

## Comparison of Analgesic Efficacy of Wound Infiltration with Bupivacaine versus Bupivacaine and Tramadol for Postoperative Pain Relief in Lower Segment Caesarean Section under Spinal Anaesthesia

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### Abstract

**Background:** Effective postoperative pain management after lower segment caesarean section (LSCS) is essential for early maternal recovery, initiation of breastfeeding, and improved maternal–infant bonding. Inadequate analgesia may lead to delayed ambulation, prolonged hospital stay, and increased postoperative complications. Wound infiltration with local anesthetics is a simple and effective technique for providing postoperative analgesia following caesarean section. Bupivacaine is widely used for wound infiltration because of its long duration of action and favourable safety profile. Tramadol, an opioid analgesic with additional monoaminergic activity, has been studied as an adjuvant to local anesthetics to enhance postoperative analgesia. The addition of tramadol to bupivacaine may prolong analgesic duration and improve postoperative pain control.

**Aim:** To compare the analgesic efficacy of wound infiltration with bupivacaine alone versus bupivacaine combined with tramadol for postoperative pain relief in patients undergoing lower segment caesarean section under spinal anaesthesia.

**Materials and Methods:** This prospective, randomized, double-blinded comparative clinical study was conducted in the Department of Anaesthesiology at Sri Siddhartha Medical College and Research Institute, Tumkur, Karnataka, India, over a 24-month period. A total of 60 parturients undergoing elective LSCS under spinal anaesthesia were included in the study. Patients were randomly allocated into two groups (n = 30 each): Group B (Bupivacaine group) received wound infiltration with 0.25% bupivacaine alone, whereas Group BT (Bupivacaine + Tramadol group) received 0.25% bupivacaine combined with tramadol at a dose of 2 mg/kg. Postoperative pain was assessed using the Visual Analogue Scale (VAS), and parameters such as duration of analgesia, time to first rescue analgesic, total analgesic consumption, and adverse effects were recorded.

**Results:** Patients receiving bupivacaine combined with tramadol demonstrated significantly prolonged postoperative analgesia, lower VAS pain scores, and delayed requirement for rescue analgesia compared with patients receiving bupivacaine alone. The combination group also showed reduced total analgesic consumption in the postoperative period without significant increase in adverse effects.

**Conclusion:** Wound infiltration with bupivacaine combined with tramadol provides superior postoperative analgesia compared with bupivacaine alone in patients undergoing LSCS under spinal anaesthesia. The addition of tramadol enhances the duration and quality of postoperative pain relief without significant complications.

**Keywords:** Caesarean section; postoperative analgesia; bupivacaine; tramadol; wound infiltration; spinal anaesthesia.

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### Introduction

Lower segment caesarean section (LSCS) is one of the most commonly performed surgical procedures worldwide. The incidence of caesarean deliveries

has increased significantly in recent decades due to advances in obstetric care, increased maternal age, and improved surgical techniques. Adequate

postoperative pain control following caesarean section is essential for early maternal recovery, improved maternal comfort, early ambulation, and successful initiation of breastfeeding. Effective pain management also plays a crucial role in preventing postoperative complications such as thromboembolism, delayed wound healing, and prolonged hospital stay. [1,2]

Postoperative pain following caesarean section originates from multiple sources, including surgical incision, uterine contractions, and visceral manipulation. Inadequate pain control can negatively affect maternal well-being and delay early mother–infant bonding. Therefore, optimal postoperative analgesia is a key component of perioperative care in obstetric anesthesia. [3,4]

Spinal anesthesia is the most commonly used anesthetic technique for caesarean section because it provides rapid onset, reliable anesthesia, and minimal drug exposure to the fetus. However, once the effect of spinal anesthesia wears off, patients may experience significant postoperative pain. Various analgesic strategies have been developed to manage postoperative pain following caesarean section, including systemic opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), neuraxial opioids, and local anesthetic techniques. [5-7]

Among these approaches, wound infiltration with local anesthetics has gained increasing popularity as a simple, safe, and cost-effective technique for postoperative pain management. Wound infiltration involves the injection of local anesthetic agents into the surgical incision site at the end of surgery, providing localized analgesia by blocking peripheral nociceptive pathways. This technique has been widely used in abdominal surgeries, including caesarean sections, with promising results. [8]

Bupivacaine, a long-acting amide local anesthetic, is commonly used for wound infiltration because of its prolonged duration of action and effective sensory blockade. Bupivacaine works by blocking voltage-gated sodium channels in nerve membranes, thereby preventing the propagation of nerve impulses and producing analgesia at the site of infiltration. Several studies have demonstrated that wound infiltration with bupivacaine significantly reduces postoperative pain and analgesic requirements following abdominal surgeries. [9,10]

Despite the advantages of bupivacaine, the duration of analgesia provided by local anesthetic infiltration alone may be limited. As a result, various adjuvants have been investigated to enhance the analgesic effect of local anesthetics. One such adjuvant is tramadol, a centrally acting synthetic opioid analgesic that also inhibits the

reuptake of serotonin and norepinephrine. These dual mechanisms contribute to its analgesic properties while producing fewer respiratory depressive effects compared with traditional opioids. [11] Tramadol has been studied extensively as an adjuvant in regional anesthesia and wound infiltration techniques. When combined with local anesthetics, tramadol may prolong analgesic duration by acting on peripheral opioid receptors and enhancing inhibitory pain pathways. In addition, tramadol has been shown to possess local anesthetic-like properties by blocking sodium channels in peripheral nerves. [12,13]

Several clinical studies have evaluated the efficacy of tramadol as an adjuvant to local anesthetics for postoperative pain control. Research has demonstrated that the addition of tramadol to bupivacaine for wound infiltration significantly prolongs analgesia and reduces postoperative analgesic requirements. These findings suggest that tramadol may enhance the analgesic efficacy of local anesthetics without significantly increasing adverse effects. [14]

Furthermore, wound infiltration techniques are particularly advantageous in obstetric anesthesia because they avoid systemic opioid administration and reduce potential maternal and neonatal side effects. Effective local analgesia allows early mobilization of the mother, promotes early breastfeeding, and improves maternal satisfaction during the postoperative period. [15,16]

Although numerous studies have explored the use of tramadol in combination with local anesthetics, limited data are available regarding its efficacy specifically in caesarean section patients undergoing spinal anesthesia. Comparative studies evaluating wound infiltration with bupivacaine alone versus bupivacaine combined with tramadol are therefore important to determine whether the addition of tramadol offers significant clinical advantages in postoperative pain management following LSCS.

Therefore, the present prospective, randomized, double-blinded comparative clinical study was undertaken to evaluate and compare the analgesic efficacy of wound infiltration with bupivacaine alone versus bupivacaine combined with tramadol for postoperative pain relief in patients undergoing lower segment caesarean section under spinal anesthesia at Sri Siddhartha Medical College and Research Institute, Tumkur.

## Materials and Methods

**Study design:** It was a prospective, randomized, double-blinded comparative clinical study.

**Study setting:** This research was conducted in the Department of Anaesthesiology at Sri Siddhartha

Medical College and Research Institute, Tumkur, Karnataka, India.

**Study duration:** The study extended over a 24-month period. During this time, eligible patients were screened, recruited, randomized, and subsequently observed for 24 hours following surgery.

**Study population:** Participants included parturients scheduled for elective LSCS under spinal anaesthesia who satisfied the predetermined inclusion and exclusion criteria.

**Study sample:** The total sample size for the study was 60 patients. Patients were randomly allocated to either Group B or Group BT using a computer-generated randomization sequence. Allocation concealment was maintained using sealed opaque envelopes.

- **Group B (Bupivacaine Group):** Patients received wound infiltration with 0.25% bupivacaine alone.
- **Group BT (Bupivacaine + Tramadol Group):** Patients received wound infiltration with 0.25% bupivacaine combined with tramadol at a dose of 2 mg/kg.

#### Inclusion criteria

- Women between 18 and 40 years of age · ASA physical status I or II
- Singleton gestation
- Planned elective LSCS under spinal anaesthesia
- Provision of written informed consent

#### Exclusion criteria

- Known allergy to local anaesthetic agents or tramadol
- History of opioid dependence, seizure disorders, or psychiatric illness
- Coagulation disorders or infection at the proposed injection site
- Significant cardiac, renal, hepatic, or neurological pathology
- High-risk or complicated pregnancy (e.g., pre-eclampsia, placenta previa, fetal distress)
- Failed spinal block or need for conversion to general anaesthesia.

#### Drug preparation

The study drugs were prepared by an anaesthesiologist who was not involved in patient management or postoperative assessment, ensuring double blinding.

- **Group B:** Required volume of 0.25% bupivacaine diluted with normal saline to obtain the desired total volume.
- **Group BT:** Tramadol 2 mg/kg was added to 0.25% bupivacaine, and the solution was

diluted with normal saline to achieve the same total volume as Group B.

Both solutions were prepared in identical syringes and labelled only with the study code.

**Anaesthetic technique:** All patients underwent a standard pre-anaesthetic evaluation and were kept fasting as per institutional guidelines. On arrival in the operating theatre, routine monitoring was instituted, including, Heart rate (HR), Non-invasive blood pressure (NIBP) and Peripheral oxygen saturation (SpO<sub>2</sub>).

Spinal anaesthesia was administered in the sitting position at the L3–L4 or L4–L5 interspace using a 25G spinal needle. After confirmation of free flow of cerebrospinal fluid, 0.5% hyperbaric bupivacaine was injected intrathecally in an appropriate dose. Adequate sensory block to T6 level was ensured before commencement of surgery.

At the end of surgery and prior to skin closure, wound infiltration was performed by the operating surgeon using the prepared study solution.

**Data collection:** All relevant data were collected using a pre-designed and pre-tested case record form (CRF). The following parameters were documented for each participant:

- Demographic data: age, weight, height, BMI
- ASA physical status
- Duration of surgery
- Group allocation (B or BT)
- Postoperative VAS scores at 1, 2, 4, 6, 12 and 24 hours
- Time to first rescue analgesic (in minutes)
- Number of rescue analgesic doses in 24 hours
- Total analgesic consumption in 24 hours
- Occurrence of adverse effects such as nausea, vomiting, dizziness, sedation, pruritus, or wound-related complications.

All observations were recorded by an anaesthesiologist who was blinded to group allocation to minimize observer bias.

#### Parameters assessed

- Postoperative analgesic protocol
- Pain assessment (VAS score)
- Assessment of adverse effects

**Statistical analysis:** The collected data were compiled and subsequently analysed using the Statistical Package for the Social Sciences (SPSS) software, version 26. Continuous variables were expressed as mean ± standard deviation (SD). Comparison between the two groups was performed using the Student's t-test for normally distributed data, while the Mann–Whitney U test was used for non-parametric data. Categorical variables were expressed as frequency and

percentage, and comparisons between groups were carried out using the Chi-square test or Fisher's exact test, wherever appropriate.

A p-value < 0.05 was considered statistically significant, whereas a p-value < 0.001 was considered highly significant.

**Ethical considerations:** Prior approval for the study was obtained from the Institutional Ethics Committee of Sri Siddhartha Medical and Hospital, Tumkur, Karnataka, India, before commencement of the study (IEC approval number: SSMC/MED/IEC-050/FEB-2024, Dated: 09/02/2024).

The study was conducted in accordance with the Declaration of Helsinki and ICMR ethical guidelines for biomedical research involving human participants. Written informed consent was obtained from all patients before enrolment. Patient

confidentiality and anonymity were strictly maintained throughout the study. No additional financial burden was imposed on the participants, and all standard treatment protocols were followed.

## Results

A total of 60 patients scheduled for elective Lower Segment Caesarean Section under spinal anaesthesia were included in the study. The patients were randomly allocated into two equal groups:

- Group B (Bupivacaine group): 30 patients
- Group BT (Bupivacaine + Tramadol group): 30 patients

Both study groups were comparable with respect to demographic variables and perioperative characteristics. There were no statistically significant differences between the two groups, ensuring homogeneity of the study population.

**Table 1: Baseline Demographic and Clinical Characteristics of Study Participants**

Parameter	Group B (Bupivacaine) n = 30	Group BT (Bupivacaine + Tramadol) n = 30	p-value
<b>Age distribution (years)</b>			
20–24	8 (26.7%)	7 (23.3%)	>0.05
25–29	14 (46.7%)	15 (50.0%)	
30–34	6 (20.0%)	6 (20.0%)	
≥35	2 (6.6%)	2 (6.6%)	
<b>Mean Age (years)</b>	27.8 ± 4.2	28.1 ± 4.5	0.78
<b>Body Mass Index (kg/m<sup>2</sup>)</b>	24.6 ± 2.8	24.9 ± 3.1	0.69
<b>ASA Physical Status</b>			
ASA I	19 (63.3%)	20 (66.7%)	>0.05
ASA II	11 (36.7%)	10 (33.3%)	

The table presents the baseline demographic and clinical characteristics of patients in both study groups.

The majority of participants in both groups belonged to the 25–29 years age category, and the mean age was comparable between Group B (27.8 ± 4.2 years) and Group BT (28.1 ± 4.5 years) with no statistically significant difference (p > 0.05).

Similarly, the mean body mass index (BMI) was 24.6 ± 2.8 kg/m<sup>2</sup> in Group B and 24.9 ± 3.1 kg/m<sup>2</sup> in Group BT, showing no significant difference between the groups (p > 0.05).

With regard to ASA physical status, most patients in both groups belonged to ASA Grade I, and the distribution of ASA grades was also comparable between the groups (p > 0.05).

**Table 2: Intraoperative and Postoperative Outcomes in the Study Groups**

Parameter	Group B (Bupivacaine) n = 30	Group BT (Bupivacaine + Tramadol) n = 30	p-value
<b>Duration of Surgery (minutes)</b>	51.4 ± 6.8	52.1 ± 7.2	0.70
<b>VAS Score – 1 hour</b>	4.2 ± 0.7	2.8 ± 0.6	<b>0.01</b>
<b>VAS Score – 2 hours</b>	4.8 ± 0.8	3.1 ± 0.7	<b>0.001</b>
<b>VAS Score – 4 hours</b>	5.3 ± 0.9	3.5 ± 0.8	<b>&lt;0.001</b>
<b>VAS Score – 6 hours</b>	5.9 ± 1.0	4.1 ± 0.9	<b>&lt;0.001</b>
<b>VAS Score – 12 hours</b>	4.7 ± 0.8	3.6 ± 0.7	<b>0.002</b>
<b>VAS Score – 24 hours</b>	3.2 ± 0.6	3.0 ± 0.5	0.09
<b>Time to First Rescue Analgesia (minutes)</b>	218.6 ± 44.3	364.8 ± 52.1	<b>&lt;0.001</b>
<b>Total Diclofenac Consumption (24 hrs)</b>	170.4 ± 28.5	108.2 ± 22.6	<b>&lt;0.001</b>
<b>Adverse Effects</b>			
Nausea	3 (10.0%)	4 (13.3%)	>0.05
Vomiting	2 (6.7%)	3 (10.0%)	>0.05
Sedation	1 (3.3%)	2 (6.7%)	>0.05

Dizziness	1 (3.3%)	2 (6.7%)	>0.05
Pruritus	0	1 (3.3%)	>0.05
Wound-related complications	0	0	-

The table summarizes the intraoperative and postoperative outcomes in both study groups. The mean duration of surgery was comparable between Group B ( $51.4 \pm 6.8$  minutes) and Group BT ( $52.1 \pm 7.2$  minutes), with no statistically significant difference ( $p > 0.05$ ), indicating similar operative conditions in both groups.

Postoperative Visual Analogue Scale (VAS) pain scores were consistently lower in Group BT compared to Group B at 1, 2, 4, 6, and 12 hours, with the maximum difference observed during the early postoperative period (first 6 hours). However, by 24 hours the difference in VAS scores was not statistically significant, suggesting convergence of pain levels later in the postoperative period.

The mean time to first rescue analgesia was significantly prolonged in Group BT ( $364.8 \pm 52.1$  minutes) compared to Group B ( $218.6 \pm 44.3$  minutes), demonstrating significantly longer postoperative analgesia with the addition of tramadol ( $p < 0.001$ ). Furthermore, total diclofenac consumption during the first 24 hours was significantly lower in Group BT, indicating a notable analgesic-sparing effect of tramadol.

Regarding postoperative adverse effects, the incidence of nausea, vomiting, sedation, dizziness, pruritus, and wound-related complications was low in both groups, and no statistically significant differences were observed ( $p > 0.05$ ). These findings suggest that the addition of tramadol to bupivacaine wound infiltration improves postoperative analgesia without increasing the risk of adverse effects.

## Discussion

Effective postoperative pain management after lower segment caesarean section (LSCS) is essential for early maternal mobilization, improved maternal–neonatal bonding, and prevention of complications such as thromboembolism and delayed recovery.

Multimodal analgesia strategies are commonly employed to optimize pain control while minimizing systemic opioid requirements. Wound infiltration with local anesthetics is widely accepted as a simple, safe, and cost-effective method for postoperative analgesia in caesarean section. The addition of adjuvants such as tramadol has been investigated to enhance the analgesic duration and quality of local anesthetics. The present prospective randomized double-blinded comparative study evaluated the analgesic efficacy of wound infiltration using 0.25% bupivacaine alone versus 0.25% bupivacaine combined with tramadol (2

mg/kg) in patients undergoing LSCS under spinal anesthesia.

In the present study, baseline demographic characteristics including age, BMI, and ASA physical status were comparable between the two groups. The majority of patients in both groups belonged to the 25–29 year age group, and the mean age was  $27.8 \pm 4.2$  years in Group B and  $28.1 \pm 4.5$  years in Group BT, with no statistically significant difference. Similarly, BMI and ASA status were evenly distributed between the groups. These findings indicate that the study population was homogenous and that baseline patient characteristics did not influence postoperative analgesic outcomes. Comparable demographic distribution has also been reported in previous studies evaluating local anesthetic infiltration in caesarean section patients. For example, Milkias M et al. (2019) reported similar baseline characteristics when comparing wound infiltration with bupivacaine alone and bupivacaine with tramadol in obstetric surgeries. [1]

The mean duration of surgery was  $51.4 \pm 6.8$  minutes in Group B and  $52.1 \pm 7.2$  minutes in Group BT, which was statistically comparable. Similar operative duration between groups indicates uniformity in surgical exposure and procedural complexity. Comparable surgical duration was also observed in many studies evaluating local wound infiltration for postoperative analgesia following LSCS. [2,3]

Postoperative pain intensity was evaluated using the Visual Analogue Scale (VAS) at multiple time intervals. The results demonstrated significantly lower VAS scores in the bupivacaine + tramadol group (Group BT) at 1, 2, 4, 6, and 12 hours postoperatively compared with the bupivacaine-only group. The most pronounced difference in pain scores occurred during the early postoperative period (first 6 hours). This finding suggests that tramadol enhances the analgesic effect of bupivacaine by prolonging local anesthetic activity and providing additional analgesia through its central and peripheral mechanisms.

Tramadol is a synthetic opioid with dual mechanisms of action. It acts as a weak  $\mu$ -opioid receptor agonist and inhibits the reuptake of serotonin and norepinephrine, thereby enhancing descending inhibitory pain pathways. Additionally, tramadol has been reported to exhibit local anesthetic properties when administered peripherally. The synergistic action between tramadol and bupivacaine likely contributes to the enhanced postoperative analgesia observed in the

present study. Similar findings have been reported in previous studies demonstrating that the addition of tramadol to local anaesthetic infiltration significantly reduces postoperative pain scores following abdominal surgery. [4]

Another important finding in the present study was the significantly prolonged time to first rescue analgesia in the bupivacaine–tramadol group. Patients in Group BT required their first rescue analgesic at  $364.8 \pm 52.1$  minutes, compared with  $218.6 \pm 44.3$  minutes in Group B, and this difference was highly statistically significant ( $p < 0.001$ ). This represents nearly a 2.4-hour prolongation of analgesia, indicating that tramadol substantially extends the analgesic duration when used as an adjuvant to bupivacaine.

These results are consistent with previous research findings. Tramadol to bupivacaine infiltration significantly increased the duration of postoperative analgesia in caesarean section patients.<sup>5</sup> Similarly, Sahmeddini MA et al. (2021) reported prolonged analgesic duration and reduced pain scores when tramadol was used as an adjuvant in wound infiltration techniques. [6]

Another clinically relevant outcome assessed in this study was the total postoperative diclofenac consumption during the first 24 hours. Patients in Group BT required significantly lower doses of rescue analgesic medication compared with those in Group B. This finding highlights the analgesic-sparing effect of tramadol, which reduces the need for additional systemic analgesics and may minimize the risk of NSAID-related side effects. Reduced postoperative analgesic consumption has also been reported by Bolinao MD et al. and Haliloglu, M et al. when tramadol was used in combination with local anesthetics. [7,8]

The mechanism behind reduced analgesic consumption is likely due to the prolonged local anesthetic action combined with the systemic and peripheral analgesic effects of tramadol. This multimodal mechanism contributes to improved postoperative pain control and enhanced patient comfort. In obstetric patients, effective pain control is particularly important as it facilitates early ambulation, improved breastfeeding, and better maternal recovery.

The safety profile of the analgesic technique was also assessed in this study by monitoring postoperative adverse effects. The incidence of side effects such as nausea, vomiting, sedation, dizziness, and pruritus was low in both groups, and no statistically significant difference was observed between them. Importantly, no wound-related complications such as infection, hematoma, or delayed healing were observed in either group. These findings indicate that the addition of

tramadol to bupivacaine infiltration does not increase the risk of adverse effects.

Previous studies have also demonstrated a favorable safety profile for tramadol infiltration. Roopa S et al. and Taksakande K et al. reported that tramadol used as a local infiltration adjuvant did not significantly increase postoperative complications in obstetric patients. [9,10] The minimal systemic absorption of tramadol when administered locally likely contributes to its favorable safety profile.

The results of the present study also align with findings from multimodal analgesia research. Enhanced recovery protocols in obstetric surgery emphasize the importance of combining different analgesic techniques to achieve optimal pain control while minimizing opioid consumption. Wound infiltration with local anesthetic and adjuvants represents a valuable component of such multimodal strategies. Bupivacaine infiltration combined with tramadol may therefore serve as an effective and economical method for improving postoperative analgesia in resource-limited healthcare settings.

Another important consideration in obstetric analgesia is maternal safety and neonatal well-being. Since tramadol was administered locally rather than systemically in this study, systemic exposure was minimal, thereby reducing potential risks to the mother and neonate. Previous research has suggested that local administration of tramadol provides adequate analgesia without significant systemic opioid effects. [11]

Despite the positive findings of this study, certain limitations should be acknowledged. The sample size was relatively small (60 patients), and the study was conducted in a single tertiary care institution, which may limit generalizability. Additionally, long-term outcomes such as chronic postoperative pain and patient satisfaction were not evaluated. Future multicenter studies with larger sample sizes may provide further evidence regarding the efficacy and safety of tramadol as an adjuvant in wound infiltration analgesia.

Nevertheless, the present study provides valuable clinical evidence supporting the use of tramadol as an adjunct to bupivacaine for postoperative pain management following caesarean section. The technique is simple to perform, inexpensive, and easily reproducible in routine obstetric anesthesia practice.

#### Limitations of study

The present study has certain limitations. The sample size was relatively small and the study was conducted at a single tertiary care centre, which may limit the generalizability of the findings. In

addition, longer-term outcomes such as patient satisfaction and chronic postoperative pain were not assessed.

**Future Recommendations:** Future studies with larger sample sizes and multicenter participation are recommended to further validate the findings and improve the generalizability of the results.

Additional research may also evaluate different doses of tramadol when combined with bupivacaine to determine the optimal dose that provides maximum analgesic benefit with minimal side effects.

### Conclusion

This prospective randomized double-blind study demonstrates that wound infiltration with a combination of bupivacaine and tramadol provides superior postoperative analgesia compared with bupivacaine alone in patients undergoing lower segment caesarean section under spinal anaesthesia. The addition of tramadol significantly prolonged the duration of analgesia, reduced postoperative pain scores, delayed the requirement for rescue analgesics, and decreased total analgesic consumption without increasing adverse effects. Therefore, tramadol appears to be an effective and safe adjuvant to bupivacaine for postoperative pain management following caesarean section and may be considered as a useful component of multimodal analgesic strategies in obstetric anesthesia.

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