



Comparison of subcutaneous sterile water injection versus normal saline water injection over the sacrum in females presenting with severe back pain undergoing normal vaginal delivery at term.

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ABSTRACT... Objectives: Compare the mean pain score with subcutaneous sterile water injection versus normal saline water injection over the sacrum in females presenting with severe back pain undergoing normal vaginal delivery at term. **Study Design:** Randomized Control Trial. **Setting:** MCH Centre, Pakistan Institute of Medical Sciences, Islamabad. **Period:** 21-08-2019 to 20-11-2019. **Material & Methods:** The non-probability, consecutive sampling technique was used to include patients. In group A, patients injection was given 4 intracutaneous injections of 0.5 ml sterile water in the lumbar- sacral region in the sitting position. One injection was given at the posterior superior iliac spine on both sides and second injection at 1 cm medial, and 1-2 cm inferior to the first point on both the sides using an insulin needle. These points overlie the area called Michaelis' rhomboid. In group B, patients were given injections of 0.5 ml isotonic saline in the same region using an insulin needle. Then patients were followed-up for 90 minutes (1.5hours). After 90 minutes, pain on VAS was again measured. **Results:** In this study the mean pain score at baseline of the patient was 79.82 ± 12.99 and the mean pain score after the 90 minutes was 54.05 ± 18.52 . Statistically there is highly significant difference was found between the study groups and pain after 90 minutes of the patients i.e. p-value=0.000 **Conclusion:** Our study results concluded that sterile water group patients showed better pain relief as compared to normal saline group in in females presenting with severe back pain undergoing normal vaginal delivery at term.

Key words: Back Pain, Female, Labor Pain, Normal Saline, Pain Relief, Sterile Water.

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INTRODUCTION

A unique visceral pain is known as labor pain, it is associated with meaningful and wonderful life occasion regarding childbirth.¹ It is a complex process experience individually and also changes during labor process.²

It arises due to stimulation of C-afferent nerve fibers originates from uterine corpus and cervix. The fibers are terminated in the dorsal horn of the spinal segment T10 to L1 and causing visceral pain leads to lower back. Methods to reduce this pain are of major concern for the caregivers and mothers as well. The use of pharmacological methods is associated with increase mortality and morbidity for the mother and respiratory complications of the new born. For some women this approach may not be available because

of need for specialized anesthetic service availability.³

The procedure is relatively simple and not technology dependent; may be a feasible and effective analgesic strategy is convenient for maternity model or a care setting.⁴

Previous trial are of the opinion that a dramatic and significant analgesic effect is recorded with sterile water injection on low back pain in cases during the labor lasts for 2.3 hours. Majority of women experienced a good analgesic effect by using sterile water injection when compared to those with placebo treatment.⁵ A randomized trial had reported that with sterile water injection (n=50), the mean pain score was 49.3 ± 33.96 while

with normal saline (n=50) was 83.7 ± 18.81 . The difference between both groups was significant ($P=0.000$).¹

This study was to compare the mean pain score with subcutaneous sterile water injection versus normal saline water injection over the sacrum in females presenting with severe back pain undergoing normal vaginal delivery at term. Literature has reported that with sterile water injection can be helpful in reducing severe lower back pain due to labor pains. But controversy exists in literature and there was no local study we observed in literature which can help us to implement the use of injection of sterile water to reduce the lower back pain. Because of severe lower back pain, often females anxiously choose cesarean section to be relieved from this pain. But this method can be helpful in reducing pain. So through this study we want to confirm whether sterile water injection is helpful in reducing pain as compared to normal saline injection or not.

MATERIAL & METHODS

In this Randomized Controlled Trial at MCH Centre, Pakistan Institute of Medical Sciences, Islamabad we enrolled a total of 200 cases (100 in each group) where age range was 18-40 years, and all cases were at stage 1 (cervical dilatation 3cm) active labour pain >3 in 10 minutes, with severe back pain ($VAS \geq 60$). We excluded all cases 1) with multiple pregnancy, malpresentation (breech, transverse) and pharmacological analgesia prior to sterile water injection. Approval from hospital ethical committee was obtained before the start of study, a total of 200 females fulfilling the selection criteria were the part of this study. Routine informed consent of the participants was taken. After taking detailed demographic info (name, age, gestational age, parity), patients were screened for VAS score at baseline. Random allocation of patients to either group was done by lottery method. In group A, patients injection was given 4 intracutaneous injections of 0.5 ml sterile water in the lumbar- sacral region in the sitting position. One injection was given at the posterior superior iliac spine (Point.1) on both sides and second injection at 1 cm medial, and 1-2 cm inferior to the first point on both the sides

(Point.2) using an insulin needle. These points overlie the area called Michaelis' rhomboid. In group B, patients were given injections of 0.5 ml isotonic saline in the same region using an insulin needle. Then patients were followed-up for 90 minutes (1.5hours). After 90 minutes, pain on VAS was again measured. Data was collected on a standardized performa. Data analysis was done with the help of SPSS-18. Independent sample t-test was used to compare mean pain score in both groups.

RESULTS

In this present study total 200 cases were enrolled. The mean age of the patients was 28.18 ± 6.48 years with minimum and maximum ages of 18 & 40 years respectively. Table-I

The study results showed that the mean pain score at baseline of the patient was 79.82 ± 12.99 with minimum and maximum pain values of 60 & 100 respectively. Table-II

In this study the mean pain score after 90 minutes of the patient was 54.05 ± 18.52 with minimum and maximum pain values of 10 & 95 respectively. Table-III

| | | |
|-------------|---------|-------|
| Age (years) | n | 200 |
| | Mean | 28.18 |
| | SD | 6.48 |
| | Minimum | 18 |
| | Maximum | 40 |

Table-I. Descriptive statistics of age (years).

| Study Groups | | n | Mean | SD |
|------------------|---------------|-----|-------|-------|
| Pain at baseline | Sterile water | 100 | 79.30 | 12.83 |
| | Normal saline | 100 | 80.35 | 13.20 |

Table-II. Comparison of pain at baseline in both study groups.

t-value=-0.57 P-value=0.57 (Insignificant)

| Study Groups | | n | Mean | SD |
|--------------------|---------------|-----|-------|-------|
| Pain at 90 minutes | Sterile water | 100 | 42.60 | 15.25 |
| | Normal saline | 100 | 65.50 | 13.86 |

Table-III. Comparison of pain after 90 minutes in both study groups.

t-value=-11.11 P-value=0.000 (significant)

DISCUSSION

In our study the mean pain score at baseline of the patient was 79.82 ± 12.99 and the mean pain score after 90 minutes was 54.05 ± 18.52 .

In this study the mean value of pain at baseline in sterile water group patient was 79.30 ± 12.83 and in normal saline group the mean value was 80.35 ± 13.20 . Similarly the mean value of pain after 90 minutes in sterile water group patients was 42.60 ± 15.25 and in normal saline group the mean value was 65.50 ± 13.86 . Statistically there is highly significant difference was found between the study groups and pain after 90 minutes of the patients. i.e p-value=0.000. So according to our study sterile water group patients showed better pain reduction as compared to normal saline group patients. Some of the studies are discussed here which are supporting the results of our finding and some are in contrary.

A study by Labrecque et al⁶ reveal that sterile water injection group had less pain as compared to TENS group.

Meta-analysis and systematic reviews^{5,7} reported a significant reduced self-reported pain in SWI group versus controls. Authors are of the opinion that sterile water injection is an effective therapeutic modality while managing continuous back pain during the course of labour.

A randomized trial had reported that with sterile water injection (n=50), the mean pain score was 49.3 ± 33.96 while with normal saline (n=50) was 83.7 ± 18.81 . The difference between both groups was significant (P=0.000).¹

Another study⁸ is evident that number of cases self-scoring at-least 4/10 cm less pain at 10, 45, and 90 mins after administration of sterile water injection, and recorded insignificant difference between subcutaneous sterile water and intracutaneous, but significantly majority of the cases had sterile water (about 50% to 60%) than with placebo (20% to 25%).

Intracutaneous injections of sterile water in the skin over the sacrum have been shown to relieve

the pain of labour in open studies and in controlled prospective studies.⁹⁻¹¹

All studies reported treatment group average pain intensity, six studies (Ader 1990; Bahasadri 2006; Martensson 1999; Saxena 2009; Trolle 1991; Wiruchpongsanon 2006)^{1,8-13} finding superiority of sterile water over saline, but this is of uncertain significance because the underlying distributions were not explicitly or convincingly shown to be normal, with the possible exception of Bahasadri 2006.¹³

On the other hand three studies¹¹⁻¹² reported no significant differences between sterile water and saline groups, however, these studies enrolled smaller sample size. However, in our study, subcutaneous injections were less painful during administration as compared to those with normal saline group.

CONCLUSION

Our study results concluded that sterile water group patients showed better pain relief as compared to normal saline group in females presenting with severe back pain undergoing normal vaginal delivery at term.







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AUTHORSHIP AND CONTRIBUTION DECLARATION

| Sr. # | Author(s) Full Name | Contribution to the paper | Author(s) Signature |
|-------|---------------------|--------------------------------------|---|
| 1 | Asia Nazir | Conceived main idea. |  |
| 2 | Adeela Ameen | Article writing. |  |
| 3 | Shaista Naheed | Data collection. |  |
| 4 | Tahira Jabeen | Data collection, Manuscript writing. |  |
| 5 | Rukhsana Shaheen | Data formalling. |  |
| 6 | Tanzila Aftab | Data analysis. |  |