

## USE OF STERILE WATER FOR INJECTION IN THE MANAGEMENT OF LABOR PAIN: A RANDOMIZED CONTROLLED TRIAL

PALASH MAZUMDER<sup>1</sup>, SWADHA PANDEY<sup>2</sup>, DEBJIT MANDI<sup>3</sup>, SHYAMALI DUTTA<sup>2\*</sup>

<sup>1</sup>Department of Obstetrics and Gynaecology, Deben Mahata Government Medical College, Purulia, West Bengal, India. <sup>2</sup>Department of Obstetrics and Gynaecology, Medical College, Kolkata, West Bengal, India. <sup>3</sup>Department of Obstetrics and Gynaecology, Gangarampur Sub Divisional Hospital, West Bengal, India.

\*Corresponding author: Shyamali Dutta; Email: drshyamali2011@gmail.com

Received: 02 February 2024, Revised and Accepted: 14 April 2024

### ABSTRACT

**Objectives:** The objectives of the study are to assess the efficacy of sterile water for injection (SWI) in reducing labor pain, compare it with a saline procedure, and see which one is superior. Parameters assessed were pain relief based on the numeric pain rating scale (NPRS) and duration of labor from intervention to delivery associated with administration of subcutaneous SWI versus normal saline injection (NSI).

**Methods:** This is a prospective randomized interventional hospital-based comparative study of mothers who were in active labor with back pain and undergoing treatment in the labor room of Eden Hospital, Medical College and Hospital, Kolkata. The study was conducted on 66 willing pregnant mothers, divided into two groups of 33 each with one injected with normal saline and the other with sterile water.

**Results:** The NPRS score was almost equal in 2 groups at 15 min, but with an increase in duration, it was seen that the score was low in the sterile water group compared to the normal saline group. The association was statistically significant ( $p < 0.05$ ).

**Conclusion:** This study hypothesized that subcutaneous SWI for relieving labor pain is better than subcutaneous NSI. Based on this study, it is concluded that both the SWI and NSI reduce labor pain, but the SWI produced a significantly greater reduction of pain as measured by the numeric pain rating score and also better satisfaction. Therefore, SWI is a safe, simple, and cost-effective method and can be used as a pain-relieving method, especially in the absence of other pain-relieving options.

**Keywords:** Pregnancy, Saline solution, Injection subcutaneous, Labor pain, Back pain, Mothers, Prospective studies.

© 2024 The Authors. Published by Innovare Academic Sciences Pvt Ltd. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>) DOI: <http://dx.doi.org/10.22159/ajpcr.2024v17i5.50495>. Journal homepage: <https://innovareacademics.in/journals/index.php/ajpcr>

### INTRODUCTION

A vaginal delivery typically involves significant pain and discomfort, particularly during the initial stage of labor, which can be challenging to endure. Women may experience lower back pain, abdominal pain, or both. The pain of childbirth normally starts as the contractions commence, with the intensity increasing gradually. Lower back pain can sometimes be felt during the intervals between uterine contractions. Around 30% of women endure persistent back pain throughout contractions, making it notably harder to manage the pain, especially when contractions occur without any breaks in between [1].

Potential reasons for back pain include posterior occipital positioning, stable asynclitism, individual pelvic and lumbar characteristics of each mother, and referred pains from the uterus. This discomfort originates from the stimulation of C afferent nerves originating from the uterus corpus and cervix. These fibers terminate in the dorsal horn of spinal segments T10-L1 and cause visceral pain that is perceived as back pain [2].

Based on the gate control theory, administering a subcutaneous injection of sterile water during labor introduces a novel pain stimulus, altering the perception of pain in women experiencing intense back pain during labor. This occurs because of the activation of delta fibers supersedes the visceral pain signals from the C fibers.

The administration of subcutaneous sterile water during labor aligns with Melzack and Wall's gate control theory. Essentially, this involves introducing a new pain stimulus through cutaneous injection, altering the pain perception in women experiencing severe back pain during labor [3,4]. While sterile water injection (SWI) reduces labor pain, its

impact on delivery outcomes remains debated. Intracutaneous injection creates osmotic pressure and mechanical stimulation in the injection area for about 20–30 s, which is generally tolerable for most women. Pain relief usually begins immediately and lasts up to 2 h. Subcutaneous injection is proposed as an alternative to intracutaneous injection due to its lower pain rate around the injection site [5]. However, one drawback of intradermal saline injection is brief pain at the injection site, causing some women to decline reinjection. This discomfort likely arises from the high osmotic pressure in the skin and edema in the superficial layers. Various modifications to the injection method aim to minimize injection site discomfort without compromising effectiveness, advocating for the replacement of intradermal injection with subcutaneous SWI [5,6].

### METHODS

The study was an open-label randomized clinical trial conducted in the Department of Obstetrics and Gynecology of Medical College and Hospital, Kolkata, India, after getting approval from the Institutional Ethics Committee (Ref. no. MC/KOL/IEC/NON-SPON/12/01-2019) from June 2019 to May 2020.

### Inclusion and exclusion criteria

Mothers of age 18–35 years with a gestation of 37–40 weeks, singleton pregnancy, cephalic presentation with spontaneous onset of labor, expecting vaginal delivery having cervical dilatation  $>4$  cm, and experiencing severe labor pain with a numeric pain rating scale (NPRS)  $>7$  requiring pain relief. Those who received pharmacological analgesia before SWIs or having skin infections around injection sites and high-risk pregnancies were not included in the study. Study variables were the NPRS score at intervals of 15 min, 45 min, 90 min, 120 min, and 180 min, delivery outcome, adverse effects, and baby outcome.

### Study procedure

After counseling and proper consent, 66 mothers who are in active labor with back pain, abdominal pain, and thigh pain and are undergoing treatment in the labor room of Eden Hospital, Medical College, and Hospital, Kolkata, were selected. They were divided into two groups of 33 people apiece at random. A computer was used to generate the random allocation. One of the authors recruited participants and separated them into two groups at random out of the 66 mothers who were assigned to interventions (Fig. 1). Mothers were followed up until 2 h after delivery.

Group 1 was given subcutaneous SWI, and Group 2 was given subcutaneous normal saline injection (NSI). 2 mL of injection (either sterile water or normal saline) were injected at 4 sites, as shown pictorially below (Fig. 2). Repeat doses were not given in any of the groups, and the numeric pain rating score (0–10) was assessed in both groups at 15 min, 45 min, 90 min, 120 min, and 180 min. The parameters assessed included the assessment of pain relief, the duration of labor from intervention to delivery, the delivery outcome, any side effects, and the outcome of the baby. The study variables were grouped as sociodemographic variables which included age, occupation, general characteristics, body weight and height, body mass index (BMI), per vaginal examination findings, which included cervical dilatations, fetal position and presentation, and the NPRS. Partograph was also taken into consideration for maternal and fetal well-being as well as the outcome and type of delivery.

### Statistical analysis

For statistical analysis, data were entered into a Microsoft Excel spreadsheet and then analyzed by the Statistical Package for the Social Sciences, version 24.0, and GraphPad Prism, version 5.0. For numerical variables, the data were summarized as mean and standard deviation, and for categorical variables, as count and percentages. For a mean difference, independent or unpaired samples were used in two-sample t-tests. Fisher's exact test or Chi-square test, if applicable, was used to compare unpaired proportions. A table of values from the student's t-distribution was used to find the p-value once the t-value was established. A  $p < 0.05$  was deemed statistically significant.

### RESULTS

In our study, all mothers belonged to the 18–35-year age group. Multipara mothers (66%) were more compared to primipara mothers in both the study and control groups. The maximum portion (SWI-45% and NSI-36%) of mothers was at 38-week gestational age, followed by

39 weeks and 40 weeks. In both groups, the majority of mothers (SWI-84.8% and NSI-78.8%) had a BMI of 18.5–24.9 (Table 1).

The NPRS score was not significantly decreased in the SWI group after 15 min ( $7.90 \pm 0.765$ ) and also in the NSI group ( $8.06 \pm 0.704$ ). This association was not statistically significant ( $p > 0.05$ ). But almost 50% reduction in pain relief at 45 min ( $4.90 \pm 0.842$ ), 90 min ( $2.84 \pm 0.75$ ), 120 min ( $1.45 \pm 1.033$ ), and 180 min ( $1.21 \pm 0.857$ ) compared to the NS group (45 min -  $6.90 \pm 0.678$ ; 90 min -  $6.21 \pm 0.857$ ; 120 min -  $5.78 \pm 0.820$ ; 180 min -  $5.12 \pm 0.820$ ). This difference was statistically significant ( $p < 0.05$ ) (Table 2).

Among vaginal delivery mothers, a major portion (92%) belonged to the SWI group compared to the NSI group (81%) (Table 3), but this association was not statistically significant ( $p > 0.05$ ).

The time of delivery after injection was early in group NSI ( $166.66 \pm 32.755$  min) compared to group SWI ( $173.93 \pm 35.261$  min), but this association was not significant ( $p > 0.05$ ). Neonatal APGAR scores were almost equal in two groups at 1 min (median 7) and 5 min (median 9) (Table 4).

Regarding maternal complications, more mothers in the NSI group had complications like burning sensations at the injection site than in the SWI group, and this association was significant ( $p < 0.05$ ). Maximum patients in SWI group (64.3%) were satisfied than saline water injection group (25%). This association was statistically significant ( $p < 0.01$ ) (Table 5).

### DISCUSSION

The number of studies demonstrating positive results in the application of the SWI method has increased. In most of these studies, SWI and placebo (isotonic saline, dry injection, and standard care) were compared [7-9].

In our study, the analgesic effectiveness of sterile water was assessed by NPRS at multiple time intervals (15–180 min). The basal pain level was used to establish whether or not SWI significantly reduced pain. Furthermore, two meta-analyses have shown that SWI is beneficial for labor pain.

In my study, the NPRS score was significantly lower in the SWI group compared to the NSI group at 45, 90, 120, and 180 min ( $p < 0.05$ ). It was also observed that both SWI and NSI effectively reduce labor pain. In the SWI group, labor pain was reduced promptly. NSI also reduced labor

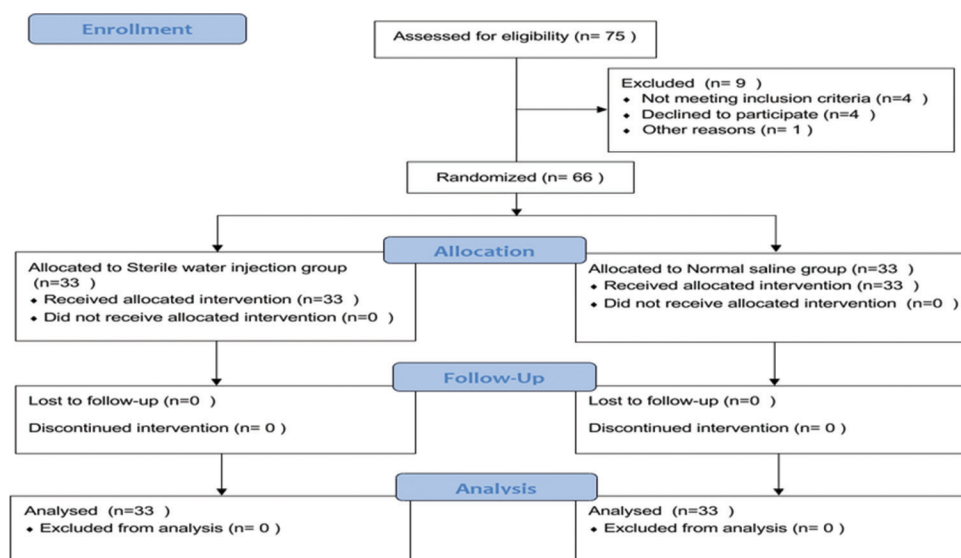


Fig. 1: Consort 2010 flow diagram

**Table 1: Distribution according to age (years), mean gestational age (weeks), and BMI (kg/m<sup>2</sup>)**

Variables	Groups	Number	Mean	SD	Minimum	Maximum	p-value
Age (in years)	SWI	33	23.454	6.586	18	32	0.62
	NSI	33	22.575	7.996	18	35	
Gestational age (in weeks)	SWI	33	38.93	0.826	38	40	0.957
	NSI	33	38.75	0.791	38	40	
BMI	SWI	33	24.12	2.835	18.5	26	0.37
	NSI	33	23.42	1.744	18.0	27.5	

BMI: Body mass index, SWI: Sterile water injection, NSI: Normal saline injection

**Table 2: Distribution according to NPRS before injection and time intervals of 15 min, 45 min, 90 min, 120 min, and 180 min**

Variables	Groups	Number	Mean	SD	Minimum	Maximum	p-value
NPR before injection	SWI	33	8.03	0.769	8	10	0.679
	NSI	33	8.27	0.761	8	10	
NPR at 15 min	SWI	33	7.90	0.765	7	10	0.416
	NSI	33	8.06	0.704	8	10	
NPR at 45 min	SWI	33	4.90	0.842	4	8	<0.05
	NSI	33	6.90	0.678	6	9	
NPR at 90 min	SWI	33	2.84	0.755	2	7	<0.05
	NSI	33	6.21	0.857	6	8	
NPR at 120 min	SWI	33	1.45	1.033	1	5	<0.05
	NSI	33	5.78	0.820	5	7	
NPR at 180 min	SWI	33	1.21	0.857	1	3	<0.05
	NSI	33	5.12	0.820	5	6	

NPR: Numeric pain rating, SWI: Sterile water injection, NSI: Normal saline injection

**Table 3: Distribution according to the mode of delivery**

Mode of delivery	Group (%)		Total (%)
	SWI	NSI	
LSCS	3 (9)	6 (18)	9
Vaginal delivery	30 (91)	27 (82)	57
Total	33	33	

SWI: Sterile water injection, NSI: Normal saline injection

**Table 4: Distribution according to the time of delivery after injection (min), mean APGAR scores at 1 min and 5 min, and mean birth weight of the baby (kg)**

Variables	Groups	Number	Mean	SD	Minimum	Maximum	p-value
Time of delivery after injection (in min)	SWI	33	173.93	35.26	165	182	0.398
	NSI	33	166.66	32.75	160	178	
Apgar score at 1 min	SWI	33	6.636	1.27	6	8	>0.05
	NSI	33	6.939	1.02	6	8	
Apgar score at 5 min	SWI	33	8.667	0.816	8	9	>0.05
	NSI	33	8.788	0.696	8	9	
Weight of baby (kg)	SWI	33	2.97	0.312	2.82	3.12	0.004
	NSI	33	2.93	0.299	2.80	3.04	

SWI: Sterile water injection, NSI: Normal saline injection

**Table 5: Association with maternal complications**

Maternal complications	Group (%)		Total (%)
	SWI	NSI	
Burning sensation	1 (3)	8 (24.2)	9 (13.6)
No complaint	32 (97)	25 (75.8)	57 (86.4)
Total	33	33	

SWI: Sterile water injection, NSI: Normal saline injection

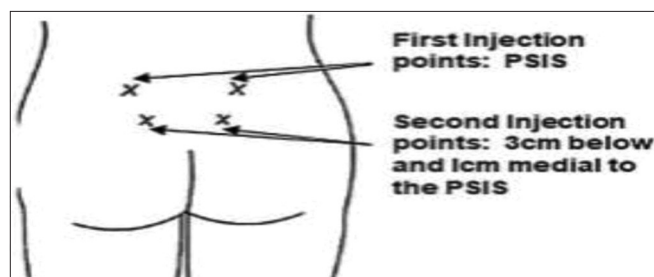
pain but to a lesser extent. The analgesic effectiveness of SWI was found until 3 h after intervention.

Similarly, Koyucu *et al.*, [10] demonstrated in a study that subcutaneous SWI led to a significant reduction in pain relative to the baseline pain level. Furthermore, two meta-analyses have shown SWI's effectiveness

in alleviating labor pain [3,11]. In their study, a notable decrease in pain scores was observed after SWI administration, surpassing 50% reduction at 45, 90, and 120 min. Despite a slight decline, the pain-relieving effects of SWI persisted at 180 min. These findings of the present study align with other studies, indicating that SWI effectively alleviates back pain during labor.

Meta-analyses indicate that the analgesic efficacy of SWI persists for around 2 h and can be repeated as needed [3,9,11,12]. The highest analgesic effectiveness of SWI was observed within the 30–120-min timeframe.

Marzouk *et al.* found that their study aimed to assess the impact of subcutaneous SWI in the lumbosacral region on labor pain. Instead of NPRS, he used a 5-point Likert's scale to gauge the mother's satisfaction with the pain relief. The baseline pain score averaged 8±0.8. This score



**Fig. 2:** Site of injection of subcutaneous sterile water and normal saline. PSIS: Posterior superior iliac spine

decreased by 2.5, 3.5, 4.5, and 5 points at 10 min, one, two, and 3-h post-injection, respectively [13]. Bahasadri *et al.* [8] from Iran revealed that the median pain score was comparable between both groups before the injection. Pain severity decreased in both groups following the injection. However, the median pain score in the sterile water group was significantly lower than the NSI group at 15 min ( $p < 0.01$ ) and 45 min ( $p < 0.01$ ) post-injection. These findings are consistent with our own observations.

Saxena *et al.* [14] from India concluded that the median pain score was significantly lower in the sterile water group, corroborating our study findings. Fouly *et al.* observed a statistically significant pain reduction with SWI compared to NSI. Assessment of subsequent pain at 30, 45, 90, and 120 min revealed a statistically significant difference ( $p = 0.001$ ) [15]. The results of our current study align with those of these two previous studies.

Supporting our study, Rezaie *et al.* [16] similarly demonstrated lower pain severity upon SWI injection compared to NSI. However, in their study, the pain severity score decreased at 150 min following the subcutaneous injection of normal saline. In the NSI group, a second injection was required, whereas in the SWI group, no further injection was needed within 150 min. In contrast, in our study, no additional injection was required in either the SWI or the NSI group within the same timeframe.

#### Limitations

Despite every sincere effort, our study has lacuna.

The notable shortcoming of this study is that the study has been done in a single center in a tertiary care hospital, and the sample size was small. Only 66 cases are not sufficient to draw any firm conclusion.

#### CONCLUSION

This study hypothesized that subcutaneous SWI for relieving labor pain is better than subcutaneous NSI. Based on the present study, it is concluded that both the SWI and NSI reduce labor pain, but the SWI produced a significantly more reduction in pain as measured by the numeric pain rating score. Regarding satisfaction, subcutaneous SWI is better than saline procedures to relieve from labor pain during childbirth; therefore, SWI is a safe, simple, and cost-effective method. It can be used as a pain-relieving method, especially in the absence of other pain-relieving options.

#### AUTHORS' CONTRIBUTION

Study conception and design – Palash Mazumder Data collection – Debjit Mandi Data analysis – Swadha Pandey Interpretation of results – Palash Mazumder Manuscript Preparation – Shyamali Dutta.

#### CONFLICTS OF INTERESTS

Nil.

#### AUTHORS' FUNDING

The authors did not receive any funding from any organization for the submitted work.

#### REFERENCES

- Hoy D, Brooks P, Blyth F, Buchbinder R. The epidemiology of low back pain. *Best Pract Res Clin Rheumatol.* 2010;24(6):769-81. doi: 10.1016/j.berh.2010.10.002, PMID 21665125
- Simkin P, Klaus P. When Survivors Give Birth: Understanding and Healing the Effects of Early Sexual Abuse on Childbearing Women. Seattle: Classic Day Publishing; 2004. p. 127-56.
- Mårtensson L, Wallin G. Sterile water injection as treatment for low-back pain during labour: A review. *Aust N Z J Obstet Gynaecol.* 2008;48(4):369-74. doi: 10.1111/j.1479-828X.2008.00856.x, PMID 18837842
- Hawkins J, Bucking B. Obstetrical anesthesia. In: Gabbe S, Niebyl J, Simpson J, Landon MB, Galan HL, editors. *Obstetrics Normal and Problem Pregnancies.* 6<sup>th</sup> ed. Philadelphia, PA: Saunders; 2012. doi: 10.1016/B978-1-4377-1935-2.00017-x
- Hosseini L, Najari S, Haghhighizadeh MH. Effect of subcutaneous injection of isotonic, sterile water, labour pain, type of labour, and satisfaction with pain management in nulliparous women. *Hayat J.* 2010;16:41-7.
- Mårtensson L, Nyberg K, Wallin G. Subcutaneous versus intracutaneous injections of sterile water for labour analgesia: A comparison of perceived pain during administration. *BJOG.* 2000;107(10):1248-51. doi: 10.1111/j.1471-0528.2000.tb11615.x, PMID 11028576
- Ader L, Hansson B, Wallin G. Parturition pain treated by intracutaneous injections of sterile water. *Pain.* 1990;41(2):133-8. doi: 10.1016/0304-3959(90)90017-8, PMID 2142271
- Bahasadri S, Ahmadi-Abhari S, Dehghani-Nik M, Habibi GR. Subcutaneous sterile water injection for labour pain: A randomised controlled trial. *Aust N Z J Obstet Gynaecol.* 2006;46(2):102-6. doi: 10.1111/j.1479-828X.2006.00536.x, PMID 16638030
- Wiruchpongson P. Relief of low back labor pain by using intracutaneous injections of sterile water: A randomized clinical trial. *J Med Assoc Thai.* 2006;89(5):571-6. PMID 16756038
- Genç Koyucu R, Demirci N, Ender Yumru A, Salman S, Ayanoğlu YT, Tosun Y, *et al.* Effects of intradermal sterile water injections in women with low back pain in labor: A randomized, controlled, clinical trial. *Balk Med J.* 2018 Mar;35(2):148-54. doi: 10.4274/balkanmedj.2016.0879, PMID 29072177
- Fogarty V. Intradermal sterile water injections for the relief of low back pain in labour -- a systematic review of the literature. *Women Birth.* 2008;21(4):157-63. doi: 10.1016/j.wombi.2008.08.003, PMID 18926789
- Trolle B, Moller M, Kronborg H, Thomsen S. The effect of sterile water blocks on low back laborpain. *Am J Obstet Gynecol.* 1991;164(1):1277-81.
- Marzouk T, Abd-Eiftah H, Nabi H. Effect of subcutaneous isotonic, sterile water injection at the lumbosacral region on labour back pain. *J Nurs Educ Pract.* 2015;5:98-104.
- Saxena KN, Nischal H, Batra S. Intracutaneous injections of sterile water over the Secrum for labour analgesia. *Indian J Anaesth.* 2009;53(2):169-73. PMID 20640118
- Fouly H, Herdan R, Habib D, Yeh C. Effectiveness of injecting lower dose subcutaneous sterile water versus saline to relief labor back pain: randomized controlled trial. *Eur J Midwifery.* 2018;2(3):3. doi: 10.18332/ejm/85793, PMID 33537564
- 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. *Iran J Nurs Midwif Res.* 2019 Sep;24(5):365-71. doi: 10.4103/ijnmr.IJNMR\_87\_18, PMID 31516523