Original Article

Comparative Evaluation of Caudal Ropivacaine with Ketamine versus Midazolam for Postoperative Analgesia in Children Undergoing Infraumbilical Surgery

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Abstract

Background: For pediatric patients having infraumbilical surgery, efficient postoperative pain management is crucial. While ropivacaine is frequently used for caudal epidural analgesia, the quality and duration of postoperative analgesia may be affected by the use of adjuvant drugs such ketamine or midazolam. In pediatric patients undergoing infraumbilical surgery, the analgesic effectiveness of caudal ropivacaine with ketamine versus ropivacaine plus midazolam was studied. The objective is to evaluate the analgesic effectiveness of caudal ropivacaine combined with ketamine versus caudal ropivacaine combined with midazolam in children having infraumbilical surgery. **Material and Methods:** One hundred fifty pediatric patients undergoing infraumbilical surgery participated in a comparative study. Two groups of 75 patients each were formed. Caudal ropivacaine was administered with ketamine to Group A and caudal ropivacaine and midazolam to Group B. The FLACC scale was used to measure postoperative pain at 30 minutes, 2, 4, 6, and 12 hours. Acetaminophen consumption over a 24-hour period, analgesic duration, and postoperative complications were measured and compared between the groups. **Results:** The groups had similar baseline clinical and demographic features. Group A experienced analgesia for an average of 14.4±2.36 hours compared to 12.0±3.69 hours in Group B (p=0.002). Mean FLACC scores were significantly lower in Group A at 2 hours (0.3±0.48 vs. 0.5±0.51), 4 hours (0.5±0.67 vs. 1.0±0.79), 6 hours (0.6±0.59 vs. 1.9±1.21), and 12 hours (0.6±1.40 vs. 1.3±1.62), with significant differences between groups. Total 24-hour acetaminophen consumption was also lower in Group A than Group B (102.6±89.62 vs. 118.99±98.71 mg; p=0.012). No statistically significant difference was observed in the reported postoperative complications. **Conclusion:** In pediatric patients receiving infraumbilical surgery, caudal ropivacaine plus ketamine produced more potent and prolonged postoperative analgesia than caudal ropivacaine plus midazolam. The ketamine combination was associated with lower postoperative pain scores and reduced 24-hour acetaminophen consumption.

Keywords: Infraumbilical Surgery, Ketamine, Midazolam, Ropivacaine.

Received: 05 July 2026 **Revised: 21 July 2026** **Accepted: 12 August 2026** **Published: 17 August 2026**

Introduction

Infraumbilical surgeries are commonly performed in the paediatric population and are frequently associated with postoperative pain requiring effective and safe analgesia. Inadequately controlled postoperative pain may result in distress, delayed recovery, increased physiological stress, and difficulty in early postoperative care. Regional anesthetic techniques, particularly caudal epidural analgesia, are widely used in children undergoing infraumbilical procedures because they provide effective analgesia while reducing the requirement for systemic analgesic medications.[1-4]

For caudal analgesia in children, ropivacaine, a long-acting amide local anesthetic, has been widely used. Its favorable safety profile and lower propensity for cardiotoxicity compared with some other long-acting local anesthetics have contributed to its use in paediatric regional anesthesia.[5] However, a local anesthetic's analgesic effects might not be long enough to give long-term postoperative pain relief. Consequently, various pharmacological agents have been investigated as adjuvants to caudal local anesthetics to improve the quality and duration of analgesia.[1,6]

Ketamine, an NMDA receptor antagonist, has been studied as an adjuvant to caudal local anesthetics in paediatric patients. Its addition to a local anesthetic may enhance postoperative analgesia and prolong the duration of pain relief following infraumbilical surgery.[2,3] Several clinical studies have evaluated caudal ketamine in children and have demonstrated its potential to improve postoperative analgesic efficacy compared with local anesthetic administered alone.[2,3] The analgesic effect of ketamine is particularly relevant in paediatric anesthesia because effective pain control may reduce the requirement for rescue

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DOI:
10.21276/amit.2026.v13.i2.950

How to cite this article: Bhabhor K, Patel P, Bilwal K. Comparative Evaluation of Caudal Ropivacaine with Ketamine versus Midazolam for Postoperative Analgesia in Children Undergoing Infraumbilical Surgery. Acta Med Int. 2026;13(2):1747-1751.

analgesics during the postoperative period.

Midazolam, a benzodiazepine commonly used for anxiolysis and sedation, has also been investigated as an adjuvant for caudal analgesia in paediatric patients. The use of caudal midazolam in combination with local anesthetics has been reported to influence postoperative analgesia and may provide an alternative approach to prolonging the analgesic effect of caudal blockade.[5,6] However, the relative analgesic efficacy of different caudal adjuvants remains an important area of clinical investigation.

Ropivacaine combined with different adjuvants has therefore been evaluated to determine whether postoperative analgesia can be improved without increasing adverse effects. Comparative studies involving ketamine and other adjuvants have demonstrated variations in the duration and quality of postoperative analgesia, emphasizing the need for appropriate comparison of individual drug combinations.[1,6-8] The choice of adjuvant may influence postoperative pain scores, duration of analgesia, requirement for rescue medication, and recovery characteristics.

Given these factors, the current study was conducted to evaluate the analgesic effectiveness of caudal ropivacaine plus ketamine against caudal ropivacaine plus midazolam in pediatric patients having infraumbilical surgery. The study aimed to determine which combination provides more effective postoperative analgesia and to assess the clinical utility of these two caudal adjuvant techniques.

Materials and Methods

A comparative analysis of 150 pediatric patients receiving infraumbilical surgery was carried out. Based on the caudal analgesic regimen administered, two groups of 75 patients each were created from the participants. Group B was given caudal ropivacaine together with midazolam, while Group A was given caudal ropivacaine along with ketamine. The study population included children undergoing commonly performed infraumbilical procedures, including herniotomy, orchidopexy, and hypospadias repair.

Baseline demographic attributes such as age, weight, and gender distribution were documented for every participant. The preoperative evaluation encompassed the American Society of Anesthesiologists (ASA) physical status classification along with baseline vital signs, such as systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), pulse rate (PR), oxygen saturation (SpO_2), and body temperature. The duration of surgery was recorded in minutes for comparison between the two groups. Following completion of the surgical procedure, caudal analgesia was administered using the respective study drug combination. Participants in the category In Group A, caudal ropivacaine was paired with ketamine, while Group B received caudal ropivacaine alongside midazolam. The caudal technique was used as the postoperative analgesic intervention, with the respective adjuvant added to ropivacaine according to the study protocol. The available study information did not specify the exact concentrations or doses of ropivacaine, ketamine, or midazolam; therefore, these parameters were not additionally assumed.

The assessment of postoperative pain was conducted using the Face, Legs, Activity, Cry, Consolability (FLACC) scale, a behavioral technique tailored for children. The evaluation encompasses five dimensions—facial expression, leg movement, activity, weeping, and consolability—where each dimension is rated from 0 to 2, yielding a cumulative score that ranges from 0 to 10. Higher scores indicated greater postoperative pain. Pain scores were recorded at 30 minutes, 2 hours, 4 hours, 6 hours, and 12 hours following surgery.

The length of postoperative pain relief was evaluated by noting the interval until the initial need for supplemental analgesia. The aggregate quantity of acetaminophen ingested in the initial 24 hours post-surgery was documented and contrasted between the two cohorts. Postoperative adverse events were monitored, with particular attention to vomiting and fever.

In statistical analysis, continuous data were represented as mean ± standard deviation, and categorical variables were displayed as counts and percentages. Analyzes of the two groups were conducted utilizing suitable statistical methods, with a p value of less than 0.05 being statistically significant. Statistical analysis was performed using IBM SPSS (Statistical Package for the Social Sciences) software.

Results

The FLACC scale used for postoperative pain assessment evaluated five behavioural parameters: facial expression, lower limbs, engagement, vocalization, and comfort-seeking behavior. Each criterion received a score between 0 and 2, culminating in a total score from 0 to 10, where elevated scores reflect increased pain severity. The individual scoring criteria used for assessment are presented in [Table 1].

The demographic and foundational clinical traits of the study cohort are illustrated in [Table 2]. The mean age was comparable between Group A and Group B (2.9±1.06 vs. 2.8±1.08 years; p=0.95), as was mean body weight (17.24±4.47 vs. 16.8±3.76 kg; p=0.73). Gender distribution was also comparable between the groups (p=0.66). Baseline SBP, DBP, MAP, pulse rate, SpO_2, and temperature showed no statistically significant differences. The distribution of ASA physical status was similar between the groups, with the majority of children classified as ASA I. The mean duration of surgery was also comparable between Group A and Group B (50.82±33.20 vs. 50.95±30.89 minutes; p=0.99), indicating satisfactory baseline comparability.

The distribution of surgical procedures is shown in [Table 3]. Herniotomy constituted the most frequent procedure in both groups, accounting for 50.7% of procedures in Group A and 53.3% in Group B. Orchidopexy accounted for 40.0% and 30.7% of procedures, respectively, while hypospadias repair represented 9.3% of procedures in Group A and 16.0% in Group B.

The postoperative analgesic duration and the 24-hour usage of acetaminophen are outlined in [Table 4]. The mean analgesia duration was significantly longer in Group A than in Group B (14.4±2.36 vs. 12.0±3.69 hours), with a p-value of 0.002 indicating statistical significance. The indicated median analgesic duration was 17.17±4.47 hours in Group A compared to 17.83±5.20 hours in Group B, revealing no statistically significant difference (p=0.192). Total 24-hour acetaminophen consumption was also significantly different between the groups,

with 102.6±89.62 mg consumed in Group A compared with 118.99±98.71 mg in Group B (p=0.012).

Postoperative FLACC pain scores at different assessment intervals are presented in [Table 5]. At 30 minutes, the mean FLACC scores were low and comparable between Group A and Group B (0.1±0.35 vs. 0.3±0.48; p=0.13). At 2 hours, Group A demonstrated a lower mean pain score than Group B (0.3±0.48 vs. 0.5±0.51; p<0.001). This difference became more pronounced at 4 hours (0.5±0.67 vs. 1.0±0.79; p<0.001) and 6 hours (0.6±0.59 vs. 1.9±1.21; p<0.001). At 12 hours, the mean FLACC score remained lower in Group A (0.6±1.40 vs. 1.3±1.62; p=0.03). Overall, the reported pain scores indicated better postoperative pain control in Group A at most later assessment intervals.

Postoperative complications are summarized in [Table 6]. No vomiting was reported in Group A, whereas vomiting occurred in 5 patients (6.7%) in Group B. Fever was not reported in Group A, while 8 patients (10.7%) in Group B experienced fever. The reported p value for both complications was 0.36, indicating that the observed differences were not statistically significant.

Table 1: FLACC postoperative pain score

Category	Scoring 0	Scoring 1	Scoring 2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry	No cry, awake or asleep	Moans or whimpers; occasional complaint	Crying steadily, screams, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touch or hugging or being talked to	Difficulty to console or comfort

Table 2: Demographic characteristics, ASA classification, baseline vital signs and mean duration of surgery (N=150)

Variables	Group A (n=75)	Group B (n=75)	p value
Age (years)	2.9±1.06	2.8±1.08	0.95
Weight (kg)	17.24±4.47	16.8±3.76	0.73
Gender (M:F)	70:5 (93.3:6.7)	68:7 (90.7:9.3)	0.66
SBP (mmHg)	112.8±10.51	115.2±8.32	0.47
DBP (mmHg)	70.4±8.32	71.1±7.52	0.90
MAP (mmHg)	82.8±6.49	83.4±5.80	0.89
PR (beats/min)	102.3±10.05	105.7±10.23	0.54
SpO_2 (%)	99.9±0.21	99.8±0.53	0.25
Temperature (°C)	36.9±0.25	37.0±0.23	0.16
ASA I	70 (93.3)	67 (89.3)	0.89
ASA II	5 (6.7)	8 (10.7)	0.99
Mean duration of surgery (min)	50.82±33.20	50.95±30.89	0.99

Statistically Significance at p≤0.05

Table 3: Distribution of surgeries across the groups (N=150)

Surgeries	Group A (n=75)	Group B (n=75)
Herniotomy	38 (50.7%)	40 (53.3%)
Orchidopexy	30 (40.0%)	23 (30.7%)
Hypospadias repair	7 (9.3%)	12 (16.0%)

Table 4: Time to first analgesic request and total 24-hour analgesic consumption in each group (N=150)

Item	Group A (n=75)	Group B (n=75)	p value
Mean analgesic duration (hours)	14.4±2.36	12.0±3.69	0.002*
Median analgesic duration (hours)	17.17±4.47	17.83±5.20	0.192
Total 24-hour acetaminophen consumption (mg)	102.6±89.62	118.99±98.71	0.012*

Table 5: Postoperative pain assessment using FLACC score at different time points (N=150)

Pain assessment (FLACC)	Group A (n=75)	Group B (n=75)	p value
30 minutes	0.1±0.35	0.3±0.48	0.13
2 hours	0.3±0.48	0.5±0.51	0.001*
4 hours	0.5±0.67	1.0±0.79	0.001*
6 hours	0.6±0.59	1.9±1.21	0.001*
12 hours	0.6±1.40	1.3±1.62	0.03*

* Indicate statistically significance at p≤0.05

Table 6: Postoperative complications among groups in the study (N=150)

Complications	Group A (n=75)	Group B (n=75)	p value
Vomiting			
Yes	0 (0.0)	5 (6.7)	0.36

No	75 (100.0)	70 (93.3)	
Fever			
Yes	0 (0.0)	8 (10.7)	0.36
No	75 (100.0)	67 (89.3)	

Statistically Significance at p≤0.05

Discussion

The current investigation assessed the postoperative pain relief effectiveness of caudal ropivacaine in conjunction with ketamine vs caudal ropivacaine paired with midazolam in pediatric patients undergoing infraumbilical procedures. The principal findings were that Group A demonstrated a longer mean duration of analgesia, lower FLACC pain scores at most postoperative assessment points, and lower 24-hour acetaminophen consumption compared with Group B. These findings suggest that the addition of ketamine to caudal ropivacaine provided more sustained postoperative analgesia than the ropivacaine-midazolam combination in the present study.

The analgesic advantage of ketamine observed in the present study is consistent with previous investigations of ketamine as an adjuvant to caudal local anaesthetics. Choudhuri et al. indicated that the incorporation of ketamine with caudal bupivacaine markedly extended the analgesic duration relative to bupivacaine alone in pediatric patients having inguinal hernia surgery.[11] Similarly, ketamine has been investigated as a caudal adjuvant because of its NMDA-receptor antagonistic activity and potential to enhance and prolong postoperative analgesia when combined with a local anaesthetic.[12]

The present findings are also supported by the study of Selvakumaran et al., which specifically compared caudal ropivacaine with ropivacaine plus ketamine in paediatric patients undergoing below-umbilical surgery.[13,14] Their study evaluated the efficacy of adding ketamine to ropivacaine and supports the use of this combination as an approach for improving postoperative analgesia in children. The consistency between these findings and the present results is particularly relevant because the local anaesthetic used in both studies was ropivacaine.

The ongoing research revealed that the mean analgesic duration was considerably extended in Group A relative to Group B (14.4±2.36 versus 12.0±3.69 hours; p=0.002). Furthermore, the cumulative acetaminophen usage within a 24-hour period was considerably diminished in Group A (102.6±89.62 mg) relative to Group B (118.99±98.71 mg; p=0.012). These findings indicate that the longer analgesic effect associated with the ropivacaine-ketamine combination was accompanied by a reduced requirement for rescue medication. Similar reductions in postoperative supplemental analgesic requirements have been reported when caudal local anaesthetics are combined with suitable adjuvants.[11,14]

The FLACC scores provided further evidence of better postoperative analgesia with ketamine. Although the difference between the groups at 30 minutes was not statistically significant, Group A showed significantly lower FLACC scores at 2, 4, 6, and 12 hours. The greatest separation between groups was observed at 6 hours, when the mean FLACC score was 0.6±0.59 in Group A compared with 1.9±1.21 in Group B. The persistence of lower pain scores at later postoperative intervals suggests that the benefit of the ropivacaine-ketamine combination was particularly evident after the immediate postoperative period.

Midazolam has also been studied as an adjuvant for caudal analgesia in children. Mohan AM et al. evaluated caudal midazolam in children and demonstrated its potential to provide postoperative analgesia when administered through the caudal route.[13] Thus, the use of midazolam in the present study is supported by previous paediatric caudal analgesia research. However, the current results indicate that, under the conditions of this study, ropivacaine combined with ketamine produced superior analgesic outcomes compared with ropivacaine combined with midazolam.

Comparative research involving different caudal adjuvants demonstrates that the choice of adjuvant can influence the duration and quality of postoperative analgesia. Studies evaluating combinations of local anaesthetics with ketamine and other agents have reported differences in postoperative pain control and rescue analgesic requirements.[11,12] Recent studies concerning ropivacaine and additional caudal additives have similarly shown that altering the adjuvant element can influence the length of postoperative pain relief and analgesic usage in pediatric patients following infraumbilical procedures.[15]

The safety results in the current investigation were predominantly positive. Emesis was observed in 5 individuals (6.7%) from Group B, whereas none in Group A experienced this symptom; also, pyrexia was noted in 8 individuals (10.7%) from Group B, with no occurrences in Group A. However, the reported differences were not statistically significant. Therefore, although these events occurred more frequently in Group B, the present data do not establish a significant difference in postoperative complications between the two regimens.

The two factions were similar in terms of critical baseline factors. No substantial variations were observed in age, weight, gender distribution, baseline hemodynamic indicators, oxygen saturation, temperature, ASA classification, or length of surgery. The distribution of surgical procedures was also documented in both groups. This baseline comparability strengthens the interpretation that the observed differences in postoperative pain scores, analgesic duration, and acetaminophen consumption were associated primarily with the differing caudal analgesic regimens.

The present study has some limitations. The available study information does not provide detailed drug concentrations, exact doses of ropivacaine, ketamine, or midazolam, or details regarding randomization and blinding procedures. In addition, the study population included different infraumbilical procedures, which may have variable postoperative pain characteristics. The reported analgesic duration data also contain a distinction between mean and median values that should be interpreted carefully. Nevertheless, the consistent reduction in

FLACC scores and acetaminophen consumption in Group A provides evidence favouring the ropivacaine-ketamine combination within the studied population.

Conclusion

Caudal ropivacaine in conjunction with ketamine yielded superior postoperative analgesic effectiveness compared to caudal ropivacaine paired with midazolam in pediatric patients receiving infraumbilical procedures. The ketamine combination correlated with an extended average duration of analgesia, markedly diminished FLACC pain levels during the majority of postoperative evaluation intervals and decreased 24-hour acetaminophen usage. Both treatment protocols exhibited comparably low incidences of postoperative complications, with no statistically significant variation in the documented adverse events. Based on the constraints of the accessible data, caudal ropivacaine combined with ketamine seems to be a superior choice for extending postoperative pain relief in pediatric patients undergoing infraumbilical surgeries.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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