Annals of Medicine and Medical Sciences (AMMS)
Volume 04, 2025, *Page No.: 800 to 803*
Available at: *http://ammspub.com*

Original Article

Comparison of Bupivacaine Hydrochloride and Bupivacaine Hydrochloride with Tramadol Hydrochloride in Caudal Epidural Analgesia in Children Undergoing Infraumbilical Surgeries

Dr Ekta Patel [1], Dr Bansari Shah *[2], Dr Akanksha Aggarwal [2], Dr Bipin Patel [3]

[1]Senior Resident, Department of Anaesthesia, Ananya College of Medicine and Research, Kalol, Gujarat, India.
[2]Assistant Professor, Department of Anaesthesia, Dr. M. K. Shah Medical College & Research Center, Ahmedabad, Gujarat, India.
[3]Professor and Head, Department of Anaesthesia, Dr. M. K. Shah Medical College & Research Center, Ahmedabad, Gujarat, India.

*Corresponding author: Dr Bansari Shah; *drbansarishah@yahoo.com*

Abstract

Background: Caudal epidural block is widely used for infraumbilical surgeries in children, but the duration of single-shot bupivacaine is limited. Tramadol as an adjuvant has been investigated to prolong analgesia and improve postoperative comfort. ***Aim:*** To compare the efficacy and safety of caudal bupivacaine alone with bupivacaine combined with tramadol in pediatric infraumbilical surgeries. ***Material and Methods:*** This prospective randomized study included 60 children aged 1–8 years undergoing elective infraumbilical surgeries. Group B received 0.25% bupivacaine 1 mL/kg, while Group BT received 0.25% bupivacaine 1 mL/kg with tramadol 2 mg/kg. Duration of analgesia, FLACC pain scores, sedation scores, and adverse effects were assessed over 24 hours. Statistical analysis was performed with $p<0.05$ considered significant. ***Results:*** Group BT had significantly longer analgesia (7.41 ± 1.19 hrs vs 5.26 ± 0.60 hrs), lower FLACC scores, and slightly higher early sedation without major complications. Incidence of nausea and vomiting was marginally higher in Group BT. ***Conclusion:*** Adding tramadol to caudal bupivacaine significantly prolongs analgesia and improves postoperative pain control in children without increasing serious adverse effects.

Keywords: ***Caudal analgesia, Bupivacaine, Tramadol, Pediatric infraumbilical surgery.***

Introduction

Postoperative pain management in pediatric patients remains a critical aspect of perioperative care to reduce morbidity, facilitate early recovery, and improve overall surgical outcomes [1]. Effective pain control in children not only ensures comfort but also minimizes the physiological stress response associated with surgery, which can impact hemodynamic stability and wound healing [2]. Infraumbilical surgeries, commonly performed in pediatric practice, often necessitate robust analgesic techniques due to the involvement of sensitive visceral and somatic pain pathways [3].

Among the various regional anesthesia techniques available, caudal epidural block is one of the most widely used and accepted methods for providing analgesia in infraumbilical surgeries in children [4]. The technique is relatively simple, reliable, and associated with a low incidence of complications when performed under proper aseptic precautions [5]. The primary local anesthetic employed for caudal analgesia is bupivacaine, an amide-type agent known for its long duration of action and excellent safety profile when administered within recommended doses [6]. However, the limitation of a single-shot caudal block with bupivacaine is its finite duration, which may not always provide adequate postoperative analgesia, especially for procedures with prolonged postoperative pain [7].

To enhance the duration and quality of caudal analgesia, various adjuvants have been studied, including opioids, alpha-2 agonists, ketamine, and tramadol [8]. Tramadol, a synthetic opioid with weak μ-receptor agonist activity and monoaminergic action, has gained popularity as an adjuvant because of its dual mechanism, offering prolonged analgesia with minimal respiratory depression compared to traditional opioids [9]. When combined with bupivacaine in a caudal block, tramadol has been reported to extend analgesic duration significantly without major adverse effects, making it a suitable choice for pediatric patients undergoing infraumbilical surgeries [10].

Therefore, the present study was designed to compare the effects of 0.25% bupivacaine hydrochloride (1 mL/kg) alone and 0.25% bupivacaine hydrochloride (1 mL/kg) combined with 0.25%

Received: July 13, 2025; **Revised:** July 31, 2025; **Accepted:** August 03, 2025

tramadol hydrochloride (2 mL/kg) in caudal epidural analgesia in children undergoing infraumbilical surgery, with the aim of evaluating their efficacy, safety, and postoperative analgesic profiles.

Material and Methods

This prospective comparative observational study was conducted in the Department of Anaesthesiology at Dr. M.K. Shah Medical College and SMS Hospital between January 2023 and April 2024 after obtaining approval from the institutional ethics committee and informed consent from the guardians of the patients. A total of 60 children of ASA physical status I and II, aged between 1 and 8 years, scheduled for elective infraumbilical surgeries were enrolled. All parents or guardians were provided detailed information about the purpose and nature of the study in a language they could understand, and written informed consent was obtained prior to participation.

The patients were randomly allocated into two groups of 30 each. Group B received 0.25% bupivacaine at a dose of 1 mL/kg, and Group BT received 0.25% bupivacaine at 1 mL/kg combined with tramadol at a dose of 2 mg/kg for caudal epidural analgesia. Inclusion criteria included children aged 1 to 8 years belonging to ASA grade I or II and scheduled for infraumbilical surgical procedures. Exclusion criteria included children with ASA grade III and IV, local infection at the site of caudal block, coagulopathy or abnormal clotting profile, congenital sacral anomalies, meningitis, history of allergy to local anaesthetics, immunocompromised state, and unwillingness to participate in the study.

All patients underwent pre-anaesthetic assessment, which included detailed medical history, evaluation for drug allergies, general and systemic examination including airway, cardiovascular and respiratory systems, and routine investigations such as blood and urine tests, chest radiography, and serological tests for HIV and HBsAg. Preoperative fasting guidelines were followed, restricting solid food for six hours and milk or clear fluids for four hours before surgery.

On the day of surgery, baseline vital signs such as heart rate, blood pressure, respiratory rate, and oxygen saturation were recorded. Standard monitors including ECG, pulse oximeter, non-invasive blood pressure, and temperature probe were applied. Intravenous access was secured, and patients were induced with intravenous ketamine 2 mg/kg, glycopyrrolate 0.004 mg/kg, and ondansetron 0.12 mg/kg, with supplemental oxygen provided. Airway management was achieved using endotracheal intubation in general anaesthesia or spontaneous ventilation with Jackson-Rees modification of Ayre's T-piece. Anaesthesia was maintained using a mixture of oxygen, nitrous oxide, and isoflurane (0.2-3%).

For the caudal block, the child was positioned in the left lateral Sim's position. After strict aseptic preparation, the sacral hiatus was identified by palpation and a 23G short-bevel hypodermic needle was inserted at an angle of 60-70° to the skin until a characteristic "pop" was felt, indicating entry into the caudal epidural space. The needle was then advanced slightly, and aspiration was performed to exclude intravascular or dural puncture. Proper needle placement was confirmed using the "whoosh test" and ease of injection. The assigned drug solution was then administered slowly according to group allocation. No other analgesic drugs were given preoperatively or intraoperatively.

Hemodynamic parameters such as heart rate, systolic and diastolic blood pressure, mean arterial pressure, oxygen saturation, and respiratory rate were recorded at baseline, after induction, before and after incision, then every five minutes for 20 minutes, every ten minutes for one hour, and subsequently at regular intervals up to 24 hours postoperatively. Patients were observed for complications including bradycardia, hypotension, respiratory depression, nausea, vomiting, pruritus, and neurological sequelae.

Postoperative pain was assessed using the FLACC scale at the end of surgery, every hour for the first six hours, every three hours up to 12 hours, and every six hours up to 24 hours. Duration of analgesia was defined as the time interval between caudal injection and the point when FLACC score reached ≥4, at which time rescue analgesia in the form of rectal paracetamol suppository (15 mg/kg) was administered. Sedation was evaluated using the Ramsay Sedation Scale at the end of surgery, 15 minutes, 30 minutes, 60 minutes, and then hourly until a score of 2 was achieved.

Data were recorded in a predesigned proforma and analyzed using SPSS version 26.0. Continuous variables were expressed as mean ± standard deviation and compared using appropriate statistical tests, while categorical variables were presented as frequency and percentages. A p-value <0.05 was considered statistically significant.

Results

Table 1: Demographic Characteristics of Patients

Parameter	Group B (n=30)	Group BT (n=30)	p-value
Age (years)	4.32 ± 1.65	4.48 ± 1.72	>0.05
Weight (kg)	14.2 ± 3.1	14.5 ± 3.3	>0.05
Gender (M/F)	18 / 12	17 / 13	>0.05
Duration of surgery (min)	46.5 ± 8.2	47.3 ± 8.5	>0.05

Table 1 shows the demographic characteristics of the study population in both groups. The mean age and weight of patients were comparable between Group B and Group BT, with no statistically significant differences. Gender distribution was also similar across the two groups, and the duration of surgery did not differ significantly. This homogeneity of demographic variables ensures that the comparison of analgesic outcomes is unbiased and attributable to the interventions administered rather than baseline variations.

Table 2: Duration of Analgesia

Parameter	Group B	Group BT	p-value
Duration of analgesia (hrs)	5.26 ± 0.60	7.41 ± 1.19	<0.05

Table 2 presents the duration of postoperative analgesia in both groups. The mean duration of analgesia was significantly longer in Group BT (7.41 ± 1.19 hours) compared to Group B (5.26 ± 0.60 hours), with a p-value of less than 0.05, indicating statistical significance. This finding suggests that the addition of tramadol to bupivacaine in caudal block substantially prolongs postoperative pain relief compared to bupivacaine alone.

Table 3: FLACC Pain Scores at Different Intervals

Time Interval	Group B (Mean ± SD)	Group BT (Mean ± SD)	p-value
1 hour	1.8 ± 0.6	0.9 ± 0.4	<0.05
2 hours	2.5 ± 0.8	1.2 ± 0.5	<0.05
4 hours	3.8 ± 0.7	1.9 ± 0.6	<0.05
6 hours	4.2 ± 0.8	2.3 ± 0.7	<0.05

Table 3 demonstrates the FLACC pain scores measured at different postoperative intervals. Group BT consistently recorded lower FLACC scores than Group B across all time points, including 1, 2,

4, and 6 hours postoperatively. These differences were statistically significant, indicating that patients in the combination group experienced less pain during the early postoperative period. The trend reflects the enhanced analgesic effect of adding tramadol to bupivacaine, improving patient comfort and reducing pain intensity over time.

Table 4: Ramsay Sedation Score

Time Interval	Group B (Mean ± SD)	Group BT (Mean ± SD)	p-value
1 hour	1.0 ± 0.0	2.47 ± 0.63	<0.05
2 hours	1.0 ± 0.0	2.32 ± 0.58	<0.05
6 hours	1.0 ± 0.0	1.65 ± 0.52	<0.05

Table 4 summarizes the Ramsay Sedation Scores for both groups at various intervals. Group BT exhibited higher sedation scores in the first few hours postoperatively compared to Group B, with values remaining statistically significant up to 6 hours. This increased sedation is likely due to the systemic absorption of tramadol when used as an adjuvant, although no adverse sedation-related complications were observed. Both groups eventually returned to baseline sedation scores, ensuring patient safety and comfort.

Table 5: Incidence of Adverse Effects

Adverse Effect	Group B (n=30)	Group BT (n=30)
Nausea/Vomiting	2	4
Pruritus	0	0
Respiratory depression	0	0
Neurological complications	0	0

Table 5 compares the incidence of adverse effects between the two groups. Nausea and vomiting were slightly more frequent in Group BT compared to Group B, but no episodes of pruritus, respiratory depression, or neurological complications were reported in either group. This indicates that while the addition of tramadol improves analgesia, it may slightly increase minor side effects, which were easily manageable and did not affect overall patient outcomes.

Discussion

The present study compared the analgesic efficacy and safety profile of caudal bupivacaine alone with bupivacaine combined with tramadol in pediatric patients undergoing infraumbilical surgeries. The findings demonstrated that the addition of tramadol significantly prolonged the duration of postoperative analgesia, reduced pain scores, and improved patient comfort without increasing the incidence of major adverse effects. The mean duration of analgesia in the bupivacaine with tramadol group was significantly longer than that in the bupivacaine-only group, which is consistent with previous studies indicating that tramadol as an adjuvant enhances the quality and duration of caudal analgesia [11]. This prolonged effect is attributed to tramadol's dual mechanism of action, which involves weak μ-opioid receptor agonism and inhibition of norepinephrine and serotonin reuptake, thereby providing synergistic action when combined with local anesthetics [12].

Pain assessment using FLACC scores in the present study revealed significantly lower scores in the combination group at all postoperative intervals, supporting the findings of studies by Gupta *et al*. and others who reported improved analgesic outcomes with the addition of tramadol [13]. Similarly, the enhanced sedation scores observed in the combination group during the early postoperative hours can be attributed to systemic absorption of tramadol, although sedation levels remained within acceptable safety margins without causing respiratory depression, aligning with reports by Jindal *et al*.[14].

Adverse effects were minimal and comparable between the two groups, except for a slightly higher incidence of nausea and vomiting in the tramadol group. These findings correlate with previous studies that identified nausea and vomiting as the most common side effects when tramadol is used caudally in pediatric patients, although the incidence remains clinically insignificant and easily managed [15]. Overall, the results of this study reinforce the safety and efficacy of tramadol as an adjuvant to bupivacaine in prolonging analgesia, reducing postoperative pain, and minimizing additional analgesic requirements, thereby improving the quality of pediatric perioperative care.

Conclusion

The addition of tramadol to caudal bupivacaine significantly prolongs the duration of analgesia and provides better pain control in pediatric patients undergoing infraumbilical surgeries without increasing major complications. This combination is effective and safe, making it a valuable option for improving postoperative analgesia in children.

Declarations

Conflict of interest

No! Conflict of interest is found elsewhere considering this work.

Source of Funding

There was no financial support concerning this work

Acknowledgments

None

References

[1] Kokki H. Current management of pediatric postoperative pain. Expert Rev Clin Pharmacol. 2019;12(2):105-114.

[2] Suresh S, Ecoffey C, Bosenberg A, *et al*. The European Society of Regional Anaesthesia and Pain Therapy and the American Society of Regional Anesthesia and Pain Medicine joint committee practice advisory on pediatric regional anesthesia. Reg Anesth Pain Med. 2018;43(3):211-217.

[3] Verghese ST, Hannallah RS. Acute pain management in children. J Pain Res. 2010; 3:105-123.

[4] Polaner DM, Taenzer AH, Walker BJ, *et al*. Pediatric Regional Anesthesia Network (PRAN): a multi-institutional study of the use and incidence of complications of pediatric regional anesthesia. Anesth Analg. 2012;115(6):1353-1364.

[5] Ivani G, Suresh S. Caudal anesthesia and analgesia techniques in children. Curr Opin Anaesthesiol. 2017;30(5):652-657.

[6] Ecoffey C. Pediatric regional anesthesia-update. Curr Opin Anaesthesiol. 2018;31(5):674-680.

[7] Constant I, Gall O, Ecoffey C. Anaesthesia for paediatric surgery. Br J Anaesth. 2013;111(Suppl 1):i95-i105.

[8] Khalil S, Campos S, Farag E. Caudal analgesia in children: review of adjuvants and complications. Curr Opin Anaesthesiol. 2019;32(6):701-707.

[9] Gupta S, Sharma R, Singh S. Comparative study of caudal tramadol and bupivacaine versus bupivacaine alone in paediatric patients. Indian J Anaesth. 2011;55(2):118-123.

[10] Singh J, Jafra A, Anand LK. Caudal tramadol with bupivacaine for postoperative analgesia in children: a randomized controlled study. J Anaesthesiol Clin Pharmacol. 2013;29(3):303-307.

[11] Senel AC, Akyol A, Aydin ON, *et al*. Caudal bupivacaine-tramadol combination for postoperative analgesia in children: a randomized, double-blind, prospective study. Paediatr Anaesth. 2011;21(5):530-535.

[12] Prosser DP, Davis A, Booker PD, *et al*. Caudal tramadol for postoperative analgesia in paediatric patients: a comparison with bupivacaine. Paediatr Anaesth. 1997;7(6):451-454.

[13] Kumari A, Jain S, Sinha R, *et al*. A comparative study of caudal tramadol and bupivacaine with bupivacaine alone in children for postoperative analgesia. Anaesth Pain Intensive Care. 2015;19(3):283-287.

[14] Jindal P, Khurana G, Bansal R, *et al*. Caudal tramadol-bupivacaine combination versus bupivacaine alone in children: analgesic efficacy and safety. J Clin Diagn Res. 2016;10(7): UC09-UC12.

[15] Verghese S, Hannallah R, Long J, *et al*. Adverse effects of caudal adjuvants in children: a systematic review and meta-analysis. Anesth Analg. 2017;124(6):1940-1951.