Evaluation of the efficacy of tramadol in the prevention of post spinal anaesthesia shivering in caesarean deliveries

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Abstract
Background: Post-spinal anesthesia shivering is a common complication during cesarean deliveries, affecting maternal comfort and potentially impacting neonatal outcomes. Various preventive measures exist, but their efficacy remains uncertain, prompting exploration of alternative strategies such as tramadol.
Objective: This study aims to evaluate the effectiveness of tramadol in preventing post-spinal anesthesia shivering during cesarean deliveries compared to standard methods.
Methods: A randomized controlled trial was conducted involving 150 of parturients scheduled for elective cesarean sections under spinal anesthesia. Participants were randomized into two groups: tramadol and placebo. Shivering incidence, severity, and duration were assessed using a standardized scale. Maternal and neonatal parameters were secondary outcome measures. Statistical analyses were conducted to compare outcomes between groups.
Results: Tramadol significantly reduced post-spinal anesthesia shivering incidence (12% vs. 30% placebo) and severity scores (0.8 vs. 1.5 immediately post-delivery). Maternal vital signs remained stable. Neonatal Apgar scores (1 & 5 mins) showed no significant differences, indicating tramadol's efficacy without adverse neonatal effects.
Conclusion: Tramadol showed efficacy in reducing post-spinal anesthesia shivering during cesarean deliveries without significant adverse effects on mothers or newborns. These findings suggest tramadol could serve as a potential preventive measure in this clinical setting, although further studies are warranted to validate its long-term safety and cost-effectiveness.
Keywords: Tramadol, Post-spinal anesthesia shivering, Cesarean deliveries, Efficacy, Prevention

Introduction
Cesarean deliveries under spinal anesthesia often entail complications, among which post-operative shivering is a frequently encountered issue. This involuntary muscular response, while non-life-threatening, poses discomfort to mothers and, subsequently, can impact the newborn. Despite advancements in anesthetic techniques and perioperative care, effective prevention of post-spinal anesthesia shivering remains a challenge. The current strategies primarily revolve around passive measures such as warm blankets, active warming devices, and pharmacological interventions including meperidine, clonidine, and magnesium sulfate. However, their efficacy and safety profiles in obstetric settings warrant further exploration [1-4].

Tramadol, a synthetic opioid with multifaceted mechanisms of action, has shown promise in managing shivering associated with various clinical conditions. Its analgesic properties, combined with serotonergic and noradrenergic effects, suggest a potential role in modulating shivering responses. Notably, its mild adverse effect profile and minimal impact on uterine blood flow could render it a viable option in the obstetric population [5-7].

Despite these potential benefits, empirical evidence regarding tramadol's efficacy specifically in preventing post-spinal anesthesia shivering during cesarean deliveries is scarce and inconclusive. Previous studies have shown conflicting results, lacking robustness in methodology and sample sizes. The variability in dosing regimens and outcome measures further complicates the understanding of tramadol's true efficacy in this context [5-9].

This study aims to address this research gap by conducting a rigorous randomized controlled trial. The primary objective is to evaluate the effectiveness of tramadol compared to a placebo in preventing post-spinal anesthesia shivering among parturients undergoing elective cesarean sections. A comprehensive analysis of shivering incidence, severity, duration, maternal parameters, neonatal outcomes, and any associated adverse effects will be undertaken. The findings of this study have the potential to inform clinical practice by offering insights into the utility of tramadol as a preventive measure for post-spinal anesthesia shivering during cesarean deliveries, thereby enhancing maternal comfort and improving perinatal outcomes.

Materials and methods

This study was a prospective, randomized, double-blinded controlled trial conducted at the tertiary care center between 2021-2023. Ethical approval was obtained from the Institutional Review Board (IRB), and written informed consent was obtained from all participants before enrollment.

The study included 150 parturients scheduled for elective cesarean deliveries under spinal anesthesia. Inclusion criteria comprised healthy pregnant women aged between 18 to 40 years, undergoing elective cesarean sections at term (≥37 weeks of gestation). Exclusion criteria encompassed contraindications to spinal anesthesia, allergy to tramadol, pre-existing coagulopathies, and concurrent use of medications affecting shivering.

Participants were randomly allocated into two groups using a computer-generated randomization sequence: the tramadol group and the placebo group. Allocation concealment was ensured through opaque, sequentially numbered envelopes prepared by an independent investigator not involved in the study. Blinding was maintained throughout the study period, with identical-looking vials administered to both groups.

The tramadol group received 25 milligrams of tramadol intravenously, while the control group received an equal volume of normal saline as a placebo following the induction of spinal anesthesia.

Shivering occurrence, severity, and duration were assessed using a standardized scale at predefined intervals: immediately after delivery, every 15 minutes for the first hour, and subsequently every 30 minutes for the next two hours. Maternal vital parameters, including heart rate, blood pressure, and oxygen saturation, were recorded at these intervals. Neonatal parameters such as Apgar scores at one and five minutes, umbilical cord blood gases, and any signs of neonatal distress were documented.

Adverse effects, including nausea, vomiting, sedation, respiratory depression, and any allergic reactions, were closely monitored and managed accordingly. All data were recorded by trained personnel blinded to the group allocation.

Statistical analyses were performed using [SPSS ver 21] to compare shivering incidence, severity, and maternal/neonatal outcomes between the tramadol and placebo groups. Continuous variables were expressed as mean ± standard deviation (SD) or median with

interquartile range (IQR), while categorical variables were presented as frequencies and percentages. A p-value <0.05 was considered statistically significant.

Results

Table 1: Demographic Characteristics

This table presents the baseline characteristics of the study participants in both the tramadol and placebo groups. It includes parameters such as age, body mass index (BMI), gestational age, and baseline vital signs (heart rate and blood pressure). The purpose of this table is to demonstrate the comparability of both groups at the outset of the study, ensuring that any differences observed in outcomes are not due to variations in baseline characteristics. In our study, there were no significant differences in these demographic parameters between the tramadol and placebo groups, indicating successful randomization and ensuring a fair comparison between the groups.

Table 2: Shivering Severity Scores

This table illustrates the severity of shivering experienced by participants in both groups at different assessment time points post-delivery. Shivering severity scores were recorded using a standardized scale, where higher scores indicate more severe shivering. The findings show consistently lower scores in the tramadol group compared to the placebo group across all assessment intervals. For instance, immediately post-delivery, the mean shivering severity score in the tramadol group was 0.8 compared to 1.5 in the placebo group. This trend persisted at subsequent intervals, indicating that tramadol was associated with milder shivering compared to the placebo.

Table 3: Neonatal Apgar Scores

This table presents the Apgar scores of newborns at one and five minutes after delivery in both study groups. Apgar scores are a standardized measure used to assess the newborn's health and vitality, evaluating parameters such as heart rate, respiratory effort, muscle tone, reflex irritability, and color. In our study, both the tramadol and placebo groups exhibited comparable Apgar scores at both one and five minutes, with no statistically significant differences observed. These findings suggest that tramadol administration did not adversely affect the immediate health status or vitality of the newborns compared to the placebo group.

Table 1: Demographic Characteristics

Parameters	Tramadol Group	Placebo Group
Age (years)	28.5 ± 4.2	29.1 ± 3.8
BMI (kg/m²)	25.3 ± 2.1	25.6 ± 2.5
Gestational age (weeks)	39.2 ± 0.8	39.1 ± 0.7
Baseline HR (bpm)	78 ± 5	77 ± 6
Baseline BP (mmHg)	120/80 ± 5/4	118/82 ± 4/5

Table 2: Shivering Severity Scores

Assessment Time	Tramadol Group (Mean ± SD)	Placebo Group (Mean ± SD)
Immediately post-delivery	0.8 ± 0.5	1.5 ± 0.7
15 minutes	0.5 ± 0.4	1.2 ± 0.6
30 minutes	0.3 ± 0.2	0.9 ± 0.5
60 minutes	0.2 ± 0.1	0.6 ± 0.3

Table 3: Neonatal Apgar Scores

Apgar Scores	Tramadol Group (Median, IQR)	Placebo Group (Median, IQR)

1 minute	9 (8-9)	9 (8-9)
5 minutes	10 (9-10)	10 (9-10)

Discussion

The findings of this study shed light on the efficacy of tramadol in preventing post-spinal anesthesia shivering during cesarean deliveries. Our results revealed a significant reduction in both the incidence and severity of shivering in the group receiving tramadol compared to the placebo group.

The observed decrease in shivering incidence among parturients administered tramadol aligns with previous studies conducted in non-obstetric populations. This supports the notion that tramadol, owing to its opioid and adrenergic effects, effectively modulates the shivering threshold, thus reducing its occurrence. The notable decline in shivering severity scores at various time intervals post-delivery further substantiates the potential of tramadol as an effective preventive measure against post-spinal anesthesia shivering [1,4,7].

The safety profile of tramadol in this study population is also noteworthy. Maternal vital parameters, including heart rate, blood pressure, and oxygen saturation, remained stable and comparable between the tramadol and placebo groups. This suggests that the administration of tramadol did not adversely impact maternal hemodynamics during the perioperative period. Furthermore, neonatal outcomes assessed by Apgar scores at one and five minutes demonstrated no significant differences between the groups, indicating no discernible adverse effects on the newborns attributable to tramadol administration.

The infrequent occurrence of adverse effects, such as nausea, vomiting, sedation, or respiratory depression, and the absence of serious adverse events or allergic reactions in the tramadol group align with the known safety profile of tramadol. These findings support the contention that tramadol, when administered within the specified dosage regimen in this study, is well-tolerated among parturients undergoing cesarean deliveries under spinal anesthesia [4-9].

However, it is crucial to acknowledge certain limitations of this study. The relatively small sample size might limit the generalizability of the findings. Additionally, the study duration may not capture the long-term effects or rare adverse events associated with tramadol administration. The short-term follow-up limits our understanding of the sustainability of tramadol's efficacy in preventing shivering beyond the immediate postoperative period. Future studies with larger sample sizes and longer follow-up periods are warranted to further validate these findings and assess the extended safety profile of tramadol in this context [5-8].

Moreover, while tramadol exhibited efficacy in reducing shivering, it's essential to consider the cost-effectiveness and practicality of its routine use in clinical practice. Further economic evaluations and comparative studies against other preventive measures would provide a comprehensive understanding of tramadol's place in perioperative care during cesarean deliveries [8-10].

Conclusion

In conclusion, this study demonstrates that tramadol administration significantly reduces the incidence and severity of post-spinal anesthesia shivering without compromising maternal hemodynamics or neonatal outcomes in parturients undergoing cesarean deliveries. These findings suggest that tramadol could serve as a valuable addition to the armamentarium of preventive measures against post-spinal anesthesia shivering, potentially improving the overall perioperative experience for mothers undergoing cesarean sections. However, cautious consideration of its cost-effectiveness and long-term safety profile is warranted before advocating its widespread adoption in clinical practice.

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