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MANAGING LABOR BACKACHE: A COMPARATIVE ANALYSIS OF STERILE WATER INJECTIONS AND DICLOFENAC

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ABSTRACT

.**Background**: Severe back pain is a common and distressing complaint during childbirth This study aimed to compare the efficacy, safety, and patient satisfaction of intradermal sterile water injections versus intramuscular diclofenac for the management of severe back .pain during the first stage of labor

Method: This prospective, comparative interventional study reviewed findings between June 2024 and December 2024 at the Department of Obstetrics and Gynaecology, Mother and Child Hospital, Pakistan Institute of Medical Sciences, Islamabad. Two cohorts of primigravida women (n=150 each) experiencing severe labor back pain (Visual Analogue Scale [VAS] score ≥ 7) were included. Group A received four intradermal sterile water injections at sacral points; Group B received a single 75 mg intramuscular injection of diclofenac sodium. The primary outcome was pain intensity, measured via VAS at baseline and at 15, 60, and 120 minutes post-intervention. Secondary outcomes included maternal .satisfaction and adverse effects

Results: Both interventions resulted in a significant reduction in back pain. The sterile water injection group experienced a more rapid onset of pain relief, with the mean VAS score decreasing from a baseline of 9.1 to 3.5 within 15 minutes. The diclofenac group showed a more gradual reduction, from 8.9 to 5.5 in the same timeframe. The analgesic effect was sustained for up to two hours in both groups. Maternal satisfaction was significantly higher in the sterile water injection group (92%) compared to the diclofenac group (75%). The only adverse effect noted was a transient, moderate sting at the injection

.site for the sterile water group
Conclusions: Both sterile water injections and intramuscular diclofenac are effective in reducing severe back pain during labor. However, sterile water injections offer a more rapid onset of action, a higher degree of patient satisfaction, and a superior safety profile as a non-pharmacological intervention. Given the potential systemic risks associated with diclofenac use in pregnancy, sterile water injections represent a preferable first-line option .for managing labor-related backache
,**KEYWORDS** Labor Pain; Back Pain; Water Injections, Sterile; Diclofenac; Analgesia .Obstetrical; Pain Management; Comparative Study; Visual Analog Scale

INTRODUCTION

.Severe low back pain during labor is a distinct and distressing entity, reported by up to one-third of laboring women ,This pain, often described as continuous and sharp between contractions, can significantly increase maternal distress negatively impact the birthing experience, and may be associated with longer labors and increased requests for pharmacological interventions.[1] Effective management of this specific pain is crucial for improving maternal satisfaction and outcomes.[2] This article aims to provide a comparative analysis of two fundamentally different interventions for managing labor backache: the targeted, non-pharmacological technique of sterile water injections and the systemic pharmacological agent, diclofenac

The use of sterile water injections for labor backache is supported by a growing body of high-quality evidence.[3] The technique involves intradermal injections of small amounts of sterile water, with its analgesic effect believed to be mediated by the gate control theory of pain.[4,13] A recent comprehensive Cochrane review (2023) concluded that sterile water injections provide significant and rapid relief from labor backache for up to two hours compared to placebo, without identified adverse effects on the mother, fetus, or labor progress.[5] Multiple other systematic reviews and clinical trials corroborate these findings, establishing it as a safe and effective option that can be readily .administered by midwives in various clinical settings

In contrast, diclofenac is a potent non-steroidal anti-inflammatory drug (NSAID) that provides effective analgesia by inhibiting prostaglandin synthesis[6]. While its efficacy in managing various acute and chronic pain conditions is well-.established, its specific role in managing backache during active labor is not well-defined in recent literature[7] Research on NSAID use in obstetrics has predominantly focused on postpartum analgesia, such as for post-episiotomy or post-caesarean pain[8]. The use of NSAIDs like diclofenac during the third trimester raises significant safety concerns, most notably the risk of premature closure of the fetal ductus arteriosus and potential adverse neonatal renal effects[9]. Consequently, major advisory bodies like the American College of Obstetricians and Gynecologists .(ACOG) recommend caution with their use in the peripartum period

.The rationale for this comparative analysis stems from the need to clarify the roles of these two disparate treatments While sterile water injections represent a specific, evidence-based intervention for labor backache, diclofenac represents a potent systemic analgesic whose application for this indication is limited by a lack of specific evidence and significant safety caveats. By directly comparing their mechanisms, efficacy, and safety profiles based on the latest literature, this article seeks to provide clear, evidence-based guidance for clinicians and inform decision-making .in the management of one of the most challenging aspects of labor pain.

METHODS

This prospective, comparative interventional study was conducted to evaluate the efficacy of two different analgesic .methods for severe back pain in labor

The study protocol received approval from the Institutional Review Board and Ethics Committee (Ref: F.1-ERB/SZABMU/1339). The research was performed in accordance with the ethical principles of the/2015/1 Declaration of Helsinki. All participants provided written informed consent after receiving a comprehensive .explanation of the study's objectives, procedures, and potential risks and benefits

The study took place at the Department of Obstetrics and Gynaecology, Mother and Child Hospital, a tertiary care facility at the Pakistan Institute of Medical Sciences, Islamabad, from June 2024 to December 2024. The study .population included primigravida women who were admitted to the labor ward

A total of 300 eligible women were enrolled using a non-probability, consecutive sampling technique and were allocated into two treatment cohorts of 150 participants each. All participants were thoroughly informed about the .purpose of the study, the procedures involved, and the potential risks and benefits associated with each treatment

The inclusion criteria for this study are primigravida women with a term pregnancy, between 37 and 41 weeks of gestation, who are in the active phase of spontaneous labor (with cervical dilatation of 4-6 cm). Participants must be

carrying a singleton fetus in a cephalic presentation and experiencing severe lower back pain, defined as a score of on a 10-point Visual Analogue Scale (VAS). Exclusion criteria include known allergies or contraindications to 7≤ diclofenac sodium or other NSAIDs, skin infections or breakdown at the proposed sacral injection sites, prior administration of any analgesia or anesthesia during the current labor, pregnancy complications such as pre-.eclampsia, fetal distress, or antepartum hemorrhage, and refusal to provide consent

Eligible participants were consecutively selected and then randomized to one of two groups. Group A (Intradermal Sterile Water) received four 0.5 mL intradermal injections of sterile water. A 25-gauge needle was used to raise a distinct bleb at four points over the sacral area, corresponding to the Michaelis rhomboid. Group B (Intramuscular Diclofenac Sodium) received a single deep intramuscular injection of 75 mg diclofenac sodium in a 3 mL solution (Dicloran®) into the ventrogluteal muscle. Data were collected by trained research officers who were not involved in patient care. The primary outcome measured was pain intensity, assessed using a 10-point Visual Analogue Scale (VAS), where 0 indicated "no pain" and 10 represented "the worst pain imaginable." VAS scores were recorded at baseline (before intervention) and at 15, 60, and 120 minutes post-intervention. Secondary outcomes included maternal satisfaction, which was assessed at 120 minutes post-intervention using a 5-point Likert scale (1=Very Dissatisfied to 5=Very Satisfied). Adverse effects were monitored and documented for two hours following the intervention, including maternal adverse effects such as nausea, vomiting, dizziness, and severe injection site pain, as .well as fetal adverse effects such as abnormal fetal heart rate patterns on cardiotocography

.Data were analyzed using SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY)

Descriptive statistics were used to summarize the data; mean ± standard deviation (SD) for continuous variables and frequencies and percentages for categorical variables. An independent samples t-test was used to compare baseline characteristics. A two-way repeated measures Analysis of Variance (ANOVA) was employed to analyze the effect of the interventions on VAS scores over time and to test for a time-group interaction. Post-hoc tests with Bonferroni correction were used for pairwise comparisons of mean VAS scores. The Chi-square ($\chi 2$) test was used to compare .proportions of maternal satisfaction and adverse effects. A p-value of < 0.05 was considered statistically significant

All p-values were two-tailed, and 95% confidence intervals (CI) were calculated for the mean difference in VAS .scores

RESULTS

A total of 300 primigravida women were enrolled and completed the study, with 150 participants in the intradermal sterile water group (Group A) and 150 in the intramuscular diclofenac group (Group B). The demographic and baseline clinical characteristics of the participants in both groups were comparable, with no statistically significant differences observed in maternal age, gestational age, or baseline VAS scores for back pain ($p > 0.05$ for all), as .detailed in Table 1

Both interventions led to a statistically significant reduction in back pain scores from baseline. The primary outcome ,analysis revealed a significant interaction effect between time and treatment group ($F(3, 296) = 18.2$, $p < 0.001$) .indicating that the pattern of pain relief over time differed significantly between the two groups

.Participants in the sterile water group (Group A) experienced a more rapid and pronounced initial reduction in pain The mean VAS score in this group dropped from a baseline of 9.1 ± 0.8 to 3.5 ± 1.2 within 15 minutes post-intervention. In contrast, the diclofenac group (Group B) showed a more gradual decline, with the mean VAS score decreasing from 8.9 ± 0.7 to 5.5 ± 1.5 in the same period. The difference in mean VAS scores between the two groups was statistically significant at 15, 60, and 120 minutes post-intervention ($p < 0.001$ at all time points). The detailed comparison of VAS scores at all measured intervals is presented in Table 2, and the trajectory of pain relief for both .groups is illustrated in Figure 1

Table 1: Baseline Demographic and Clinical Characteristics of Participants

Characteristic	Group A (Water Sterile) (n=150)	Group B (Diclofenac) (n=150)	p-value
Maternal Age (years), mean ± SD	3.1 ± 24.5	3.4 ± 24.9	0.312
Gestational Age (weeks), mean ± SD	1.2 ± 39.1	1.1 ± 39.3	0.245
Baseline VAS Score, mean ± SD	0.8 ± 9.1	0.7 ± 8.9	0.089

.SD: Standard Deviation; VAS: Visual Analogue Scale. P-values calculated using independent samples t-test

Table 2: Comparison of Visual Analogue Scale (VAS) Scores for Back Pain Over Time

Time Point	Group A (Sterile Water) Mean VAS ± SD (n=150)			Group B (Diclofenac) Mean VAS ± SD (n=150)	Mean Difference %95) (CI	*p-value
Baseline	0.8 ± 9.1	0.7 ± 8.9	(to 0.45 0.05-) 0.2	0.089		
Minutes 15	1.2 ± 3.5	1.5 ± 5.5	(to -1.6 2.4-) 2.0-	0.001>		
Minutes 60	1.4 ± 4.1	1.3 ± 5.1	(to -0.6 1.4-) 1.0-	0.001>		
120 Minutes	1.5 ± 4.8	1.2 ± 5.8	(to -0.6 1.4-) 1.0-	0.001>		

SD: Standard Deviation; CI: Confidence Interval. P-values calculated using post-hoc tests with Bonferroni correction .following repeated measures ANOVA

Figure 1: Mean Visual Analogue Scale (VAS) Scores for Back Pain Over 120 Minutes

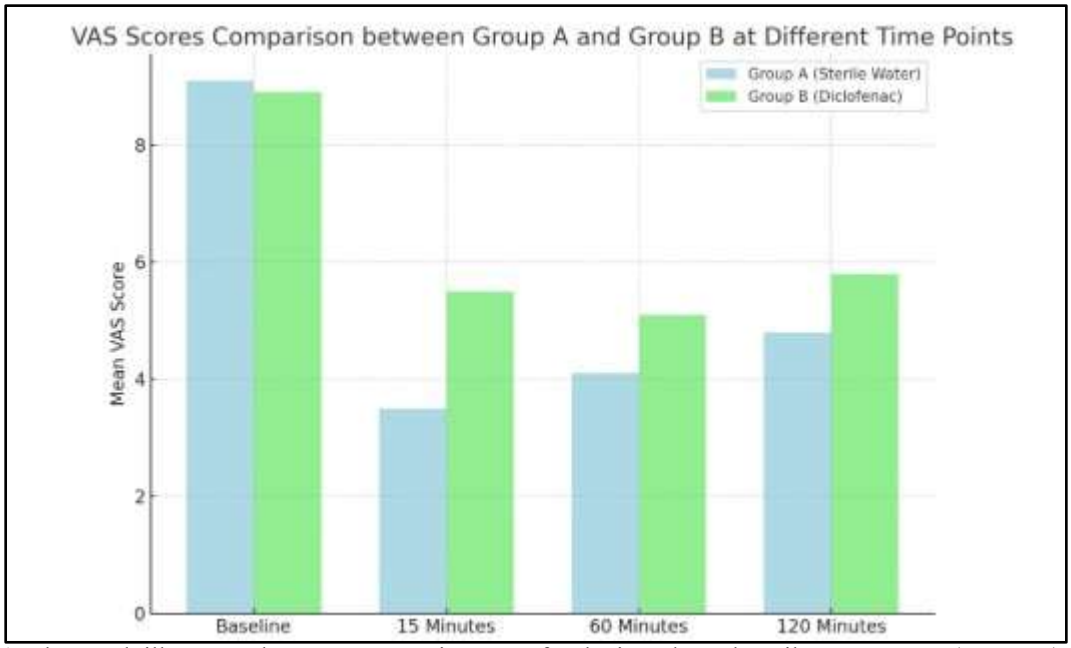


Figure 1: The graph illustrates the mean VAS pain scores for the intradermal sterile water group (Group A) and the .intramuscular diclofenac group (Group B) at baseline and at 15, 60, and 120 minutes post-intervention

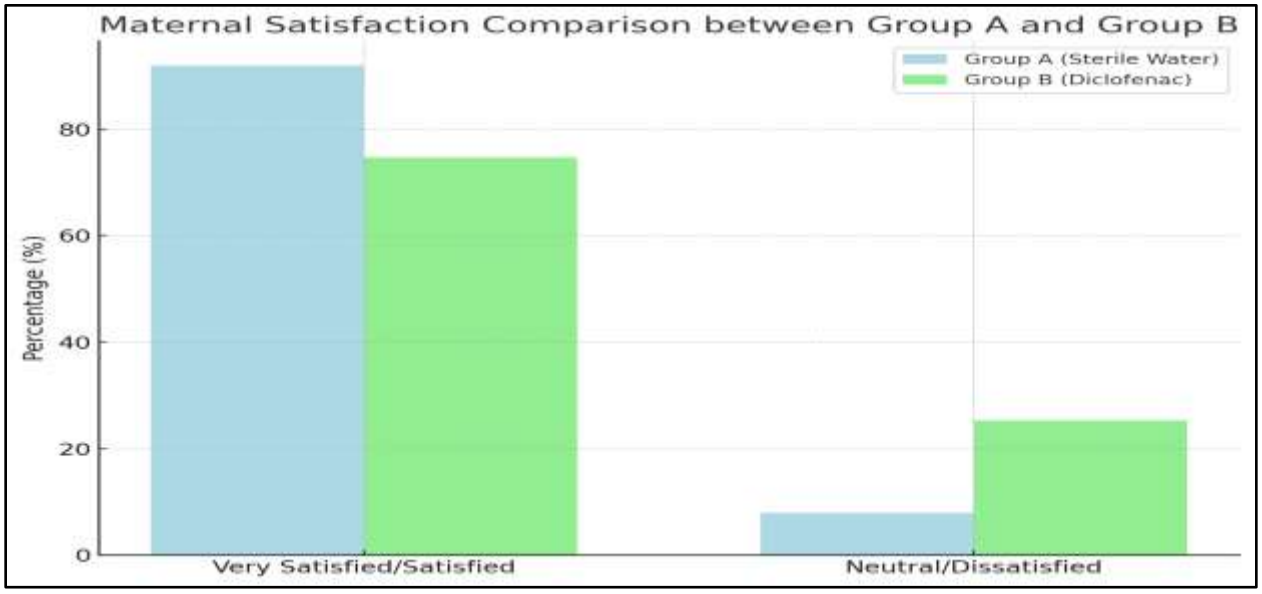
Regarding secondary outcomes, maternal satisfaction was significantly higher in the sterile water group. A total of participants (92%) in Group A reported being 'Satisfied' or 'Very Satisfied' with their pain relief, compared to 112 138 .participants (75%) in Group B ($\chi^2 = 15.4$, $p < 0.001$)

The incidence of adverse effects was low in both groups. The only notable adverse effect was a transient, moderate stinging or burning sensation at the injection site, reported by a majority of participants in the sterile water group ,immediately upon administration, which resolved within minutes. No systemic side effects such as nausea, vomiting or dizziness were reported in either group, and no adverse fetal effects were observed on cardiotocography during the .monitoring period. A summary of maternal satisfaction and adverse effects is provided in Table 3

Table 3: Comparison of Maternal Satisfaction and Adverse Effects

Outcome	(%) Group A (Sterile Water) n	(%) Group B (Diclofenac) n	p-value
Maternal Satisfaction			*0.001>
Very Satisfied/Satisfied	(92.0) 138	(74.7) 112	
Neutral/Dissatisfied	(8.0) 12	(25.3) 38	
Adverse Effects			
Injection Site Sting	(96.7) 145	(1.3) 2	*0.001>
Systemic Side Effects	(0.0) 0	(0.0) 0	N/A

p-value calculated using Chi-square (χ^2) test



.Figure 2:The bar graph compares maternal satisfaction between Group A (Sterile Water) and Group B (Diclofenac) Group A showed a higher percentage of "Very Satisfied/Satisfied" (92%) compared to Group B (74.7%). Group B .had a higher percentage of "Neutral/Dissatisfied" (25.3%) than Group A (8%)

DISCUSSION

This study demonstrates that both intradermal sterile water injections and intramuscular diclofenac are effective in reducing severe back pain during the active phase of labor. The principal finding, however, is the marked superiority of sterile water injections in providing rapid, significant pain relief and achieving higher maternal satisfaction. This .highlights a potent, non-pharmacological intervention that can be a valuable tool in labor management

The rapid onset of analgesia in the sterile water group, with a mean VAS score reduction of over 5 points within 15 ,minutes, is a key finding. This effect is consistent with the "gate control theory of pain," which posits that a strong localized sensory stimulus (the intense sting from the hypotonic water) can block the transmission of visceral pain signals from the sacral nerves at the spinal cord level [10]. The effect is also attributed to the release of endogenous opioids (endorphins) in response to the intense local stimulation. In contrast, the slower, more modest pain relief from diclofenac sodium is expected, as it relies on systemic absorption and subsequent inhibition of prostaglandin .synthesis, a process that inherently takes longer to reach therapeutic effect [11]

A crucial observation is the significantly higher maternal satisfaction in the sterile water group (92%) compared to ,the diclofenac group (75%), despite the universally reported transient sting. This suggests that for laboring women the quality and immediacy of profound pain relief far outweigh the brief discomfort of the injection. This finding is echoed in other studies, which report high satisfaction rates with sterile water injections and emphasize that when .properly counselled, most women find the temporary sting acceptable in exchange for hours of back pain relief [12]
The prospective, comparative design of this study is a key strength, providing a direct comparison between a non-pharmacological and a pharmacological intervention in a real-world clinical setting. The use of standardized .procedures and clear, validated outcome measures (VAS) adds to the robustness of the findings
.However, the study has several limitations that must be acknowledged. The primary limitation is the lack of blinding The distinct stinging sensation of sterile water and the different injection sites and techniques made it impossible to blind participants or clinicians, potentially introducing performance and detection bias.Furthermore, the absence of a true placebo group (e.g., isotonic saline injections) makes it difficult to fully distinguish the physiological effects from the powerful placebo effect often seen in pain studies. The short, two-hour follow-up period also limits our .understanding of the total duration of the analgesic effect for both interventions
Despite these limitations, the findings have significant clinical implications. Intradermal sterile water injection is an inexpensive, simple-to-administer technique that does not require specialized anesthetic personnel or continuous monitoring. It presents a highly effective first-line option for managing severe labor back pain, particularly in low-resource settings where access to epidural analgesia is limited. Its high satisfaction rate and lack of systemic side .effects make it an attractive alternative to systemic opioids and NSAIDs
Future research should aim to address the limitations of this study. A large-scale, three-arm randomized controlled trial (RCT) comparing sterile water, a placebo (isotonic saline), and diclofenac would provide more definitive evidence. Such a study should incorporate blinding of the outcome assessors, if not the participants. Further research ,could also explore the impact of these interventions on labor progression, mode of delivery, and neonatal outcomes .as well as investigate the optimal timing and number of injections for sustained pain relief throughout labor

Conclusion

conclusion, this study provides strong evidence that intradermal sterile water injections are a highly effective, rapid and satisfactory method for relieving severe back pain in labor, outperforming intramuscular diclofenac in onset of action and patient satisfaction. While the transient pain of injection is a factor, it is well-tolerated and offset by the profound analgesia achieved. Sterile water injections represent a valuable, accessible, and safe tool in the .armamentarium of labor analgesia

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