

International Journal of Clinical Obstetrics and Gynaecology

ISSN (P): 2522-6614
ISSN (E): 2522-6622
© Gynaecology Journal
www.gynaecologyjournal.com
2018; 2(5): 92-96
Received: 28-07-2018
Accepted: 29-08-2018

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Intracutaneous sterile water versus intramuscular tramadol injection in relief of low back pain in labour

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Abstract

Objectives: To study the effectiveness of intracutaneous injection of sterile water over sacrum (Group A) and the effectiveness of intramuscular injection of tramadol (Group B) in relieving low back pain during labour. To compare the effectiveness of pain relief in group A and group B. To subject the results for statistical analysis.

Materials and Methods: This randomized control trial was conducted for a period of 3 years in the Labour room, Department of Obstetrics and Gynecology, Rajah Muthiah Medical College and Hospital. A total of 100 primigravida admitted in labour pain were randomly divided into two groups alternatively with 50 patients in each group. Group A were treated with Sterile water injection (Study Group) and Group B patients treated with Tramadol Injection.

Results: In this study, the patients were randomly subjected to either one of the injections for pain relief and the degree of pain relief assessed by Visual Analogue Scale were subjected to statistical analysis and compared with each other. The pain score was significantly different at various times of measurement for both the groups. The pain was significantly reduced for both the groups after treatment.

Conclusion: In this study, intracutaneous sterile water injection over sacrum and intramuscular injection of tramadol were both equally effective in relieving low back pain during labour.

Keywords: Intracutaneous sterile water, tramadol, labour analgesia

Introduction

Labour pain is considered to be one of the most intense and stressful experiences especially for nulliparous woman. Although studies have found a significant rise in pain threshold during labour it is an important goal to provide safe and effective method of analgesia for woman in pain in order to obtain her maximum cooperation. Most women in the first stage of labour feel pain predominantly in the lower abdomen, whereas other experience severe low back pain, and in approximately 30% of cases the pain is continuous and annoying known as "back labour".

The uterine cervix and corpus are supplied by afferent neurons ending in the dorsal horns of spinal segments (T10 - L1). Since the cutaneous afferents from lower back converge to the dorsal horns in the same segment, there is anatomical support for the assumption that low back pain in labour is referred pain (Wiruchpongson, 2006). Based on gate control theory or counter irritation theory, many trials have been done to alleviate labour pain by treating dermatomes containing the same cutaneous innervations with techniques such as transcutaneous electric Nerve Stimulation, Intradermal Sterile Water Injections and acupuncture with varying results.

Pharmacological methods utilised to relieve labour pain like narcotics are not suggested because these agents have various maternal and fetal side effects such as drowsiness, vomiting, loss of control and neonatal respiratory depression. Although Epidural analgesia has now become the gold standard for diminishing pain of labour it has its own complications such as increase in pyrexia during labour, long term backache and neurological symptoms. It produces sufficient motor block to adversely affect the mobility of the laboring woman and many patients lose the reflex desire to push. It also has an impact on breast feeding leading to lactational failure.

Intracutaneous injection of sterile water in the skin over the sacrum has been shown to relieve the pain of labour without concerns that the method might harm the mother and fetus or slow the labour pattern. The method began to be used in the obstetric field in the late 1920. Sterile water has been used for pain relief other than labour pain with positive outcomes including acute attack of urolithiasis, for neck and shoulder pain after whiplash injury and chronic myofascial pain syndrome.

Materials and methods

This study was conducted in the Department of Obstetrics and Gynecology - Rajah Muthiah Medical College and Hospital, Chidambaram, from 2016 to 2018. Under this study 100 consecutive primigravida admitted to clean labour theatre, in labour pain were enrolled for the study. Out of which 50 patients who received sterile water injection served as study group (Group A) and 50 patients who received inj. tramadol served as the control group (Group B). The study group and control group involved 100 primigravida who were selected alternatively from each group. The study group and control group were well matched in age, parity and labour characteristics. Informed consent was obtained from parturient of both study and control groups.

Criteria for Sample Selection

Inclusion Criteria

Primigravida with gestational age (37-41 weeks). Age of the patient 18-30 years. Single foetus with vertex presentation.

Patient at the onset of labour with a cervical dilatation of 1-2 cms complaining of low back pain.

Exclusion Criteria

Patient not willing for the procedure Patient with contraindication for spontaneous vaginal delivery Fetal distress, CPD, Malpresentation, Placenta previa, Macrosomic baby. Medical disorders associated with pregnancy, Diabetes, Hypertension, Neurological diseases, Blood dyscrasias. Suspicious or presence of dermatological pathology interfering with injection.

Method of administration

Patient at the onset of labour with a cervical dilation of 1-2cms complaining of low back pain.

Procedure explained and informed consent obtained.

The selected patient was made to assess the pain using Visual Analogue Scale before the procedure.

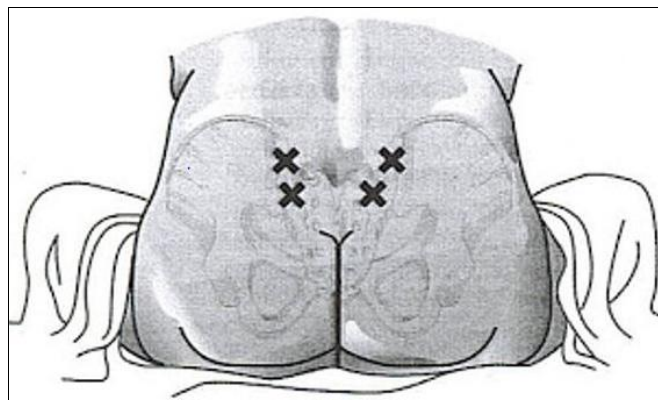


Fig 1: Sites of injection

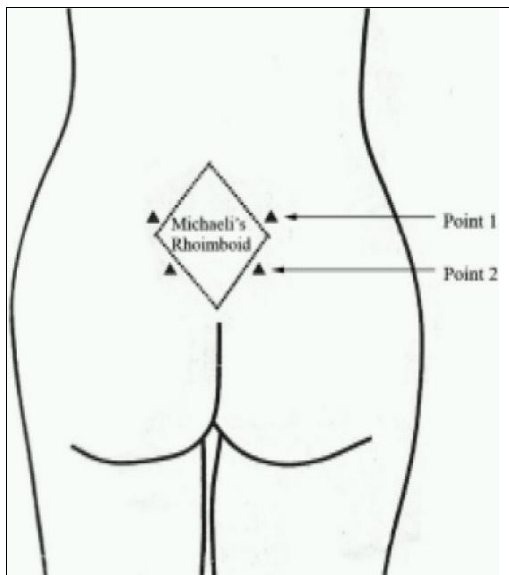


Fig 2: Michaelis rhomboid

Group A

- Patient position - sitting position.
- Anatomical points (injection sites) located as follows:

Point 1 - The posterior superior iliac spines palpated just below the dimple of venus just lateral to the sacrum and below the iliac crest.

Point 2-3 cms below and 1 cm medial to point 1. Point 1 and 2 on both sides form an area referred as the Michaelis rhomboid.

- The injection sites identified and marked with pen.
- Skin cleansed with alcohol wipes.
- 0.5 ml of sterile water taken in an insulin syringe and rapidly injected in the already marked 4 points (0.125ml) intradermally to raise a bleb in the skin in each point.

Group B

- Patient in left lateral position.
- Skin cleansed with alcohol wipes.
- Single dose of inj. Tramadol 100 mg given intramuscularly in gluteal region.

Assessment of pain relief is performed using Visual Analogue scale at 0 minutes, 45 minutes, 90minutes and 2 hours.

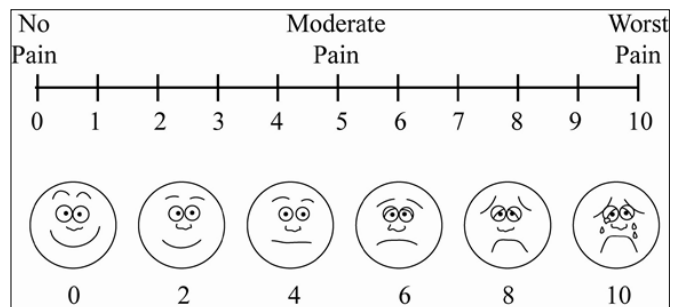


Fig 3: Visual Analogue scale

Results

The aim of present procedure was to compare the intramuscular injection of tramadol versus intradermal injection of sterile water over sacrum to relieve low back pain during labour. A total of 100 patients were selected and randomly assigned equally to each group alternatively. Group A treated with intracutaneous sterile water injection and Group B treated with

intramuscular Tramadol injection. The pain rating at different time intervals in both groups were analysed by repeated measures of analysis of Variance (ANOVA). Pain score comparison was done by Bonferroni post hoc analysis. Degree of pain relief (categorical variable) was compared by Chi Square test of association. The entire statistical procedure was carried out by statistical package of social science (SPSS-21).

Table 1: Pain Score at Various Times between Groups

	Sterile water		Tramadol	
	Mean	S.D	Mean	S.D
0 Minutes	7.88	.66	7.86	.67
10 Minutes	5.54	.84	5.86	1.07
45 Minutes	4.80	.93	4.96	1.32
90 Minutes	4.96	1.19	5.18	1.69
2hours	5.70	1.75	5.42	2.12
Wilk's Lambda	'F' 119.75	'P'.001	'F' 76.62	'P'. 001

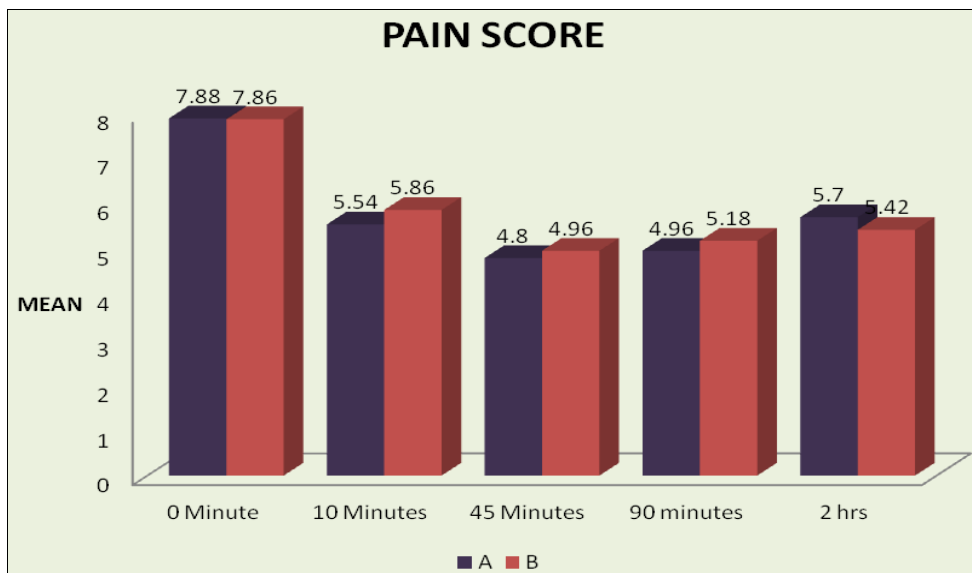


Fig 4: Pain Score Comparison

Repeated measurements of variance (ANOVA) test showed that the pain score at various times were significantly different for group 'A' (F=119.75, P=0.001) as well as for group 'B' (F=76.62, P=0.001). Mean score was highest at '0' minute for both the

groups. It was inferred that during the other times of measurement the mean score was reduced. Therefore both treatment were effective in reducing pain score.

Table 2: Pain Scores Comparison - Bonferroni Post Hoc Analysis

		Sterile Water		Tramadol	
		Mean Difference	'P'	Mean Difference	'P'
0 Minute	10 Minute	2.34	.001	2.00	.001
	45 Minute	3.08	.001	2.90	.001
	90 Minute	2.92	.001	2.68	.001
	2 Hours	2.18	.001	2.44	.001
10 Minute	45 Minute	.740	.001	.900	.001
	90 Minute	.580	.007	.680	.001
	2 Hours	.160	.563	.440	.098
45 Minute	90 Minute	.160	.220	.220	.109
	2 Hours	.900	.001	.460	.022
90 Minute	2 Hours	.740	.001	.240	.063

Post hoc analysis showed that there was significant reduction in pain score at most of the possible combination of times of treatment. In group 'A' statistical significant was not obtained for 10 minutes versus 90 minutes (P=.563) and between 45 minutes

versus 90 minutes (p=.220). Likewise in group 'B' statistical significant was not achieved for 10 minutes versus 2 hours (P=.098), 45 minutes versus 90 minutes (P=.109) and 90 minutes versus 2 hours (P=.063).

Table 3: Degree of Pain Relief Comparison Between Groups Decrease in pain score at the end of 2 hours, by 2 or less ⇒ Mild; by 3-4 ⇒ moderate; by 5 or more ⇒ excellent; remains the same ⇒ nil.

	Sterile Water		Tramadol	
	Number	%	Number	%
Mild	18	36	13	26
Moderate	17	34	16	32
Excellent	11	22	10	30
Nil	4	8	11	22
Total	50	100	50	100
Chi - square Test	Value		'P'	
	4.94		.84	

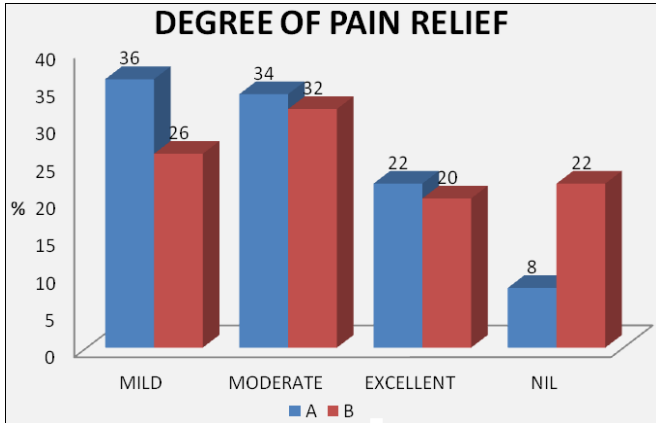


Fig 5: Degree of Pain Relief Comparison

Mild improvement in pain was 36% in group 'A' and 26% in group 'B'. Moderate improvement was achieved for 34% in group 'A and 32% in group 'B'. The improvement was excellent for 22% in group 'A' and 20% in group 'B'. No improvement was observed in 8% of group 'A' and 22% of group 'B'. The difference in degree of pain relief was statistically in significant.

Discussion

Various non pharmacological methods for pain relief are available such as, acupuncture, yoga, counter pressure, acupressure, music, hydrotherapy relaxation, breathing technique and TENS. Pharmacological methods such as nitrous oxide, opioids, spinal, epidural, and combined analgesia are available for managing labour pain. Regional analgesia methods (epidural, spinal, or epidural-spinal combination) are considered the most famous and effective methods for combating labour pain [5, 11]. Although these methods provide potent pain relief they have the drawback of restricting the mother's mobility, loss of sensation to push, delayed and operative deliveries [3, 7]. These techniques are not easily available extensively in developing countries especially with a majority of rural population. Hence it has become a need for an effective, simple, easily available, cost effective method to alleviate labour pain. Sterile water injection has shown to fulfill this need. There are a lot of studies emphasizing the benefits of this technique. In most of the studies, sterile water injection effectiveness was compared to a placebo similar to the present analysis [1, 2, 4, 6, 9]. In the previous and the present studies, the analgesic effect of sterile water was assessed by VAS at various time intervals (10-2hours). In previous studies it was concluded that sterile water was efficient in reducing the pain score from the base level. Moreover these injections has been proven to produce desired pain relief in labour in two meta-analyses [6, 8]. The conclusion of the present analysis seem to be in concordance with the results of other studies further emphasizing the competency of sterile water injection in

relieving back pain during labour.

Previous studies have reported that the analgesic effectiveness of SWI lasted for approximately 2 hours [5, 6, 7, 8] which was in concordance with the present study.

Newer methods used to relieve labour pain bring anxieties about their possible effects on labour, method of delivery, and the effects on mother and fetus. Previous studies reported that sterile water did not by any means affect the method of delivery [8, 12, 13]. Additionally, these injections seem to reduce the caesarean rates in a systematic review of eight Randomized Control Studies. Lee *et al.* initiated a study with the basis that the beneficial effect of sterile water could decrease the caesarean rates. In this study, even though caesarean deliveries were lesser in the study group, it was not statistically significant.

Similar to the study conducted by Wiruchpongson [9], the time duration from injection till birth were similar in both the groups of the present study.

Satisfaction of the mother from the pain killer effect, and desire to use this technique in subsequent pregnancies were significantly greater in sterile water group.

Conclusion

The study concludes that intracutaneous sterile water injection over sacrum and intramuscular injection of tramadol had statistically significant analgesic effect in reducing low back pain experienced by antenatal mothers during labour from a minimum of 10 minutes to maximum of 2 hours post administration. Sterile water injections are simple, easily available, cost effective have no concerns of harm to the mother or fetus and hence this technique could be of particular use in hospitals that don't have access to epidural analgesia and also for women who want to avoid medications during labour.

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