

Comparison of Pre-incisional Infiltration of Ketamine and Levobupivacaine for Postoperative Analgesia and Quality of Recovery in Caesarean Section under Spinal Anaesthesia: A Prospective Randomized Study

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Abstract

Background: Effective postoperative analgesia after caesarean section facilitates early mobilization, breastfeeding, maternal–neonatal bonding, and overall recovery. This study compared pre-incisional ketamine and levobupivacaine infiltration for postoperative analgesia and quality of recovery following caesarean section under spinal anaesthesia.

Methods: This prospective randomized study included 70 ASA II pregnant women aged 18–40 years undergoing caesarean section under spinal anaesthesia. Patients were randomized into Group K (n=35), receiving ketamine 2 mg/kg diluted to 20 mL with normal saline, and Group L (n=35), receiving 20 mL of 0.5% levobupivacaine. The study drug was infiltrated subcutaneously along the incision site 5 minutes before incision. Postoperative VAS scores, time to first rescue analgesia, rescue analgesic requirement, ObsQoR-11 score at 24 hours, haemodynamic variables, and adverse events were assessed.

Results: The groups were comparable in demographic characteristics and duration of surgery. VAS at 4 hours was significantly lower in Group K than Group L (1.14 ± 0.69 vs. 2.43 ± 1.12 ; $p=0.001$). Time to first rescue analgesia was significantly prolonged with ketamine (8.27 ± 1.59 vs. 5.63 ± 1.21 hours; $p=0.001$), with significantly lower rescue analgesic requirements. The ObsQoR-11 score at 24 hours was significantly higher in Group K (66.14 ± 3.99 vs. 62.17 ± 3.88 ; $p=0.001$). Haemodynamic parameters were generally comparable. Nausea was significantly more frequent with ketamine (68.6% vs. 11.4%; $p=0.001$), whereas vomiting and shivering were comparable.

Conclusion: Pre-incisional ketamine infiltration provided better postoperative analgesia, prolonged the time to rescue analgesia, reduced rescue analgesic requirement, and improved quality of recovery compared with levobupivacaine following caesarean section under spinal anaesthesia.

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Introduction

Caesarean section is one of the most frequently performed surgical procedures worldwide, and effective postoperative analgesia is essential for early mobilization, maternal–neonatal bonding, breastfeeding, and overall recovery. Contemporary

recommendations emphasize multimodal, opioid-sparing analgesia after caesarean delivery to achieve adequate pain control while minimizing opioid-related adverse effects [1]. Local anaesthetic wound infiltration represents a simple component

of multimodal analgesia and may reduce postoperative pain and supplementary analgesic requirements following caesarean delivery [2].

Ketamine, an N-methyl-D-aspartate (NMDA) receptor antagonist, possesses potent analgesic and antihyperalgesic properties. When administered by local wound infiltration, ketamine may provide peripheral analgesia in addition to its systemic effects. Recent evidence suggests that ketamine-containing wound infiltration can improve postoperative analgesic outcomes following caesarean section [3]. A systematic review and meta-analysis also demonstrated that ketamine wound infiltration can reduce postoperative pain and analgesic consumption across surgical procedures [4]. In women undergoing caesarean section, subcutaneous ketamine infiltration has been associated with lower postoperative pain scores and reduced opioid consumption [5].

Levobupivacaine is a long-acting local anaesthetic commonly used for regional and wound infiltration techniques because of its prolonged analgesic action and favourable safety profile. Regional blocks and local anaesthetic wound infiltration are established opioid-sparing strategies following caesarean delivery [6]. Evidence comparing abdominal wall blocks with wound infiltration further supports the role of local infiltration as a practical component of multimodal post-caesarean analgesia [7].

However, evidence directly comparing pre-incisional ketamine and levobupivacaine infiltration for postoperative analgesia and quality of recovery following caesarean section under spinal anaesthesia remains limited. The comparative effects of these two agents on pain scores, rescue analgesic requirement, and patient-reported recovery are therefore not clearly established.

Therefore, the present study was undertaken to compare the effects of pre-incisional ketamine and levobupivacaine infiltration on postoperative analgesia and quality of recovery in patients undergoing caesarean section under spinal anaesthesia.

Materials and Methods

Study Design and Setting: This prospective, randomized, double-blind comparative study was conducted in the Operation Theatre Complex, Department of Anaesthesiology, Bhagat Phool Singh Government Medical College for Women, Khanpur Kalan, Sonapat, Haryana, over a period of 18 months, from May 2021 to October 2022. A total of 70 pregnant women scheduled for caesarean section under spinal anaesthesia were enrolled after obtaining written informed consent.

Study Population: Pregnant women aged 18–40 years, belonging to American Society of Anaesthesiologists (ASA) physical status II and scheduled for caesarean section through a Pfannenstiel incision under spinal anaesthesia were considered eligible.

Patients who declined participation; had known hypersensitivity to the study drugs; neurological, psychiatric, neuromuscular, cardiovascular, pulmonary, renal or hepatic disease; diabetes mellitus; complicated pregnancy including severe fetal distress; contraindications to spinal anaesthesia; chronic treatment with magnesium or calcium-channel blockers; or a history of opioid, steroid or analgesic abuse were excluded.

Sampling Technique: Eligible patients meeting the predefined inclusion and exclusion criteria were enrolled until the required sample size was achieved.

Sample Size: The sample size was calculated based on a previous study comparing pre-incisional ketamine and levobupivacaine infiltration. Considering a clinically relevant difference in mean time to first analgesic demand of 30.6 minutes, standard deviation of 2.2, statistical power of 80%, and alpha error of 5%, the required sample size was estimated using nMaster 2.0 software. A total of 70 patients, with 35 patients in each group, were included.

Ethical Considerations and Informed Consent:

The study was conducted after obtaining approval from the Institutional Ethics Committee of the concerned institution.

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. All eligible participants were informed about the nature, purpose, procedures, potential benefits, and possible risks of the study in a language understandable to them. Written informed consent was obtained from each participant before enrolment. Participants were informed that participation was voluntary and that they had the right to withdraw from the study at any time without affecting their medical care. Confidentiality and privacy of participant information were maintained throughout the study, and the collected data were used only for academic and research purposes.

Randomization, Allocation concealment and Blinding: Participants were randomly allocated in a 1:1 ratio using a computer-generated randomization sequence into two groups:

Group K (n=35): Patients received subcutaneous infiltration of ketamine 2 mg/kg, diluted with sterile 0.9% normal saline to a total volume of 20 mL.

Group L (n=35): Patients received subcutaneous infiltration of 20 mL of 0.5% levobupivacaine.

The study solution was infiltrated subcutaneously along the proposed Pfannenstiel incision approximately 5 minutes before skin incision. The study solutions were prepared by an anaesthesiologist who was not involved in patient assessment or data collection and were placed in identical 20-mL syringes. The anaesthesiologist administering the infiltration, the surgeon, the participants, and the postoperative outcome assessor were blinded to group allocation.

The allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes, which were opened only after enrolment and completion of baseline assessment.

Anaesthetic Technique: All patients underwent routine pre-anaesthetic evaluation and investigations according to institutional protocol. The visual analogue scale (VAS) for postoperative pain and the Obstetric Quality of Recovery-11 (ObsQoR-11) questionnaire were explained preoperatively.

After arrival in the operating theatre, standard monitoring comprising electrocardiography, non-invasive blood pressure, heart rate, peripheral oxygen saturation, respiratory rate, and temperature was instituted. A 20-G intravenous cannula was secured, and patients were preloaded with Ringer's lactate solution at 10 mL/kg over 5–10 minutes.

Under strict aseptic precautions, spinal anaesthesia was administered at the L3–L4 intervertebral space in the lateral position using a 25-G Quincke spinal needle. Hyperbaric 0.5% bupivacaine 10 mg was administered intrathecally. After confirming adequate sensory and motor blockade, patients were placed supine and supplemental oxygen was administered through a face mask at 5 L/min.

After painting and draping, the allocated study solution was infiltrated subcutaneously along the proposed incision site. Surgery was commenced after establishment of adequate surgical anaesthesia.

Intraoperative Monitoring: Heart rate, systolic and diastolic blood pressure, respiratory rate, and SpO₂ were recorded at baseline and at 5-minute intervals during the initial 30 minutes, followed by assessment at 1 hour and at the completion of surgery. A haemodynamic change of $\geq 20\%$ from baseline was considered clinically significant and managed according to institutional protocol with intravenous ephedrine and/or atropine when indicated.

Oxytocin was administered after umbilical cord clamping according to the standard protocol for active management of the third stage of labour.

Intravenous midazolam 1 mg was administered after delivery of the baby as per institutional protocol. Sedation was assessed using the Ramsay Sedation Scale.

No additional intraoperative analgesic was administered apart from the study protocol. The use of antiemetics and other perioperative medications was standardized according to institutional protocol and was identical between groups.

Postoperative Assessment: Following surgery, patients were transferred to the postoperative care unit and subsequently to the ward after achieving an acceptable Modified Aldrete score. Pain intensity was assessed using the VAS at 1, 2, 4, 8, 12, and 24 hours postoperatively.

Pain intensity was assessed using a 10-point visual analogue scale (VAS), with rescue analgesia administered when VAS > 3 . Intravenous paracetamol 1 g was given as the first rescue analgesic. If adequate pain relief was not achieved within 30 minutes, intravenous diclofenac 75 mg was administered as second-line rescue analgesia. The time to first rescue analgesic requirement and total rescue analgesic requirement during the first 24 hours were recorded.

Quality of recovery was evaluated using the ObsQoR-11 score at 24 hours postoperatively. Patients were also monitored for hypotension, bradycardia, nausea, vomiting, respiratory depression, excessive blood loss, excessive sedation, and other adverse events. Breastfeeding was initiated as early as clinically feasible.

Data Collection: Data were collected in three stages. Preoperatively, demographic and clinical details, relevant comorbidities, fasting status, diagnosis and indication for caesarean section, physical and systemic examination findings, airway and spine examination, and routine laboratory investigations were recorded after obtaining written informed consent.

During the intraoperative period, heart rate, systolic and diastolic blood pressure, respiratory rate, SpO₂, blood loss, adverse events, and sedation using the Ramsay Sedation Scale were recorded. Postoperatively, vital parameters, adverse events, complications, time to rescue analgesic requirement corresponding to VAS > 3 , and the ObsQoR-11 score at 24 hours were documented.

Outcome Measures: The primary outcomes were time to first rescue analgesic demand and total rescue analgesic requirement during the first 24 postoperative hours.

The secondary outcomes were ObsQoR-11 score at 24 hours, perioperative haemodynamic variables, postoperative pain scores, sedation, and incidence of adverse effects.

Statistical Analysis: Data were entered into Microsoft Excel and analysed using SPSS software. Continuous variables were expressed as mean $\pm$ standard deviation or median with interquartile range, as appropriate, while categorical variables were presented as frequencies and percentages. Intergroup comparisons of continuous variables were performed using the independent Student's t-test or Mann-Whitney U test according to data distribution. Categorical variables were compared using the Chi-square test or Fisher's exact test, where appropriate. Changes in repeatedly measured variables between and within groups were evaluated using repeated-measures analysis of variance (ANOVA) or an appropriate non-

parametric equivalent. A two-sided p-value <0.05 was considered statistically significant.

Results

A total of 70 patients undergoing caesarean section under spinal anaesthesia were included and randomly allocated to Group K (ketamine, $n=35$) and Group L (levobupivacaine, $n=35$).

The two groups were comparable with respect to baseline demographic characteristics and duration of surgery. The principal differences between the groups were observed in postoperative pain, time to first rescue analgesia, rescue analgesic consumption, quality of recovery, and incidence of nausea.

Table 1: Baseline characteristics and duration of surgery

Parameter	Group K ($n=35$)	Group L ($n=35$)	p-value
Age (years)	23.97 $\pm$ 3.02	24.26 $\pm$ 3.76	0.72
Weight (kg)	66.60 $\pm$ 4.13	68.64 $\pm$ 4.78	0.07
Duration of surgery (min)	76.00 $\pm$ 11.32	75.56 $\pm$ 11.59	0.59

Values are expressed as mean $\pm$ SD.

There was no statistically significant difference in age, body weight, or duration of surgery between the two groups (all $p>0.05$), indicating satisfactory baseline comparability.

Table 2: Comparison of postoperative VAS scores between the groups

Postoperative time	Group K ($n=35$), Mean $\pm$ SD	Group L ($n=35$), Mean $\pm$ SD	p-value
1 hour	0.03 $\pm$ 0.17	0.09 $\pm$ 0.28	0.31
2 hours	0.17 $\pm$ 0.45	0.25 $\pm$ 0.89	0.87
4 hours	1.14 $\pm$ 0.69	2.43 $\pm$ 1.12	0.001
8 hours	3.09 $\pm$ 1.15	2.60 $\pm$ 0.74	0.03
12 hours	2.54 $\pm$ 0.85	2.69 $\pm$ 0.87	0.48
24 hours	2.60 $\pm$ 0.88	2.63 $\pm$ 0.81	0.88

VAS: Visual Analogue Scale; $p<0.05$ considered statistically significant.

Postoperative pain scores were comparable at 1 and 2 hours. At 4 hours, Group K had a significantly lower VAS score than Group L (1.14 $\pm$ 0.69 vs. 2.43 $\pm$ 1.12; $p=0.001$). Conversely, at 8 hours, the

VAS score was significantly higher in Group K (3.09 $\pm$ 1.15 vs. 2.60 $\pm$ 0.74; $p=0.03$). No significant differences were observed at 12 or 24 hours.

Table 3: Comparison of rescue analgesia and quality of recovery

Outcome	Group K ($n=35$)	Group L ($n=35$)	p-value
Time to first rescue analgesia (h)	8.27 $\pm$ 1.59	5.63 $\pm$ 1.21	0.001
First rescue analgesic doses (Paracetamol 1 g IV)	1.11 $\pm$ 0.42	1.46 $\pm$ 0.78	0.04
Second rescue analgesic doses (Diclofenac 75 mg IV)	1.00 $\pm$ 0.00	1.29 $\pm$ 0.49	0.01
Total rescue analgesic doses during 24 h	2.29 $\pm$ 0.62	2.86 $\pm$ 0.55	<0.001
ObsQoR-11 score at 24 h	66.14 $\pm$ 3.99	62.17 $\pm$ 3.88	0.001

The mean time to first rescue analgesic requirement was significantly prolonged in Group K compared with Group L (8.27 $\pm$ 1.59 vs. 5.63 $\pm$ 1.21 hours; $p=0.001$). Patients receiving ketamine also required significantly fewer first and second rescue analgesic doses. Consequently, overall rescue

analgesic consumption during the first 24 hours was significantly lower with ketamine. Quality of postoperative recovery was also better in Group K. The mean ObsQoR-11 score at 24 hours was 66.14 $\pm$ 3.99 in Group K compared with 62.17 $\pm$ 3.88 in Group L ($p=0.001$).

Table 4: Comparison of intraoperative haemodynamic findings and adverse events

Parameter	Group K	Group L	p-value
Baseline heart rate (beats/min)	89.56 ± 1.03	89.43 ± 0.89	0.53
Baseline SBP (mmHg)	120.78 ± 5.71	120.44 ± 5.37	0.43
Baseline DBP (mmHg)	77.43 ± 4.87	77.23 ± 4.12	0.57
SBP at 5 min (mmHg)	122.11 ± 8.15	118.00 ± 8.37	0.04
SBP at 10 min (mmHg)	116.97 ± 6.72	113.60 ± 6.95	0.04
DBP at 5 min (mmHg)	76.74 ± 6.56	73.26 ± 5.96	0.02
DBP at 10 min (mmHg)	73.26 ± 5.31	70.86 ± 4.20	0.04
Nausea, n (%)	24 (68.6)	4 (11.4)	0.001
Vomiting, n (%)	4 (11.4)	1 (2.9)	0.53
Shivering, n (%)	7 (20.0)	6 (17.1)	0.89

SBP: systolic blood pressure; DBP: diastolic blood pressure.

Baseline haemodynamic variables were comparable between the groups. Heart rate remained comparable throughout the intraoperative period. Statistically significant differences in SBP and DBP occurred at 5 and 10 minutes; however, the values remained within clinically acceptable ranges and subsequent measurements were comparable.

Postoperative heart rate and blood pressure remained comparable between the groups throughout the 24-hour observation period.

The major difference in adverse events was nausea, which occurred significantly more frequently in Group K than Group L (68.6% vs. 11.4%; $p=0.001$). The incidences of vomiting and shivering were not significantly different.

Overall Findings: Pre-incisional ketamine infiltration produced better early postoperative analgesia, as demonstrated by the lower VAS score at 4 hours, significantly prolonged time to first rescue analgesia, and reduced rescue analgesic requirement during the first 24 hours. Furthermore, the significantly higher ObsQoR-11 score indicated better overall postoperative recovery with ketamine. However, this analgesic and recovery benefit was accompanied by a substantially higher incidence of nausea. Overall haemodynamic stability was comparable between the two interventions.

The key outcome values above are directly supported by the supplied results: VAS differences occurred at 4 and 8 hours, first rescue analgesia occurred at 8.27 vs 5.63 hours, ObsQoR-11 was 66.14 vs 62.17, and nausea was significantly more frequent with ketamine.

Although higher intraoperative Ramsay Sedation Scale scores were observed in the ketamine group, the difference was reported as statistically non-significant. All patients had a Ramsay Sedation Scale score of 1 at transfer to the PACU.

Discussion

The present prospective randomized study compared pre-incisional infiltration of ketamine

and levobupivacaine for postoperative analgesia and quality of recovery in women undergoing caesarean section under spinal anaesthesia. The principal finding was that ketamine provided superior early postoperative analgesia, prolonged the time to first rescue analgesic requirement, reduced rescue analgesic consumption, and resulted in a better ObsQoR-11 score at 24 hours. However, ketamine was associated with a higher incidence of nausea.

Quality of recovery has emerged as an important patient-centred outcome after caesarean delivery. Kumar et al. validated the ObsQoR-11 as a reliable tool for evaluating postoperative recovery following elective caesarean delivery in an Indian population [8]. Similar validation studies have demonstrated its clinical utility in assessing multidimensional recovery after caesarean section [9]. In the present study, the significantly higher ObsQoR-11 score in the ketamine group (66.14 ± 3.99) compared with the levobupivacaine group (62.17 ± 3.88 ; $p=0.001$) suggests that the analgesic benefit of ketamine translated into improved overall maternal recovery.

Ketamine has well-established analgesic and antihyperalgesic properties mediated primarily through NMDA receptor antagonism. Adhikari et al. demonstrated that perioperative ketamine can improve postoperative analgesic outcomes following caesarean delivery under spinal anaesthesia [10]. The present findings similarly demonstrated a clear analgesic advantage, particularly during the early postoperative period. The mean VAS score at 4 hours was significantly lower with ketamine than with levobupivacaine (1.14 ± 0.69 vs. 2.43 ± 1.12 ; $p=0.001$).

Patient-centred recovery instruments are particularly valuable in obstetric anaesthesia because conventional endpoints such as pain scores alone do not adequately represent maternal recovery. Ciechanowicz et al. demonstrated the usefulness of ObsQoR-11 following non-elective caesarean delivery [11], while their original development and evaluation study established its

validity, reliability, responsiveness, and clinical acceptability following elective caesarean delivery [12]. Thus, the improved ObsQoR-11 observed with ketamine in our study strengthens the clinical relevance of its analgesic effect.

The most notable finding was the prolonged time to first rescue analgesia with ketamine (8.27 ± 1.59 hours) compared with levobupivacaine (5.63 ± 1.21 hours; $p=0.001$). The requirement for rescue analgesics during the first 24 hours was also significantly lower in the ketamine group. These findings are consistent with Abdallah et al., who reported beneficial postoperative analgesic effects following pre-incisional surgical-site infiltration of ketamine or levobupivacaine [13]. The prolonged analgesic effect of locally infiltrated ketamine may be related to peripheral NMDA receptor blockade and attenuation of peripheral nociceptive sensitization.

Levobupivacaine nevertheless provided satisfactory postoperative analgesia and maintained stable haemodynamic parameters. Previous randomized evidence has demonstrated the usefulness of intraincisional levobupivacaine infiltration for postoperative analgesia following caesarean section [14]. In the present study, haemodynamic parameters were generally comparable between groups, although transient differences in blood pressure were observed at 5 and 10 minutes without apparent clinically important consequences.

An important limitation of ketamine was the significantly greater incidence of nausea (68.6% vs. 11.4%; $p=0.001$). Vomiting and shivering, however, were comparable between groups. Therefore, although ketamine provided better analgesia and quality of recovery, its increased tendency to cause nausea should be considered when selecting the infiltration technique.

The present study was limited by its single-centre design, relatively small sample size, and follow-up restricted to the first 24 postoperative hours. Further multicentre studies with larger populations and longer follow-up are warranted to determine the optimal dose of infiltrated ketamine that provides effective analgesia while minimizing adverse effects.

Limitations of the Study: This was a single-centre study with a relatively small sample size and a limited follow-up period of 24 hours. Pain and quality of recovery were assessed using subjective patient-reported tools. Variations in surgical technique and tissue handling may also have influenced postoperative outcomes.

Future Recommendations: Larger multicentre studies with longer follow-up are recommended to confirm these findings. Future studies may also evaluate different doses of ketamine, standardized

surgical techniques, and its role within multimodal postoperative analgesia.

Conclusion

Pre-incisional wound infiltration with ketamine provided superior postoperative analgesia compared with levobupivacaine in women undergoing caesarean section under spinal anaesthesia. Ketamine significantly prolonged the time to first rescue analgesia, reduced rescue analgesic requirement, and improved the ObsQoR-11 score at 24 hours. However, its analgesic advantage was accompanied by a significantly higher incidence of nausea.

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