Original Article

The Effect of Subcutaneous and Intracutaneous Injections of Sterile Water and Normal Saline on Pain Intensity in Nulliparous Women: A Randomized Controlled Trial

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Abstract

Background: Normal vaginal delivery is considered a painful process and it is difficult to tolerate the pain. The goal of this study was to compare the effect of injection of sterile distilled water and normal saline on pain intensity in nulliparous women. **Materials and Methods:** This triple-blind clinical trial was conducted on 164 nulliparous women randomly selected from among those who were hospitalized in Motahari Hospital of Jahrom, Iran, from 1 May 2012 to 1 October 2013. Women with a gestational age of 37–42 weeks, dilatation of 4–6 cm, and delivery 180 min after the intervention were selected. The subjects were randomly allocated to four groups of intracutaneous and subcutaneous sterile water and normal saline injections. Pain severity was measured 5 min before the injection and every 30 min up to 3 h after the injection using a visual analog scale. The data were analyzed using Chi-square, Scheffe, and Spearman's correlation tests in SPSS software. **Results:** There was no significant difference among the four studied groups concerning gestational age and other demographic characteristics. Chi-square test showed lower pain intensity 120 min after the injection in group 4 (subcutaneous injection of normal saline) ($F_3 = 14.75$, $p < 0.001$) and 150 min after the injection in group 3 (intracutaneous injection of normal saline) ($F_3 = 14.75$, $p < 0.001$). Chi-square test showed that the duration of the second stage of labor was shorter in group 4 participants (subcutaneous injection of normal saline) ($F_3 = -12.23$, $p < 0.001$). **Conclusions:** The study showed that subcutaneous and intracutaneous injection of normal saline reduced the intensity of pain during childbirth.

Keywords: *Labor duration, labor pain, pain relief, sterile water injections*

Introduction

Normal vaginal delivery is considered a painful process and it is drastically hard to tolerate the pain, especially during the first stage of labor. Some women experience abdominal pain, some others have lower back pain, and some have both types. Although the pain of giving birth usually appears with the onset of uterine contractions, sometimes lower back pain is also experienced in the intervals between uterine contractions. About 30% of women suffer from constant back pain simultaneously to contractions, and apparently, lack of rest in the intervals between contractions makes tolerance of pain much more difficult.[1] The probable causes of back pain can be posterior occiput, stable asynclitism, pelvic and lumbar features of each person, and referral pains of the uterus. The afferent innervation of the uterus and cervix is from T10-L1 spinal nerve roots. Moreover, dermatome innervation pattern is from the same spinal segments that this issue consolidates the theory of referred back pain.[2] Due to the fear of labor pain, particularly in nulliparous women, the tendency toward cesarean is increasing up to about 90%.[3,4] Labor analgesia methods are divided into two categories, pharmacological and nonpharmacological methods of pain reduction.[5] Pharmacological methods of pain reduction include nitrous oxide gas, intramuscular injection of drugs (opioid), and neuraxial analgesia. There is discussion in the literatures on the side effects and efficacy of these methods.[6,7] Today, nonpharmacological pain reduction methods are applied vastly as harmless and useful methods all over the world.[7,8] Pain relief reacting against the provocations is one of

How to cite this article: Rezaie M, Shaabani S, Jahromi FS, Jahromi ME, Dakhesh S. The effect of subcutaneous and intracutaneous injections of sterile water and normal saline on pain intensity in nulliparous women: A randomized controlled trial. Iranian J Nursing Midwifery Res 2019;24:365-71.

Received: October, 2018. **Accepted:** June, 2019.

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Access this article online

Website: www.ijnmrjournal.net

DOI: 10.4103/ijnmr.IJNMR_87_18

Quick Response Code:

the old methods commonly practiced by professionals with different results.

Cutaneous injection of sterile water during labor is rooted in the gate control theory of Melzack and Wall. In other words, the cutaneous injection of distilled water is a new pain stimulus that changes the perception of pain in women with severe back pain during labor.[9,10] Injection of sterile distilled water reduces pain during labor, but there is disagreement regarding its effect on improving the outcome of delivery. Intracutaneous injection of distilled water creates an osmotic pressure and mechanical stimulation in the injection area for at least 20–30 s that is endurable for most women. Usually, pain relief starts immediately and continues for up to 2 h. The use of subcutaneous injection of sterile distilled water has been proposed as an alternative to intracutaneous injection due to its lower rate of pain.[11] One of the disadvantages of dermal injection of sterile distilled water is feeling pain at the site of injection for 20–30 s as a result of which women refuse re-injection.[10] This pain probably results from the creation of high osmotic pressure in the skin and edema in the superficial layers. To reduce pain in the injection area while retaining the effectiveness, several modifications in the injection technique have been proposed. Therefore, the substitution of intradermal injection with subcutaneous injection of sterile distilled water has been proposed.[11] Due to the higher rate of pain at the injection site in intradermal method compared with subcutaneous injection and the possible impact on pain intensity in childbirth, the lack of adequate studies comparing the two methods, especially in Iran, and the existence of contradictory results on pain relief,[10] the present study compared the effect of sterile distilled water and normal saline injection on pain intensity, duration of labor, and some postpartum consequences in nulliparous women.

Materials and Methods

This randomized, triple-blind clinical trial (IRCT20180128038535N1) was conducted on nulliparous women referred to the maternity ward of Motahari Hospital of Jahrom, Iran, between 1 May 2012 and 1 October 2013.

The inclusion criteria were nulliparous pregnancy, term pregnancy of 37–42 weeks, single pregnancy, cephalic presentation, dilatation of 4–6 cm, effacement of more than 50%, fetal head station lower than −1, a minimum of three contractions per 10 min, and delivery 180 min (3 h) after the intervention. High-risk pregnant women, parturients with fetal distress in their first stage of childbirth, and parturients with drug abuse were not included in the study. Furthermore, in the case of disaffection of the cases to continue the study, the occurrence of any problems that require pharmaceutical intervention, childbirth in less than 3 h after the beginning of the study, and use of any pharmacological or nonpharmacological analgesic method during the study (atropine, promethazine, pethidine, and a variety of nonpharmacological pain reduction methods), the participants were excluded from the study. The included parturients were divided into four groups of intracutaneous injection of 0.15 cc distilled water (group 1), subcutaneous injection of 0.5 cc distilled water (group 2), intracutaneous injection of 0.15 cc normal saline (group 3), and subcutaneous injection of 0.5 cc normal saline (group 4). There were 41 parturients in each group, based on 95% confidence interval and 80% power [Figure 1].

In this study, to collect the required data, the authors used observation, examination, and questionnaire methods. The questionnaire consisted of four parts. The first part was a demographic characteristics form. The second part of the questionnaire was a childbirth information form. The third section was related to information corresponding to pain intensity 5 min before the injection, and 30, 60, 90, 120, 150, and 180 min after the injection. The fourth part of the questionnaire was a satisfaction analysis form. Pain intensity was measured using McGill's Visual Analog Scale (VAS). To allocate the therapy randomly, number cards (1–4) were used. The cards were placed inside envelopes. The participants had to select an envelope. If they selected numbers 1, 2, 3, and 4, they received intracutaneous injection of sterile distilled water, subcutaneous injection of sterile distilled water, intracutaneous injection of normal saline, and subcutaneous injection of normal saline, respectively. For groups 1 and 3 (intracutaneous), a volume of 0.15 cc sterile distilled water or normal saline was injected at each Michael rhomboid point.[1,4,8,10,11] In groups 2 and 4 (subcutaneous injection), at each Michael rhomboid point, a volume of 0.5 cc of sterile distilled water or normal saline was injected. The intensity of back pain was measured during labor 5 min before the injection, every 30 min up to 3 h after the injection, and after the delivery using McGill's VAS. The injection was performed in all four groups in the interval between contractions, in sitting position, in the Michael rhomboid area, and using an insulin syringe (SUPA Medical Devices, Tehran, Iran). To find the injection location, first, the upper limit of the iliac crest bone was determined, and its intersection point with a line passing the middle of the sacrum was marked. Then, using a rubber ruler, 2 cm from the mid-line to the right side of the sacrum was determined as the first injection point, 2 cm from the same line to the left was determined as the second point, 2 cm below the injection point of the right side and 1 cm to the inside was selected as the third injection location, and finally 2 cm below the left side injection point and 1 cm to the inner side was determined as the fourth injection site. The duration of the active phase of the first stage of labor was measured by means of a stopwatch and the stopwatch was stopped as soon as the full opening of the cervix was achieved. The

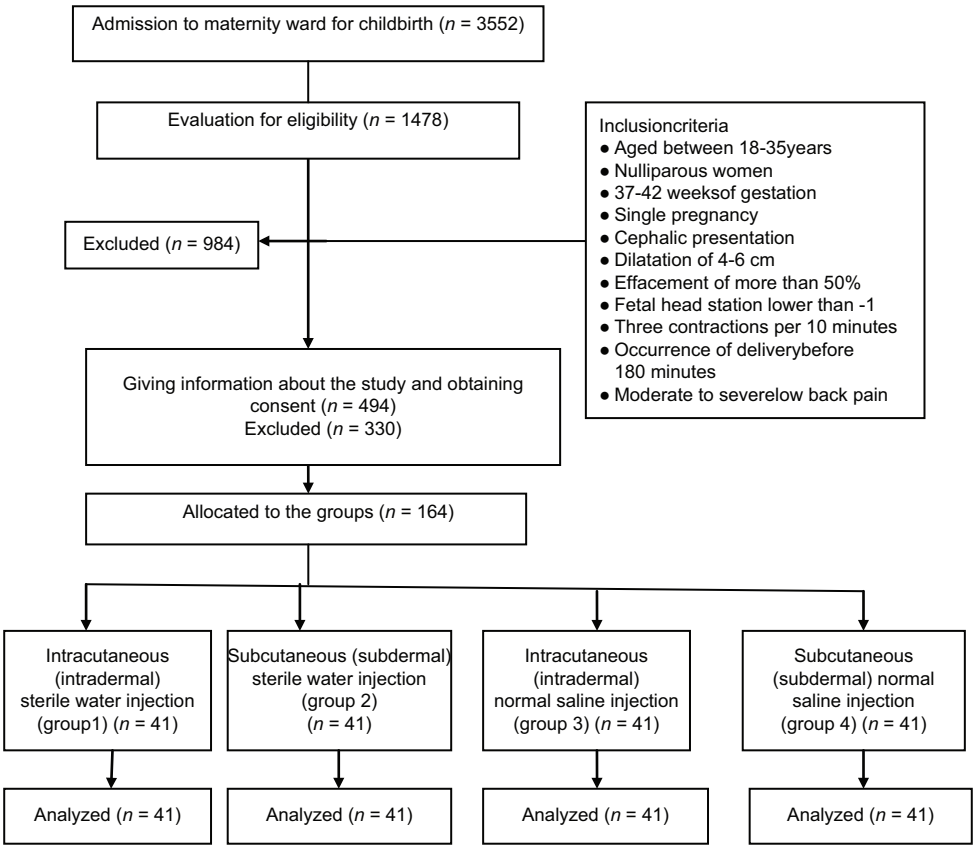

Figure 1: Study flow chart

stopwatch was started again and stopped as soon as the child was delivered to measure the duration of the second stage of labor in minutes. The Satisfaction Questionnaire was completed by the mother during the first hours after birth (fourth stage of childbirth).

To make the experiment triple-blinded, the injections were conducted by an expert midwife previously instructed and with necessary trainings. The intensity of pain and the duration of labor were measured, and questionnaires were completed by a different midwife who had no knowledge of the injection type and study groups. The author also had no knowledge of the groups selected by the participants. To analyze the data, Chi-square, Scheffe, and Spearman's correlation tests were used in SPSS software (version 15; SPSS Inc., Chicago, IL, USA). All *p* values of less than 0.05 were considered significant.

Ethical considerations

Ethical approval was obtained from the Human Research and Ethics Committee of Jahrom University of Medical Sciences, Jahrom (IR.JUMS.REC.139.076). All enrolled subjects provided written informed consents before the study. The study procedure was described in detail for all participants. The patients were provided with a separate room for their convenience and privacy. In all stages of the study, similar emotional connection was achieved with the patients of the four groups.

Results

The mean [Standard Deviation (SD)] age of group 1, 2, 3, and 4 participants was 26.63 (4.71), 25.22 (5.01), 25.87 (4.83), and 24.00 (3.01) years, respectively. The mean (SD) gestational age of the subjects of groups 1, 2, 3, and 4 was, respectively, 38.72 (1.53), 38.10 (2.35), 38.89 (1.40), and 39.00 (0.94) weeks. There was no significant difference among the four studied groups concerning the mothers' age ($p = 0.407$), gestational age ($p = 0.653$), and other demographic characteristics [Table 1].

As seen in Table 2, there was a significant difference between the four groups in terms of pain intensity at 120 min after the intervention; in group 4 (subcutaneous injection of normal saline), the severity of pain was less than other groups. Chi-square test showed a significant difference in pain intensity between the four groups at 150 min after the intervention [Table 2]; the severity of pain was lower in group 3 (intracutaneous injection of normal saline) compared with the other groups. Chi-square test showed no significant difference between the four groups in terms of pain intensity 5 min before the intervention ($p = 0.491$). Schaffe test showed no significant difference in pain intensity between each group and the three other groups. Multigroup comparison test showed that in group 1 (intracutaneous injection of distilled water), pain intensity 30 min after the intervention was significantly

lower than that at 60, 90, 120, 150, and 180 min after the intervention (F_6 = 118.57, p = 0.001). Multigroup comparison test showed that in group 2 (subcutaneous injection of distilled water), pain intensity 30 min after the intervention was significantly lower than pain severity 5 min before and 60, 90, 120, 150, and 180 min after the intervention (F_6= −57.32, p = 0.001). Multigroup comparison test showed that in group 3 (intracutaneous injection of normal saline), pain intensity 150 min after the intervention was significantly less than pain severity at 5 min before and 30, 60, 90, and 120 min after the intervention (F_6 = 112.81, p = 0.001). Likewise, pain intensity was significantly different at 150 and 180 min after the intervention (F_6 = 29.701, p = 0.001). There was a significant difference in the severity of pain before and after the intervention in group 1 ($F_{1,37}$ = 245.21, p = 0.001). A significant difference was observed in pain severity before and after the intervention in group 2 ($F_{1,36}$ = 92.66, p = 0.001). The severity of pain differed before and after the intervention in group 3 ($F_{1,51}$ = 185.15, p = 0.001). Moreover, a significant difference was observed in pain severity before and after the intervention in group 4 ($F_{1,41}$ = 23.18, p = 0.001). Chi-square test showed a difference in the duration of the second stage of labor between the four groups; it was shorter in group 4 [Table 3]. Schaffe test showed a signifcant difference between groups 1 and 4 in terms of the duration of the second stage of delivery (F_3 = 12.23, p = 0.001). Moreover, the test showed a significant difference between groups 2 and 4 in terms of the duration of the second stage of childbirth (F_3 = 5.07, p = 0.002). Furthermore, the duration of the second stage of childbirth differed significantly between groups 4 and 3 (F_3 = 12.23, p = 0.001).

Chi-square test showed that the type of delivery was not different in the four groups (p = 0.58). In group 1, 33 (79.40%), 2 (2.30%), and 6 (18.30%) participants had normal vaginal delivery, cesarean c/s, and vaccume, respectively. In group 2, 36 (88.00%), 2 (4.00%), and 3 (8.00%) patients had normal vaginal delivery, Cesarean section, and vaccume, respectively. In group 3, 35 (85.20%), 2 (3.70%), and 4 (11.10%) participants, respectively, had normal vaginal delivery, cesarean c/s, and vaccume. In

Table 1: Frequency distribution of demographic characteristics in the four groups

Group Variable		Group 1 *n* (%)	Group 2 *n* (%)	Group 3 *n* (%)	Group 4 *n* (%)	*F*	df	*p*
Occupation	Housewife	35 (85.37)	26 (63.41)	26 (63.41)	19 (46.34)	0.19	2	0.061
	Employee	6 (14.63)	15 (36.59)	15 (36.59)	22 (53.66)			
	Free							
Education level	diploma	13 (31.70)	13 (31.70)	14 (29.60)	5 (12.20)	0.19	1	0.295
	Diploma	14 (34.15)	16 (39.02)	15 (35.20)	18 90 (43.00)			
	Associate degree and bachelor's degree	14 (34.15)	12 (29.27)	15 (35.20)	18 (43.90)			
Location	Urban	30 (73.17)	25 (60.98)	27 (65.85)	18 (43.90)	0.19	2	0.710
	Rural	11 (26.83)	16 (39.02)	14 (34.15)	23 (56.10)			

Table 2: Average score of pain intensity before and after injection in the four groups

Group Variable	Group 1 Mean (SD)	Group 2 Mean (SD)	Group 3 Mean (SD)	Group 4 Mean (SD)	*F*	df	*p*
5 min before injection	5.47 (1.78)	5.78 (2.10)	5.96 (2.11)	6.00 (1.62)	0.79	3	0.498
30 min after injection	6.71 (1.73)	6.64 (1.81)	6.92 (1.86)	7.43 (1.86)	2.35	3	0.074
60 min after injection	8.11 (1.69)	8.03 (1.67)	8.83 (1.51)	7.71 (1.50)	1. 53	3	0.214
90 min after injection	9.08 (1.19)	8.68 (1.42)	9.13 (1.12)	8.5 (1.06)	1. 85	3	0.140
120 min after injection	9.89 (0.45)	9.57 (0.83)	9.69 (0.64)	8.86 (1.14)	14.75	3	0.001
150 min after injection	10 (0.00)	9.68 (1.13)	9.42 (0.73)	9.78 (0.71)	6. 08	3	0.001
180 min after injection	10 (000)	9.78 (0.88)	9.94 (0.31)	9.71 (0.71)	7.400	3	0.080

Table 3: Frequency distribution and mean of delivery outcomes

Group Variable	Mean (SD)				*F*	df	*p*
	Group 1	Group 2	Group 3	Group 4			
Duration of the first stage of labor (min)	133.33 (27.15)	143.37 (37.93)	151.83 (50.21)	153.33 (25.67)		6	0.105
Duration of the second stage of labor (min)	75.00 (23.10)	61.30 (25.04)	67.88 (25.29)	35.00 (19.25)	12.23	3	0.001
Apgar score							
The first minute after birth	8.74 (0.54)	8.96 (1.98)	8.93 (0.43)	8.86 (0.53)	7.24	9	0.267
5 min after birth	10.00 (0.00)	10.00 (0.00)	10.00 (0.00)	10.00 (0.00)	0. 27	9	0.574

group 4, 30 (75.40%), 0 (0.00%), and 11 (24.60%) patients, respectively, underwent normal vaginal delivery, cesarean c/s, and vaccume. In all four groups, the prevalence of normal vaginal delivery was 81.71% (134 cases), delivery using tools was 14.63% (24 cases), and cesarean was 3.66% (6 cases). Chi-square test showed no significant difference in the type of delivery between the four groups ($p = 0.574$).

No significant difference was observed in the Apgar score at min 1 and 5 in the four groups [Table 3]. The lowest Apgar score of the first minute was 7 and the highest score as 10. Between the four groups, there was no significant difference regarding the satisfaction rate of the delivery [Table 3].

Discussion

The study results showed lower pain severity on injection of normal saline compared with sterile distilled water. This finding was in agreement with that of previous studies.[12-14] The cause of the impact of normal saline in reducing pain is unclear. There is an assumption that intracutaneous injection of normal saline causes dermal swelling in compact layers and stimulates the terminals of the nerves.[15] On the other hand, in intracutaneous injection of normal saline, irritation and pain may be less in the injection area, so it may have less effect on pain reduction.[2] However, in this study, pain severity score was reduced at 150 min after the intracutaneous injection of normal saline.

Many theories, such as the gate control theory of pain, severe stimulation, inhibition of stimulation of the nerves transferring the pain, distracting the senses, and controlling the release of inhibitors, may focus on the release of internal opioids.[16,17] The endorphin terminals of the pain can be found in the hypothalamus and pituitary gland can be found while stimulating. Observations have shown that injection of naloxone inhibits the effects of normal saline,[12,13] and perhaps this issue shows that normal saline transmits pain to the brain through the nerves, and then alleviates pain by releasing internal opioids.

Injection of sterile distilled water also causes pain relief through the counter-irritation mechanism; it also causes the secretion of endorphins.[8] The effects of pain relief of subcutaneous or intracutaneous injection of distilled water were lower in this study, which perhaps is because of its comparison to normal saline. This observation is confirmed by Cui *et al*. in China.[14] Simkin and Klaus found that normal saline has less palliative effect. In this study, a dose of 0.15 cc normal saline was injected intracutaneously to make sufficient space for stimulation of dermal layers, and simultaneously to reduce the effects of the stimulation during the intradermal injection of distilled water in group 1 and reduce the effect on parturients' pain perception (in previous researches, injecting 0.01–0.5 cc intracutaneous had been confirmed).[2,18,19] As previous studies have shown, severe temporal pain caused by intradermal injection of sterile distilled water has negative effects on the mother's experience of understanding pain.[12,20-23] The same issue may have caused the higher pain intensity in this group (it had the highest pain score 150 and 180 min after the intervention). However, some researchers have shown that intracutaneous injection of sterile distilled water has reduced pain intensity during labor.[24] In group 2 (subcutaneous injection of sterile distilled water), pain intensity 30 min after the intervention had a significant difference with 5 min before the intervention. Studies conducted on the subcutaneous injections of sterilized distilled water confirm the reduction of pain severity 30 min after the intervention.[9,10,25]

Marzouk *et al*. reported that 10 min and 1, 2, and 3 h after the injection, pain intensity decreases 2.5°, 3.5°, 4.5°, and 5°, respectively.[25] Cui *et al*., in their study, concluded that pain severity score on a VAS had decreased 10, 45, and 90 min, and 1 day after the treatment.[14] Cui *et al*. conducted their research on men and women who suffered acute low back pain due to underlying diseases and their back pain intensity was reduced using this method.[14] In this study, because of the normal progress of the pain of childbirth, no reduction was observed in the pain severity score, but pain intensity was reduced in group 2 30 min after the intervention. Lee *et al*. showed that difference in average pain scores before and 30 min after the injection in the two groups was − 1.48 cm, and group 4 had a good condition.[12] Pain intensity in the group with four injections was significantly higher than the group with only one injection.[12] In the study by Lee *et al*., better results were observed in terms of pain intensity in other groups compared with the group of intracutaneous injection of distilled water.[19] Bahasadri *et al*. reported lower pain intensity 10 and 45 min after injection compared with the normal saline group, which is consistent with the results of this study.[18]

In a double-blind study, the results showed that 10 min after injection, 43% of women in the group receiving distilled water injection had lower VAS score versus 19% in the control group.[21] After 90 min, 32% of the injection group participants versus 17% of control group participants reported a reduction in pain, which is inconsistent with the current study results.[21] Pashib *et al*. conducted a study to determine the extent of the influence of subcutaneous injections of distilled water and fentanyl on the severity of labor pain.[26] They found that subcutaneous injection of distilled water reduced pain intensity after 45 min, and pain intensity was lower in the group with fentanyl, which is opposed to the current study findings.[26] Hosseini *et al*. showed a reduction in the average pain intensity of childbirth for up to 45 min after subcutaneous injection of distilled water, but found no difference in pain intensity in comparison to the control group 90 min after the injection.[10] This finding is inconsistent with the present

study findings. Ghanbarzadeh *et al*. conducted a study on the effect of the injection of distilled water on reducing pain in the waist in the active phase of labor.[27] Average changes in pain intensity in min 40, 60, and 90 after injection did not show a significant difference in the two groups.[27]

This study showed no significant difference between the groups in terms of the duration of the active phase of labor. The duration of the active phase of the first stage of childbirth in group 1 intracutaneous injection of distilled water was shorter than the other groups. The duration of the second stage of delivery was significantly shorter in group 4 (subcutaneous injection of normal saline) than other groups. In a research conducted by Lee *et al*., the average duration of the second stage of delivery was reported as 46.7 ± 5.1 min after subcutaneous injection of sterile distilled water.[12] In an overview and meta-analysis research on 828 participants, the rate of cesarean was reported as 4.6% in the group of distilled water injection and 9.9% in the control group.[28] In this study, lower prevalence of tools' utilization was observed in group 2 (subcutaneous injection of distilled water) and a high prevalence was observed in group 4 (subcutaneous injection of normal saline), but the difference was not significant.

Peart surveyed the satisfaction of women in the active phase of delivery after subcutaneous injections of distilled water on the second day postpartum.[29] He concluded that 90% of women were very satisfied with the pain alleviation method used.[29] Rai *et al*. reported that 83.3% of women would choose the subcutaneous injection of distilled water as their next delivery method.[30] Marzouk *et al*. reported that 87.3% of women were highly satisfied with the subcutaneous injection of distilled water.[25]

One important cause of the strength of this study was being a triple-blind research. The other cause of strength of this study was that we did not experience subject loss during the experiment. Moreover, we compared the intracutaneous and subcutaneous injections of distilled water and normal saline simultaneously. The homogeneous demographic conditions of time and place can partially have a positive impact on the analysis of the findings. Another cause of the strength of tis study was the controlling of confounding variables, including the need to use other methods of pain relief and the need to use oxytocin. Mothers who requested other pain reduction methods or requiredoxytocin injection were excluded from the study. Thus, the effects of these confounding variables on pain intensity were eliminated to the extent possible.

One of the limitations of the study was the uncertainty of the pain threshold of the participants, which was perhaps controlled with the lack of significant difference in pain intensity 5 min before the injection, but it could be considered somewhat of a limitation of control. Moreover, mothers were studied since the beginning of the active phase, that is, 4–6 cm of dilation. The intensity of pain (uterine contractions and lower back pain) is increased in the natural progress of labor, so the parturients' feeling and expression of pain intensity also increases.[31,32] Thus, it is also possible for her pain threshold and tolerance to increase, and this can justify the failure in reducing the pain severity score in the four groups. Another disadvantage of the expression was that pain intensity was measured based on the mother; s conceptual scoring; the actual measurements may show different results.[14,33] Another limitation of the study was the failure to check the status of the head of the fetus in the pelvis during labor; factors such as posterior occiput and asynclitism can affect the intensity of the pain and its duration, especially in the second stage of childbirth.

Conclusion

It can be concluded that intracutaneous and subcutaneous injections of normal saline can cause a reduction in labor pain intensity. The authors recommend the investigation of the impacts of the intracutaneous and subcutaneous injection of normal saline on laboratory markers during labor. Future studies may show that normal saline injection has a positive effect on the process of labor pain reduction.

Acknowledgements

We would like to appreciate the respected officials and our colleagues in the maternity section of Motahari Hospital who helped us in this study, and we wish them success in their career.

Financial support and sponsorship

Jahrom University of Medical Sciences, Jahrom, Iran

Conflicts of interest

Nothing to declare.

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