

Tramadol versus Bupivacaine for Wound Infiltration in Cesarean Section: A Randomized Trial Demonstrating Superior Analgesia, Prolonged Duration and Opioid-Sparing Effects

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SUMMARY

Background: Effective pain management following a Cesarean Section (CS) is vital for maternal recovery and early newborn bonding. This prospective cohort study aimed to compare the postoperative analgesic efficacy, time to first rescue analgesia request, and total 24-hour analgesic consumption between wound infiltrations with bupivacaine versus tramadol.

Patients and methods: The study included 60 healthy women aged 18–40 years undergoing elective CS under spinal anesthesia. Participants were randomly assigned to Group A (n=30), receiving intrathecal 2mg/kg tramadol, or Group B (n=30), receiving 0.25% bupivacaine. Primary outcomes included pain intensity, assessed using the Visual Analog Scale (VAS), at 1, 6, 12, and 24 hours postoperatively. Secondary outcomes were time to first rescue analgesia request, total diclofenac consumption, and incidence of adverse effects.

Results: Baseline characteristics were similar between groups. While early VAS scores at 1 and 6 hours showed no significant difference ($P > 0.05$), the tramadol group demonstrated a statistically significant reduction in pain at 12 and 24 hours compared to bupivacaine ($P < 0.001$). Time to first rescue analgesia was markedly prolonged in the tramadol group (6.42 \pm 1.52 hours) compared to bupivacaine (2.75 \pm 0.58 hours; $P < 0.001$). Furthermore, cumulative 24-hour diclofenac consumption was significantly lower in the tramadol group. No significant differences in the incidence of postoperative nausea or vomiting were observed ($P > 0.05$).

Conclusion: Wound infiltration with tramadol alone provides superior, prolonged analgesia compared to bupivacaine. It effectively delays the need for rescue analgesia and lowers VAS scores in the later postoperative period without increasing side effects.

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INTRODUCTION

A Cesarean Section (CS) is regarded as a major surgical procedure that is frequently performed today. Although CS has benefits like decreasing the risk of birth injuries such as asphyxia, shoulder dystocia, and fractures, it may also cause significant postoperative pain. Proper pain management after a CS is crucial for faster recovery, shorter hospital stay, and early bonding between mother and baby. Insufficient pain control can lead to longer hospitalization and additional health complications. Effective pain relief strategies are therefore essential to improve outcomes and ensure the well-being of the mother and newborn [1-2].

"Local infiltration analgesia" refers to using a "large amount of diluted, long-lasting local anesthetic" in tissue structures to relieve pain. Local anesthetic wound infiltration is primarily used for minor surgeries, such as laceration repair and skin surgery, and for the treatment of pain after Cesarean Section. It can also be used as a supplement to general anesthesia for various surgical procedures [3-4].

Local anesthesia, particularly infiltration, can be effectively combined with general or spinal anesthesia. This combination allows for reduced dosages of analgesic and anesthetic drugs during surgical procedures, which in turn can lead to improved postoperative pain management. When administered as an infiltration, local anesthesia produces reversible numbness confined to a specific area of the body, effectively preventing the sensation of pain without affecting vital physiological functions. Importantly, local anesthetic drugs typically do not impair essential bodily functions, and respiratory depression—a common concern with some anesthetic agents—is rarely reported when these drugs are used for wound infiltration. An example of a drug with both local anesthetic and analgesic properties is Tramadol, a selective μ -receptor agonist. Tramadol exerts its effect on peripheral nerves and inhibits pain transmission through multiple mechanisms, including opioid and non-opioid pathways. It inhibits the reuptake of norepinephrine and serotonin by displacing stored serotonin from nerve endings, mediated through α_2 -agonistic and serotonergic activity. Bupivacaine, another local anesthetic, works by blocking nerve impulse generation and conduction, making it useful for infiltrating surgical incisions [5].

One study demonstrated that subcutaneous infiltration of pethidine or tramadol at the cesarean incision site resulted in superior post-operative pain relief and significantly reduced opioid consumption compared to bupivacaine or placebo. Patients in the pethidine and tramadol groups reported lower pain intensity scores and required less supplemental analgesia, establishing these agents as effective, safe, and inexpensive options for improving pain management following spinal anesthesia for cesarean delivery [5].

This study aimed to compare the analgesic efficacy of bupivacaine wound infiltration versus tramadol postoperative pain relief, time to first rescue analgesia, and total analgesic consumption within 24 hours following elective cesarean section under spinal anesthesia.

MATERIALS AND METHODS

Ethical approval was first obtained from the institutional review board, and all participants provided written informed consent in line with ethical standards. A total of 60 antenatal women aged 18–40 years with a body mass index (BMI) of 18.5–40 kg/m² scheduled for elective cesarean delivery under spinal anesthesia were included in the study. Inclusion criteria were deliberately selected to create a homogeneous and low-risk sample: all participants were healthy antenatal mothers between the ages of 18 and 40 years with a BMI ranging from 18.5 to 40 kg/m², and all were scheduled for elective cesarean section under spinal anesthesia. This helped minimize confounding variables and maximize the internal validity of pain and recovery-related outcomes.

Exclusion criteria were applied to enhance patient safety and reduce potential bias. These exclusions comprised patients with known allergies to the study medications; pre-eclampsia or eclampsia; gestational diabetes; significant cardiopulmonary, renal, or hepatic impairment; immunocompromised status; seropositivity for infectious diseases; coagulation disorders; skin infection at the incision site; and morbid obesity (BMI > 40 kg/m²). Emergency cesarean deliveries and were also excluded.

Procedure: Under standardized spinal anesthesia, cesarean sections were performed. At skin closure, patients received intra-incisional infiltration with 20 ml of study solution. Group A (n=30) received tramadol diluted in normal saline, while Group B (n=30) received 0.25% bupivacaine at 0.7 mg/kg, similarly diluted to 20 ml with normal saline.

Primary outcome: Pain intensity was assessed using a 100-mm Visual Analog Scale (VAS) at arrival in recovery and at 60 minutes, and 2, 6, 12, and 24 hours postoperatively. Rescue analgesia intramuscular diclofenac 75 mg was administered as needed based on predetermined VAS thresholds.

Secondary outcomes included time to first rescue analgesia request, total analgesic consumption over 24 hours, incidence of adverse effects (nausea, vomiting, shivering), changes in mean arterial pressure, and patient-reported quality of pain relief at 24 hours, using a 4-point scale (poor to excellent).

Sample size justification

Based on data from Jayashree V, et al. [5], a power analysis was conducted to determine the required sample size. Using the 12-hour VAS scores (Group A: Mean=1.90, SD=0.92; Group B: Mean=1.17, SD=0.74), an alpha of 0.05, power of 80%, and a two-tailed t-test, the calculated effect size (Cohen's d=0.87) indicated that approximately 22 subjects per group are a sample size of 24 patients in each group was determined to provide 95% power for independent samples T-test at the level of 5% significance and Confidence interval 95% using G. Power 3.19.2 software.

Statistical analysis

The data is displayed as mean, Standard Deviation (SD), median, and range values. When comparing more than two means for parametric data, an Independent-samples t-test of significance was used when comparing between two means, and the Chi-square (x²) test of significance was employed. The significance level is set at $P \leq 0.05$. The statistical analysis was conducted using IBM SPSS Statistics for Windows, Version 23.0, by IBM Corp. located in Armonk, NY.

RESULTS

The baseline characteristics, including age, BMI, and gestational age, were well-matched between the bupivacaine and tramadol groups. No statistically significant differences were observed ($p > 0.05$ for all comparisons), indicating that both groups were demographically and clinically similar at the start of the study (Table 1).

There was no significant difference in pain scores between the bupivacaine and tramadol groups at the 1-hour and 6-hour postoperative assessments. However, a statistically significant reduction in pain was observed in the tramadol group compared to the bupivacaine group at both the 12-hour and 24-hour time points, demonstrating the superior and prolonged analgesic efficacy of tramadol wound infiltration in the later postoperative period. (Table 2 and Figure 1).

The time to first request for rescue analgesia was highly significantly prolonged in the tramadol group compared to the bupivacaine group ($p < 0.001$). This demonstrates that wound infiltration with tramadol provides a substantially longer duration of effective postoperative analgesia, significantly delaying the need for additional pain medication and highlighting its superior sustained analgesic effect, as shown in Table 3 and Figure 2.

Diclofenac consumption was significantly reduced in the tramadol group compared to the bupivacaine group over the 24-hour postoperative period. While no significant difference was observed in the early hours, a highly significant reduction in analgesic requirement was evident at both 12 and 24 hours, demonstrating the sustained and effective opioid-sparing effect of tramadol wound infiltration (Table 4 and Figure 3).

The cumulative diclofenac consumption over 24 hours was highly significantly lower in the tramadol group. A substantial proportion of tramadol recipients required only one or two analgesic doses, whereas nearly all

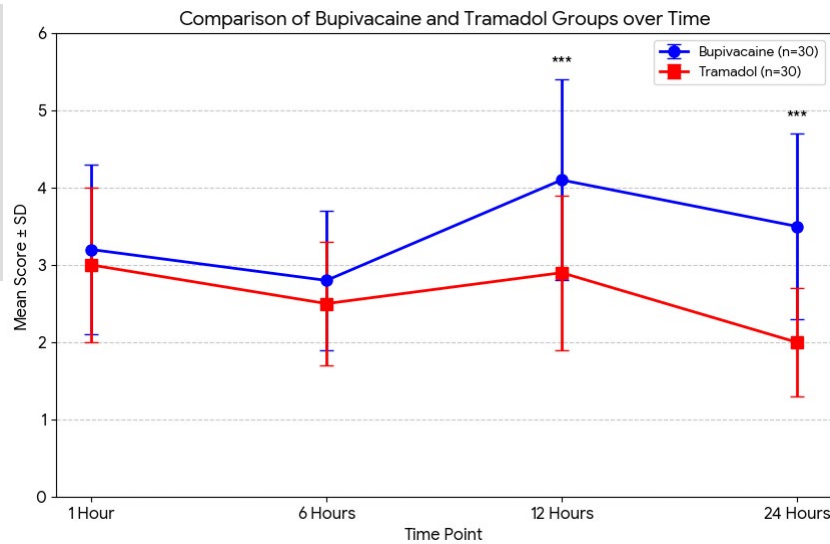
Tab. 1. Patients' Baseline Characteristics.

Characteristic	Bupivacaine Group (n=30)	Tramadol Group (n=30)	Test value	p-value	Sig.
Age (years)					
Mean ± SD	30.21 ± 3.98	30.58 ± 4.12	-0.351	0.727	NS
Range	24-38	25-38			
BMI (kg/m²)					
Mean ± SD	27.85 ± 3.25	28.20 ± 3.41	-0.406	0.686	NS
Range	22-33	23-33			
Gestational age (weeks)					
Mean ± SD	39.71 ± 1.48	39.62 ± 1.55	0.237	0.813	NS
Range	37-42	37-42			

Tab. 2. Postoperative Visual Analog Scale (VAS) Scores.

Time Point	Bupivacaine Group (n=30) Mean ± SD	Tramadol Group (n=30) Mean ± SD	t-value	p-value	Sig.
1 Hour	3.2 ± 1.1	3.0 ± 1.0	0.759	0.451	NS
6 Hours	2.8 ± 0.9	2.5 ± 0.8	1.362	0.178	NS
12 Hours	4.1 ± 1.3	2.9 ± 1.0	4.112	<0.001	S
24 Hours	3.5 ± 1.2	2.0 ± 0.7	5.873	<0.001	S

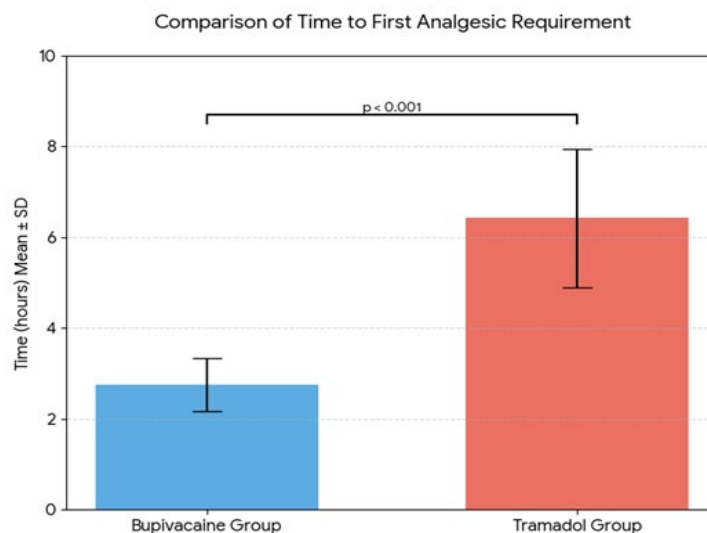
Fig. 1. This line graph compares mean scores between Bupivacaine and Tramadol groups over 24 hours. While initial results are similar, Tramadol shows significantly lower scores at 12 and 24 hours (p < 0.001).



Tab. 3. Time to First Request for Analgesia.

Parameter	Bupivacaine Group (n=30)	Tramadol Group (n=30)	t-value	p-value	Sig.
Time (hours), Mean ± SD	2.75 ± 0.58	6.42 ± 1.52	-12.741	<0.001	HS
Range	1.5 - 4.0	3.0 - 9.5			

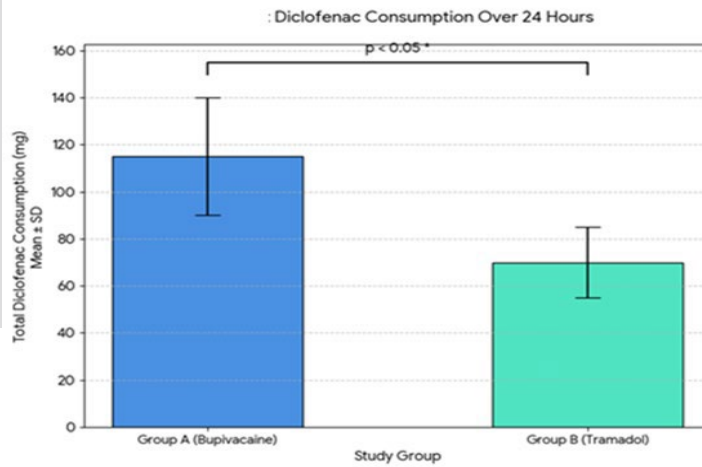
Fig. 2. This bar chart illustrates a highly significant difference in time to first analgesic requirement, showing the Tramadol group (6.42 hours) nearly tripled the Bupivacaine group's duration (2.75 hours) (p < 0.001).



Tab. 4. Diclofenac Consumption Over 24 Hours.

Time Point	Bupivacaine Group (n=30) n (%)	Tramadol Group (n=30) n (%)	χ^2 -value	p-value	Sig.
At 6 h	4 (13.3%)	6 (20.0%)	0.476	0.490	NS
At 12 h	28 (93.3%)	17 (56.7%)	11.250	0.001	S
At 24 h	29 (96.7%)	14 (46.7%)	18.279	<0.001	HS

Fig. 3. This bar chart illustrates total diclofenac consumption over 24 hours, showing a significant reduction in the Tramadol group compared to Bupivacaine alone, indicating superior opioid-sparing effects and improved analgesic efficacy ($p < 0.001$).



Tab. 5. Cumulative 24-Hour Diclofenac Consumption by Dose Frequency.

Number of Doses	Bupivacaine Group (n=30) n (%)	Tramadol Group (n=30) n (%)	χ^2 -value	p-value
Single dose	0 (0.0%)	11 (36.7%)	35.714	<0.001
Two doses	4 (13.3%)	16 (53.3%)		
Three doses	26 (86.7%)	3 (10.0%)		

Fig. 4. This bar chart compares rescue analgesia frequency, showing the Tramadol group required significantly fewer doses than the Bupivacaine group, highlighting its superior efficacy in reducing postoperative supplementary analgesic requirements ($p < 0.001$).

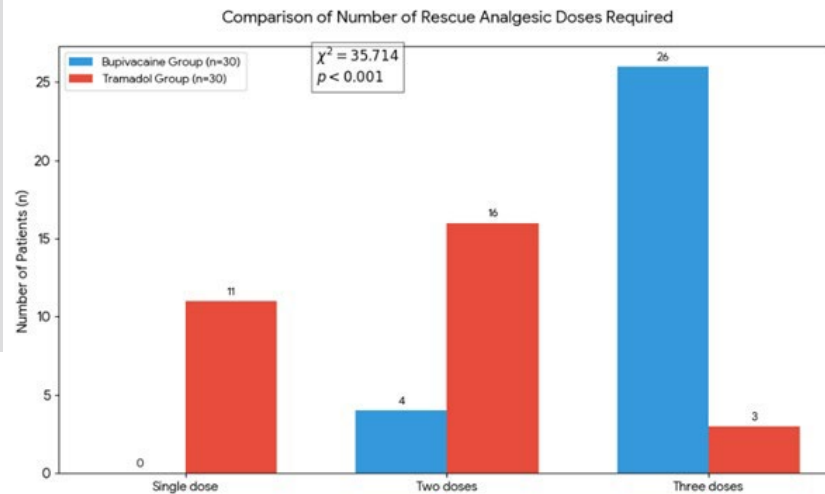
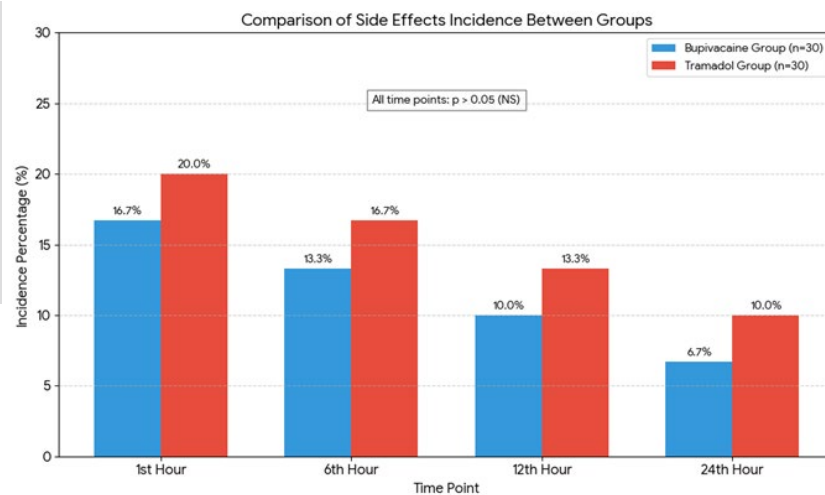


Fig. 5. This bar chart compares side effect incidence across 24 hours. While the Tramadol group shows slightly higher percentages, the differences are not statistically significant at any time point ($p > 0.05$).



bupivacaine recipients required three doses. This demonstrates a powerful opioid-sparing effect and superior sustained analgesia with tramadol wound infiltration (Table 5 and Figure 4).

No significant difference in the incidence of postoperative nausea and vomiting (PONV) was observed between the bupivacaine and tramadol groups at any assessed time point (1, 6, 12, or 24 hours). The comparable and low rates of PONV in both groups indicate that wound infiltration with tramadol does not significantly increase this common opioid-related side effect in the postoperative period (Table 6 and Figure 5).

DISCUSSION

Our results and their interpretation

The baseline demographic and clinical characteristics were well-matched between the two groups, with no statistically significant differences in age, BMI, or gestational age ($p > 0.05$). This confirms that both cohorts were equivalent at baseline, minimizing the potential for confounding variables in the analysis of postoperative outcomes.

Pain scores were comparable between groups in the immediate postoperative period (1 and 6 hours), indicating similar early analgesic efficacy. However, tramadol demonstrated significantly superior pain control at both 12 and 24 hours, with substantially lower VAS scores ($p < 0.001$). This reveals tramadol's enhanced long-lasting analgesic effect, providing sustained relief and highlighting its clinical advantage for extended postoperative pain management. Tramadol is a multimodal analgesic with central opioid and monoaminergic effects, complemented by peripheral local anesthetic properties via sodium channel blockade. This dual mechanism supports its use in wound infiltration, offering both immediate and prolonged pain relief. Our findings align with this pharmacological profile, demonstrating tramadol's superior and sustained analgesic efficacy compared with bupivacaine in cesarean section patients, thereby validating its role as an effective local infiltrative agent.

The time to first analgesia request was significantly longer in the tramadol group compared to the bupivacaine group ($p < 0.001$). This delay highlights tramadol's superior, sustained analgesic effect, reducing early postoperative opioid needs and extending pain relief after cesarean section. Its dual mechanism—as both a local anesthetic and opioid receptor agonist [6] provides a longer-lasting effect than traditional anesthetics like bupivacaine. When used for wound infiltration, this depot effect at the surgical site effectively bridges the gap between surgery and oral pain management.

Our results showed that tramadol wound infiltration produced a powerful and time-dependent effect. While early diclofenac use was comparable between groups, a highly significant reduction emerged in the tramadol group by 12 hours and intensified at 24 hours. Crucially, most bupivacaine patients required three analgesic doses, whereas over a third of tramadol recipients required only a single dose. This profound reduction in rescue medication underscores tramadol's superior, sustained analgesic efficacy, significantly minimizing systemic analgesic

exposure and enhancing the quality of postoperative recovery. The findings indicate that tramadol wound infiltration minimizes systemic analgesic exposure and improves the overall quality of postoperative recovery

Our results demonstrated a consistently low and comparable incidence of postoperative nausea and vomiting between the bupivacaine and tramadol groups at all measured times. No significant differences were found at 1, 6, 12, or 24 hours post-surgery. This suggests that tramadol used in local wound infiltration does not increase the risk of opioid-related nausea, supporting its safety in regional analgesia. The study indicates that regional analgesic benefits can be achieved without the emetogenic side effects typical of this drug class. Therefore, tramadol is a safe alternative or adjunct for surgical site infiltration, maintaining hemodynamic stability and good gastrointestinal tolerability.

Comparison of our results to similar studies

Compared to Taksakande K, et al., [7] both studies used spinal anesthesia, 60 patients, and compared bupivacaine versus tramadol for wound infiltration. Taksakande K, et al. combined tramadol (2 mg/kg) with bupivacaine, while our study compared tramadol (2 mg/kg) alone to bupivacaine alone. Both found tramadol superior: Taksakande K, et al. reported longer times to first analgesia request (386 vs. 193 minutes, $p < 0.0002$) and lower diclofenac use ($p < 0.0068$), consistent with our findings of delayed rescue analgesia and opioid-sparing effects. Safety profiles were similar across studies, with no increase in adverse events. The main difference was combination therapy versus monotherapy, but results support tramadol's role in postoperative pain management, whether used alone or with other agents. These consistent findings reinforce tramadol's value in optimizing post-cesarean analgesia protocols.

Our study and Sahmeddini MA, et al. [6] both examined wound infiltration for post-cesarean analgesia, but differing methodologies exist. Sahmeddini used general anesthesia and a higher tramadol dose (2 mg/kg), whereas we employed spinal anesthesia with a fixed 40 mg dose. Both showed tramadol's superior long-term analgesia, with lower VAS scores at 16–24 hours (their study) and 12–24 hours (ours), without increased nausea, vomiting, or respiratory depression. This confirms tramadol's safety and efficacy across protocols. Notably, our results indicated earlier analgesic superiority starting at 12 hours, possibly due to the type of anesthesia or dosing, suggesting that spinal anesthesia may enhance tramadol's effects. Both studies support tramadol as an effective local analgesic with a favorable side effect profile.

Compared to Demiraran Y, et al. [8], both studies assessed wound infiltration for post-cesarean analgesia, but with key differences. Demiraran Y, et al. used general anesthesia and compared tramadol (1.5 mg/kg) and levobupivacaine (0.25%) against saline, whereas our study employed spinal anesthesia and directly compared body weight dependent dose tramadol (2 mg/kg) with bupivacaine (0.25%), without a placebo. Both studies showed tramadol's efficacy in reducing postoperative pain; Demiraran Y, et al. reported lower 24-hour tramadol use, which aligns with our reduced rescue diclofenac consumption. However, they saw no difference in

diclofenac requirements among groups, whereas we observed significant reductions with tramadol—possibly due to differences in anesthetic potency or dosing. Both studies found no increase in adverse effects like nausea, confirming tramadol's safety. Despite variations in methodology, the consistent analgesic benefits of tramadol highlight its reliability and effectiveness in post-cesarean pain management across diverse clinical settings.

Compared with Behdad S, et al. [9], both studies evaluated wound infiltration with tramadol versus bupivacaine for post-cesarean analgesia, confirming tramadol's longer duration. Behdad used a lower volume (10 mL) and a higher concentration (0.5%) of bupivacaine, with a fixed 50 mg dose of tramadol, whereas our study employed 20 mL of 0.25% bupivacaine and 2 mg/kg of tramadol. Both observed no significant difference in early VAS scores (1–2 hours), but Behdad reported lower pain scores at 6 hours, aligning with our findings at 12 and 24 hours. Behdad found no significant reduction in total analgesic consumption, unlike our significant decrease in diclofenac use, possibly due to differences in rescue protocols or dosing. Both studies showed no significant side effects, supporting tramadol's safety. Collectively, evidence highlights tramadol's extended analgesic effect, offering a valuable alternative to bupivacaine for prolonged post-cesarean pain relief [10]

In comparing our results with the study by Jayashree V, et al. [5], both share nearly identical methodologies: spinal anesthesia, 60 patients, tramadol versus weight-based bupivacaine (0.25%, 0.7 mg/kg), wound infiltration, and assessment of VAS scores and rescue analgesia; However, the reported outcomes diverge significantly. Jayashree V, et al. concluded that bupivacaine was more effective, with lower pain scores at 6, 12, and 24 hours and higher systolic BP, whereas tramadol was associated with more nausea and bupivacaine with more rigors. In contrast, our study demonstrated superior analgesia with tramadol, showing significantly lower VAS scores at 12 and 24 hours, prolonged time to first analgesia, and reduced diclofenac consumption, without increased side effects. This discrepancy may arise from potential variations in pain assessment protocols, rescue medication thresholds, or unmeasured confounding factors.

Clinical implications of our study: Tramadol wound infiltration is a superior alternative to bupivacaine for post-cesarean analgesia. Its prolonged effect significantly delays the need for rescue medication with a good safety

profile. This method can improve patient satisfaction, enable faster mobilization, and shorten hospital stays. Offering effective, sustained analgesia with minimal side effects, tramadol infiltration supports enhanced recovery and postpartum pain management.

Strengths and limitations of the study: The key strengths of this study include its randomized design, homogeneous patient population with strict inclusion criteria, and comprehensive assessment of multiple outcomes (VAS scores, analgesic consumption, time to first request, and side effects), which enhance the internal validity and clinical relevance of the findings. The use of spinal anesthesia, consistent with current practice, also improves generalizability. However, limitations include a single-center setting and a moderate sample size, which may limit statistical power and broad applicability. The absence of blinding, though logistically challenging with wound infiltration, introduces potential for bias. Additionally, longer-term outcomes beyond 24 hours were not assessed. Future multi-center studies with larger cohorts and extended follow-up could further validate these promising results.

Recommendations for future research: Future research should focus on multi-center trials with larger sample sizes to improve statistical power and applicability. Longer follow-up beyond 24 hours is necessary to evaluate sustained analgesic effects and recovery. Double-blinded studies are recommended to reduce bias. Comparing tramadol with other adjuvants may reveal synergistic benefits, and cost analyses can support clinical use in resource-limited settings.

CONCLUSION

This study demonstrates that local wound infiltration with tramadol provides significantly superior and prolonged postoperative analgesia compared to bupivacaine in patients undergoing cesarean section under spinal anesthesia. Tramadol not only reduced pain scores at critical later time points but also delayed the first request for rescue analgesia and substantially decreased total diclofenac consumption over 24 hours, all without increasing adverse effects. These findings, consistent with emerging evidence, position tramadol as an effective, safe, and practical component of multimodal pain management strategies, offering tangible benefits for patient recovery and satisfaction in obstetric anesthesia practice.

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