., S.A.E. 10th of Ramadan City, A.R.E.), one ml plastic syringe with a 26 gauge needle, and alcohol wipes. Additionally, a paravan was prepared to maintain the woman's privacy; since the Labour and Delivery room of Mansoura University Hospital with a capacity of 6 parturients.

Each woman was asked to sit on a chair facing its back; in order to ease the anatomic points palpation. The site of injections was determined in between uterine contractions and marked by using a pen. This was done by palpating the two posterior superior iliac spines; they felt lateral the

sacrum and below the iliac crest as bony prominences. Those represent the first two points, while the second two points lying 3 cm below and 1 cm medial to the first two points; this area is known as Michael's rhomboid area (Figure 1 shows the injection sites quoted from a randomised non-inferiority controlled trial of Lee *et al.* 2011^[14]). At the peak of a uterine contraction, the area of injections was cleansed with alcohol, and then the standard four injections of 0.1 ml sterile water were given simultaneously to dull the perception of the injection pain. The four injections took about one minute.

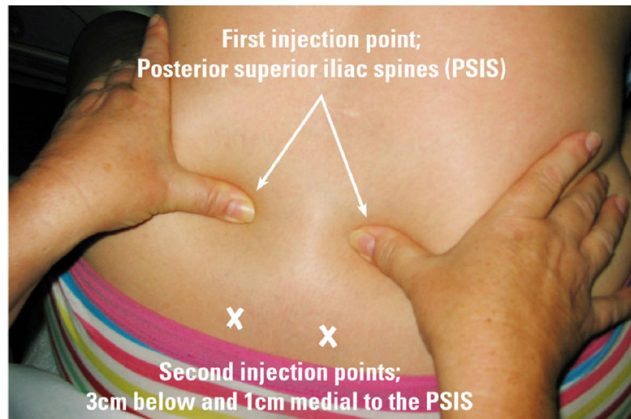


Figure 1. The injection sites

2.7.3 Outcome evaluation phase

Two outcomes were assessed in this study. Labour back pain was the first outcome. It was assessed at five points; immediately before the injection, at ten minutes, and then at one, two, and three hours after the injection; by using the numeric rating pain scale. Mother's satisfaction with the sterile water injection for back pain relief was the second outcome. Since, the hospital policy is to discharge post vaginal delivery mothers at two hours postpartum; the mother's satisfaction was assessed on that time by the one dimensional 5-points Likert scale.

2.8 Limitation of the study

One limitation of this study is that the maximum duration of labour back pain relief was not assessed; whereas, this study finding evidenced that the pain scores still in decrease even at the third hour post injection.

2.9 Data analysis

The statistical analysis of data was done by using SPSS program (statistical package for social science) version 20.0. The description of the data was done in form of mean and standard deviation for quantitative data, frequency and proportion for qualitative data. Dependent sample *t* test was

used to compare the pain scores after injection in relation to the baseline pain score. Statistical significant difference was considered at $P < .05$, and highly significant difference at $P < .001$.

3. RESULTS

3.1 Basic characteristics and current labour & delivery data of the study sample

Table 1 shows the basic characteristics of the study sample. It is clear from this table that the ages of the mothers ranged from 21 to 28 years with an average of 23.9 ± 2.2 years. The BMI of the mothers ranged from 26.9 to 35.5 kg/m² with an average of 30.8 ± 1.9 kg/m². From these mothers, 44.4% were housewives while 55.6% were employed. As regards the educational status, 23.8% were illiterate, 27% can read and write, 31.7% completed either primary or preparatory stage and 17.5% had completed the secondary or university education.

Table 1. Basic characteristics of the study sample (n = 63)

	Range	Mean \pm SD
Maternal age (years)	21-28	23.9 \pm 2.2
Height (m)	1.5-1.68	1.6 \pm 0.05
Weight (kg)	72-81	76.9 \pm 2.9
BMI	26.9-35.5	30.8 \pm 1.9
Occupation n (%)		
Housewife	28	44.4%
Working	35	55.6%
Education n (%)		
Illiterate	15	23.8%
Read/write	17	27%
Primary/preparatory	20	31.7%
Secondary/university	11	17.5%

Table 2 reveals the current labour and delivery data of the study sample. The average gestational age of the current pregnancy was 39 ± 0.8 weeks (ranged from 38 to 40 weeks). At the time of presentation, the average cervical dilatation was 5.5 ± 1.1 cm (ranged from 4 to 7 cm). The duration of the active phase of current labor was 4.7 ± 1.4 hours (ranged from 2.5 to 7 hours), the duration of the 2nd stage was 46.7 ± 5.1 minutes (ranged from 40–55 minutes) and the duration of the 3rd stage was 6.6 ± 2.5 minutes (ranged from 3 to 10 minutes). During the current labor only 4.8% of the parturient mothers needed oxytocin augmentation. As regards the newborn, the average newborn weight was 3125.6 ± 104.2 gm (ranged from 2900 to 3300 gm) and the average Apgar score at the 5th post-partum minute was 8.6 ± 1.1 (ranged from 7 to 10).

Table 2. Current labour and delivery data of the study sample (n = 63)

	Range	Mean \pm SD
Gestational age (weeks)	38-40	39 \pm 0.8
Cervical dilation on admission (cm)	4-7	5.5 \pm 1.1
Duration of labour stages		
Active phase (hours)	2.5-7	4.7 \pm 1.4
Second stage (minutes)	40-55	46.7 \pm 5.1
Third stage (minutes)	3-10	6.6 \pm 2.5
Need to oxytocin augmentation (n, %)	3	4.8%
Newborn weight (grams)	2900-3300	3125.6 \pm 104.2
Apgar score at the 5 th minute	7-10	8.6 \pm 1.1

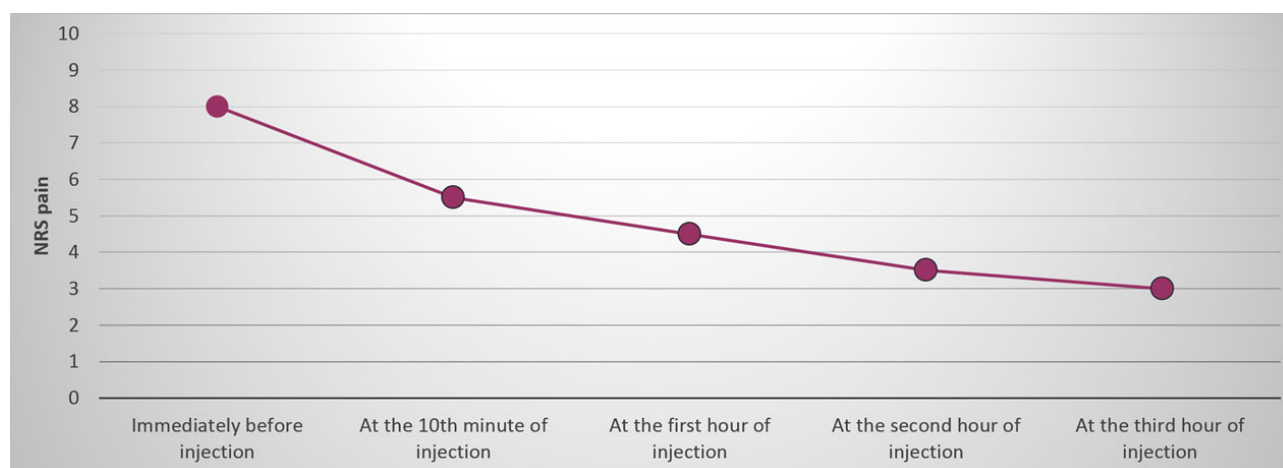
3.2 Effect of subcutaneous sterile water injections on pain scores

The baseline pain score was 8 ± 0.8 immediately before the subcutaneous injection of the sterile water. It was reduced by 2.5 points (from 8 ± 0.8 to 5.5 ± 0.5 ; $p < .001$) after 10

minutes from the injection. Moreover, it was further reduced by 3.5, 4.5, and 5 points from the baseline pain score at one, two, and three hours respectively from the injection (see Table 3 and Figure 2).

Table 3. Comparison of pain scores after injection in relation to the baseline score

	NRS-Pain	t	P
Immediately before injection (baseline)	8 ± 0.8		
After injection by			
10 minutes	5.5 ± 0.5	21.03	< .001
1 hour	4.5 ± 0.5	29.45	< .001
2 hours	3.5 ± 0.5	37.86	< .001
3 hours	3 ± 0.8	35.08	< .001

**Figure 2.** NRS-pain scores immediately before and after the subcutaneous sterile water injections

3.3 Mothers' satisfaction with the sterile water injection for the back pain relief

As regards the mothers' satisfaction for the back pain relief produced by the subcutaneous injections of sterile water,

87.3% of the mothers reported that they were strongly satisfied, 4.8% reported that they were satisfied, 4.8% were undecided while only 3.2% were dissatisfied with this procedure (see Figure 3).

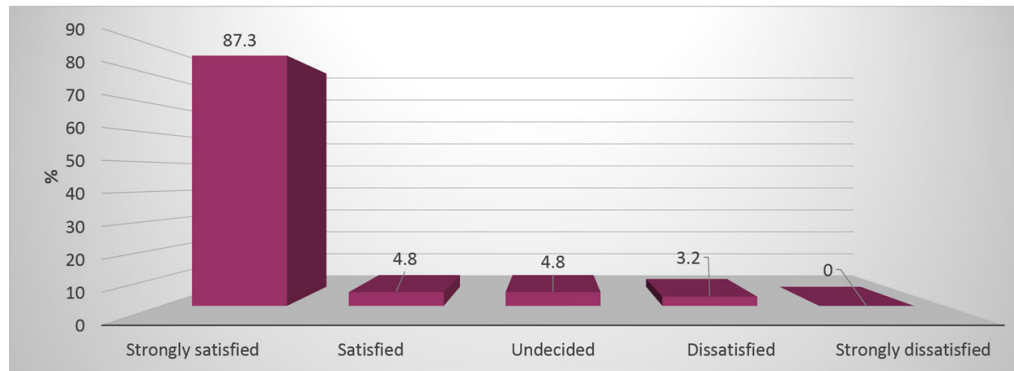


Figure 3. Mother's satisfaction with the subcutaneous injections of the sterile water for back pain relief

4. DISCUSSION

This study aimed to evaluate the effect of subcutaneous sterile water injection at the lumbosacral region on labour back pain. The present study finding revealed that the NRS-pain score was statistically significantly decreased at the four points of pain intensity evaluation compared to the pre injection score. Accordingly, the 1st study hypothesis is accepted “parturient women who receive subcutaneous sterile water injection at the lumbosacral region experience less back pain after injection than before”.

The same conclusion was given by an Egyptian study.^[10] That study evaluated the efficacy of four injections of 0.5 ml sterile water in 25 primiparous women. Using the 100-points visual analogue scale, the labour pain intensity was evaluated before the injections, and after, 10 minutes, one, two, and three hours post the injections. The parturients had reported statistically significant decrease in the labour pain intensity scores even at the third hour after the injections, where the pain scores were lower than that of the baseline (78.8) by (9.7, 21.4, 33.1, and 42.8 points respectively) at the 1 minute, one, two, and three hours post the injections.

Both findings are consistent with that of a clinical trial conducted in Nepal;^[15] where, 120 parturients were given four subcutaneous injections of 0.1 ml sterile water in the lumbosacral region. Using 10-points visual analogue scale, pain severity was rated before injection and at the 10th, 45th and 90th minute post injection. The baseline pain score was statistically significantly decreased at the three points of post injection evaluation. The labour pain score at the 10th minute post intervention (3.64 ± 2.93) was decreased by 0.4 and 0.3 points respectively at the 45th and 90th minute post injection.

Yet, these findings are partially agreed with that was evidenced by an Iranian study.^[11] Such study evaluated the effect of subcutaneous sterile water injection on the labour back pain, immediately before and at the 10th, 45th, and 90th minute post 4 subcutaneous injections of 0.5 ml sterile water

in the sacral region during the active phase of labor for 40 parturient women. Using the 10-points visual analogue scale, acuity of the back pain was found to be 7.87 ± 1.61 before the injection. It was statistically significantly decreased at the 10th and 45th minutes post injection (by 3.87 and 4 respectively; while at the 90th minute post intervention, the baseline score was increased by 0.6.

Two rationales can explain the effectiveness of injection of sterile water in reducing the back pain during labour. Counter irritation is the first; in which the injections are reducing a localized pain in one area by irritating the skin in a nearby area, while the notion that the sterile water injection leading to increase in the levels of endorphins can be the second source for reducing the labour pain intensity.^[16] Additionally, it is important to refer that the variations in the mean difference in the pain scores between the pre and post injection evaluations can be explained by the difference in the used tools for pain assessment (*i.e.*, 10-points or 100-points & visual analogue scale or numerical rating scale) and the injected amount of sterile water (*e.g.*, 0.1 ml or 0.5 ml).

Also, the current study assessed the mother's satisfaction with the subcutaneous injection of sterile water for back pain relief and the finding revealed that most of the participants were satisfied or strongly satisfied. Accordingly, the 2nd study hypothesis is accepted “parturient women who receive subcutaneous sterile water injection at the lumbosacral region exhibit high satisfaction with the back pain relief”.

Two clinical trials assessed the puerperal women satisfaction with labour pain experience after sterile water injections. Peart (2008) assessed the Australian woman's satisfaction with 4 injections of 0.2-0.5 ml sterile water at the lumbar-sacral region for relieving the pain during the active phase of labour.^[17] On the 2nd postpartum day, the author found that 47 women out of 52 (90%) had rated their satisfaction with the labour pain relief as either very satisfied or satisfied. In another way, Rai *et al.* (2013)^[15] had inquired

120 postpartum women about their concerns of the provided method for pain relief during labour (*i.e.*, 4 subcutaneous injections of 0.1 sterile water) and had asked the women whether they are willing to receive the same pain management method in their subsequent delivery or no? The authors found that 100 (83.3%) of the subjects were willing to use the method in their future labour.^[15] Additionally, a randomised non-inferiority controlled trial^[14] investigated the maternal satisfaction with a single versus a four intradermal sterile water injection technique, and found that labouring women were accepted it as an effective option in relieving severe low back pain during labour. Moreover, the finding of such trial revealed that a single intradermal sterile water injection technique is no less effective than the routinely used four injection technique for lower back pain during labour.

Maternal satisfaction that was reported by the subjects of the present study and of Peart's and Lee *et al.*'s studies,^[14,17] as well as, the majority of women who were decided to repeat the use of subcutaneous injections of the sterile water in Rai's study^[15] can be attributed to the evidence decrease in

the labour pain scores.

5. CONCLUSION AND RECOMMENDATION

Based on the present study findings, it can be concluded that subcutaneous sterile water injections is an effective pain relief method. This leading the investigators to recommend; raising the awareness of the labour and delivery nurses about this method in order to implement it in practice.

Implication for practice

Seeing sterile water injection as a safe, simple, clinically/costly effective method; beside it requires skills already found in territory of the nursing practice, it is advocate that maternity staff should use this labour pain relieving method especially in the absence of other pain relieving options in developing countries.

CONFLICTS OF INTEREST DISCLOSURE

The authors declare that there is no conflict of interest statement.

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