

Dr. B. Meenambiga Department of Obstetrics and Gynaecology, Thanjavur Medical College, Thanjavur.

(ABSTRACT) Background and Aim: To evaluate the effectiveness and parturient satisfaction with injection of sterile water intracutaneously over the sacrum in relieving pain during labour.

**Methods:** A total of 100 pregnant patients admitted in labour pain were randomly divided into two groups of 50 patients each. The study was carried out by randomized, double-blinded including a sterile water injection treated group A patients and comparing with placebo treated group B patients with normal saline.

**Results:** Pain scores were similar between both groups at time of injections but significantly lower at 10, 45 and 90 minutes in group A compared to group B.

Conclusions: To conclude sterile water injection intracutaneously over the sacrum is a simple and effective method to relive pain during labour.

KEYWORDS : Labour, analgesia, sterile water injection.

### INTRODUCTION

Labour pain is considered to be one of the most intense and stressful experiences. Most of them in the labour, feel the pain at lower back. Various attempts made to relieve this referred labour pain by treating dermatomes having the same cutaneous innervations based on gate control theory or counter irritation theory with methods such as Transcutaneous Electric Nerve Stimulation, Intracutaneous Sterile Water Injection and acupuncture with varying results.

A process by which localized pain felt in one part of the body may be relieved by irritating the skin in same dermatomal distribution with either a hot, cold, scratchy, or electrical stimulus by counter irritation theory. The sterile water injections are thought to cause distension in the skin, which stimulates nociceptors and mechanoreceptors. This method was found to be simple and efficient. No side effects observed other than injection site burning pain lasting for few seconds.

The aim of this study was to evaluate the effectiveness and patient satisfaction of sterile water injection intracutaneously in relieving the lower back pain during the first stage of labour in comparison with saline injection in the same site as a placebo.

### METHODS

A prospective double – blinded randomized control study conducted on 100 patients at age of 18 - 30 years of ASA grade I and II at term with gestational age (37 - 41 weeks) in first stage of labour (cervical dilatation around 4 cm) complaining of low back pain, Single fetus with vertex presentation, No evidence of cephalopelvic disproportion were included after approval of institutional ethical committee. Excluded from the study were patient refusal, local infection at the site, patients who have received any analgesic following onset of labour and patients with comorbids.

Patients were pre-operatively assessed and the procedure explained and written informed consent was obtained. They were randomly divided into two groups of 50 patients namely- group A and group B.

Sterile water injection group A patients received 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 1cm 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 Michaeli's rhomboid (Fig 1) Normal saline injection group B patients received injections of 0.5 ml isotonic saline in the same region using an insulin needle. All the patients had a brief stinging pain when the injection was given. The pain lasted longer in the sterile water group but subsided within a few seconds.

The following parameters were recorded 1.Pain assessment with the help of Visual Analogue scale(VAS) (0-10) at 10min, 45min and 90min after giving the injections. The obstetrician was blinded to the solution

injected for pain relief. 2. Progress and duration of labour as assessed by the obstetrician, 3. Apgar score of the neonate.



Fig: 1

### **OBSERVATIONS AND RESULTS:**

The information collected in our study Group A and Group B were recorded in a Master Chart. Data analysis was done with the help of computer using SPSS. For statistical analysis students t test was used for comparison between the groups. Using this range, frequencies,Percentages, means, standard deviations, chi square and 'p' values were calculated. A 'p' value less than 0.05 was considered statistically significant.

The women in the 2 groups were similar with regard to age, parity and gestational age and cervical dilatation at the beginning of the study (Table 1). All patients were in active stage of labour.

# Table 1 Demographic and clinical data before treatment $(mean \pm SD, n)$

	Sterile Water Group	Normal Saline Group
Age (years)	$22.92 \pm 5.42$	$23.37 \pm 4.76$
Parity (Primi / Multi)	25:25	25:25
ASA (1 / 11)	25:5	25:5
Gestational age (weeks)	38.1 ±1.2	$38.3 \pm 1.3$
Cervical dilatation (cm)	4	4

## Table 2 Comparison between both groups as regards VAS scores and further analgesia.

Group	VAS at	VAS at	VAS at	VAS at
	0 min	10 min	45 min	90 min
Sterile Water	$7.92\pm0.56$	$5.04 \pm 0.99$	$4.5 \pm 0.84$	$4.02\pm1.10$
Normal Saline	7.98±0.72	$7.37 \pm 1.74$	$7.2 \pm 1.20$	$7.8\pm0.51$

The mean VAS score at start of treatment was 7.92 in sterile water group and 7.98 in normal saline group with statistical insignificance between both groups. The mean VAS pain score 10 minutes after treatment when compared to the pre-treatment score was found to be reduced (statistically highly significant) in sterile water group but not in normal saline group. Mean VAS pain score at 45min and 90min was also found to be reduced (Table 2) considerably in the sterile water group but not the saline group. There was highly significant reduction

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of VAS scores at10, 45, 90min compared to VAS at 0min (p<0.005) in the sterile water group.

The mean period between injections and delivery was 4.01+2.15 hrs in sterile water group and 4.17+2.30 hrs in normal saline group. Mean Apgar score of the newborns in both the groups was 8.7+0.5 and 8.58+0.15 respectively. There was no difference between the two groups.

#### DISCUSSION

Uterine contractions are felt as back pain because the rami of T10-L1 supplying the uterus also supply the skin over the Lumbosacral area. The cutaneous branches of the lumbar and the lower thoracic nerves cover a considerable caudal area<sup>1</sup>. They transmit referred pain from uterus to a skin area over the vertebrae L3-S2.

Trolle et al<sup>2</sup>., first suggesting the area of Michaeli's Rhomboid to be the site for injections, being the area where labouring women acutely feel referred pain from the uterine contractions. Injections need to be multiple to stimulate the skin area of the back which is supplied by the cutaneous branches of T10-L1 spinal segments and this stimulates the surrounding nociceptors by raising a small bleb and causing a local irritation.

Injecting solutions of osmolality other than blood irritates biological tissues. Administration of hyposmolar sterile water probably irritates the nerves leading to brief pain initially followed by analgesia to a similar gate control effect or diffuse noxious inhibitory control and /or a stimulation of the endogenous opioids system as TENS and acupuncture do. While saline being isosmolar with blood does not irritate the nerves at all and therefore does not lead to analgesia and considered to be placebo treatment.

Martensson et al<sup>3</sup>. argued that an intense stimulation was obtained from intracutaneous sterile water injections provided by both osmotic stimulation and distension of the firm cutaneous layers, was more effective than subcutaneous injections which merely induced osmotic stimulation. So in our study we administered all injections intracutaneously, which produced sharp intense pain sensation that lasted for 20 - 30 seconds or more in sterile water group<sup>2</sup>

Lee et al14., found that the four injection technique was associated with increased level of analgesia at 30 minutes compared to the single injection, but with a greater injection pain.

Various authors<sup>3,6,7</sup> used 0.1 ml volume while we used 0.5 ml because of the contention that it is very difficult to pin-point the exact point of injection which we tried to overcome with a higher volume<sup>1</sup>.

This study is limited by the fact that the duration of the study of pain was restricted to 90 minutes only and the maximum duration of pain relief could not be studied. However, we had aimed only to study whether this method was actually as effective as quoted in various studies or not.

Visual analogue scale has been shown to have high validity and reliability in pain assessment and was the measuring tool used by all studies.

In our study we found that VAS score before administration was statistically insignificant between the groups and after administration mean pain score was significantly lower in sterile water group. Similar to studies conducted by Wirchpongsanon et al, Martensson et al, Kushtagi et al, Trolle et al,.

There were no significant differences between the groups in Mode of delivery and the Apgar score of new born.

Multigravidas were better able to feel the difference of pain relief and reported labour as much more satisfying.

In our study, 37 women of sterile water group (75%) accepted this technique for future pregnancies while only 3 women (6%) of saline group accepted this, with a statistically significant difference, which illustrates that intracutaneous injection of sterile water, has a satisfying effect on reducing the back pain of labouring woman, which agrees with some studies.

Except for the initial deep stinging sensation lasting for 30 seconds.

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There were no complications in the mother. Despite providing significant reductions in pain levels, some women stated they were reluctant to repeat this treatment in future labours due to this transient pain.

### **CONCLUSION:**

To conclude injection of sterile water intracutaneously have a significantly greater effect on relieving labour pain and also has no effects on maternal or in new born Apgar score.

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