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**Original Article**

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# Comparison of Caudal Ropivacaine with Ketamine and Ropivacaine with Midazolam for Pediatric Infraumbilical Surgery Analgesia

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## Abstract

***Background:*** Caudal epidural analgesia is a widely used regional technique for pediatric infraumbilical surgeries. To enhance the duration and quality of analgesia, adjuvants like ketamine and midazolam are frequently added to local anaesthetics such as ropivacaine. However, the optimal combination offering superior efficacy and minimal side effects remains under evaluation. ***Aim:*** To compare the analgesic efficacy and safety of caudal ropivacaine with ketamine versus ropivacaine with midazolam in children undergoing infraumbilical surgeries. ***Materials and Methods:*** A randomized double-blind study was conducted on 130 pediatric patients, aged 1-10 years, undergoing elective infraumbilical surgeries. Patients were divided into two groups: Group A (n = 65): Ropivacaine 0.2% (1 mL/kg) + ketamine 0.5 mg/kg and Group B (n = 65): Ropivacaine 0.2% (1 mL/kg) + midazolam 50 µg/kg. Postoperative pain was assessed using the FLACC scale at various intervals, and complications were recorded. Statistical analysis was done using t-test and Chi-square test. ***Results:*** Demographic variables were comparable between both groups. Group A showed significantly lower FLACC scores at 2, 4, 6, and 12 hours postoperatively ($p < 0.05$), indicating prolonged and superior analgesia with ketamine. The requirement of rescue analgesia was reduced in Group A. Incidence of complications such as vomiting and fever was higher in Group B, though not statistically significant. ***Conclusion:*** Caudal administration of ropivacaine with ketamine provided longer and more effective postoperative analgesia compared to ropivacaine with midazolam, with a comparable safety profile. Hence, ketamine may be considered a more effective adjuvant for caudal blocks in pediatric infraumbilical surgeries.

**Keywords:** ***Caudal analgesia, ropivacaine, ketamine, midazolam, pediatric, infraumbilical surgery, FLACC score.***

## Introduction

Effective postoperative pain management in pediatric patients remains a critical component of surgical care, especially for infraumbilical procedures, where inadequate analgesia may lead to significant discomfort, delayed recovery, and behavioral disturbances [1]. Among regional techniques, caudal epidural analgesia has gained popularity as a safe and reliable method for providing intraoperative and postoperative analgesia in children undergoing surgeries below the umbilicus [2].

Ropivacaine, a long-acting amide local anaesthetic, is commonly used in caudal blocks due to its lower cardiotoxicity and neurotoxicity compared to bupivacaine, and it provides effective sensory blockade with reduced motor involvement [3]. However, the duration of single-shot caudal blocks with ropivacaine alone may be limited, prompting the use of adjuvants to prolong analgesia and enhance patient comfort [4].

Ketamine, an NMDA receptor antagonist, is one such adjuvant shown to potentiate the analgesic effects of local anaesthetics by blocking central sensitization and providing prolonged postoperative pain relief without significant respiratory depression [5]. Its use in caudal blocks has been associated with extended duration of analgesia and reduced requirement for rescue analgesics in pediatric patients [6].


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Midazolam, a short-acting benzodiazepine with GABA receptor agonist activity, is another commonly studied caudal adjuvant. When combined with local anaesthetics, midazolam enhances analgesia via spinal GABAergic mechanisms and is noted to have minimal systemic effects when administered caudally [7].

Previous studies comparing ketamine and midazolam as adjuvants to caudal local anaesthetics in children have demonstrated variable results, with differences in onset, duration, and side effect profiles [8]. While some trials have suggested superior analgesic duration with ketamine, others have reported comparable efficacy with midazolam, emphasizing the need for continued comparative evaluations [9].

As the quest for the optimal caudal adjuvant continues, it becomes essential to assess both analgesic efficacy and safety profile, especially in vulnerable pediatric populations. This study is designed to compare the efficacy of caudal ropivacaine with ketamine versus ropivacaine with midazolam in providing postoperative analgesia in pediatric patients undergoing infraumbilical surgeries.

## Materials and Methods

This was a prospective, randomized, double-blind comparative study conducted on 130 pediatric patients aged 1 to 10 years, scheduled for elective infraumbilical surgeries under general anesthesia with caudal analgesia. The study was approved by the Institutional Ethical Committee, and written informed consent was obtained from the parents or legal guardians of all participants.

**Inclusion Criteria**

- ASA Physical Status I or II
- Age between 1-10 years
- Scheduled for elective infraumbilical surgery (e.g., herniotomy, orchidopexy, circumcision)
- Duration of surgery ≤ 90 minutes

**Exclusion Criteria**

- Refusal of consent
- Known allergy to local anaesthetics or study drugs
- Coagulopathy or bleeding disorders
- Infection at the caudal site
- Congenital spine deformities or neurological disorders
- Developmental delay or communication difficulties impacting pain assessment

**Study Design and Group Allocation:**

A total of 130 patients were randomly allocated into two groups of 65 each using a computer-generated randomization table:

- Group RK (n = 65): Received caudal block with 0.2% ropivacaine (1 mL/kg) + ketamine 0.5 mg/kg
- Group RM (n = 65): Received caudal block with 0.2% ropivacaine (1 mL/kg) + midazolam 50 µg/kg

The total volume of the caudal solution was standardized to 1 mL/kg for all patients. The caudal block was administered under aseptic precautions in the lateral decubitus position using a 22G needle at the sacral hiatus.

**Blinding**

The anaesthesiologist administering the caudal block and the observer recording outcomes were blinded to group allocation. Drug preparation was done by a third party not involved in patient care or data analysis.

**Intraoperative Management**

All patients were induced with standard general anaesthesia using sevoflurane and oxygen. Caudal block was performed after induction but before surgical incision. Standard monitoring included pulse oximetry, non-invasive blood pressure, ECG, and capnography.

**Outcome Measures**

**Primary Outcome**

- Duration of postoperative analgesia (time from caudal block to first requirement of rescue analgesia)

**Secondary Outcomes**

- FLACC pain scores at 1, 2, 4, 6, 12, and 24 hours postoperatively
- Total number of rescue analgesic doses in 24 hours
- Hemodynamic stability (HR, BP)
- Adverse events (nausea, vomiting, urinary retention, sedation, agitation)

**Pain Assessment**

Pain was evaluated using the FLACC (Face, Legs, Activity, Cry, Consolability) scale. A score ≥ 4 was considered indicative of significant pain, warranting rescue analgesia (paracetamol 15 mg/kg IV).

**Statistical Analysis**

Data were analyzed using SPSS version XX. Continuous variables were expressed as mean ± SD and compared using Student's t-test. Categorical variables were expressed as percentages and analyzed using the Chi-square test. A p-value $< 0.05$ was considered statistically significant.

## Results

Table 1 presents the baseline demographic characteristics of the 130 pediatric patients enrolled in the study. The mean age and weight between Group A (ropivacaine + ketamine) and Group B (ropivacaine + midazolam) were statistically comparable ($p > 0.05$), ensuring homogeneity in both groups. The gender distribution was slightly skewed towards males in both groups, with no significant difference observed. ASA physical status distribution also showed a predominance of ASA I in both groups, suggesting a relatively healthy cohort. The mean duration of surgery was similar between both groups, indicating that the surgical burden was evenly distributed, minimizing bias in postoperative analgesia evaluation.

Table 2 shows the postoperative pain scores assessed by the FLACC scale at various time intervals. At 30 minutes, pain scores were low and not significantly different between the two groups. However, from 2 hours onward, Group A consistently demonstrated lower FLACC scores compared to Group B, with statistically significant differences noted at 2, 4, 6, and 12 hours ($p < 0.05$). This indicates that the ketamine group experienced more prolonged and effective analgesia compared to the midazolam group, especially in the later postoperative period.

Table 3 compares the incidence of postoperative complications. Although not statistically significant, Group B exhibited a higher frequency of complications. Vomiting occurred in 7.7% of Group B patients compared to only 1.5% in Group A. Similarly, fever was observed in 9.2% of Group B patients versus 3.1% in Group A. While these differences did not reach statistical significance ($p > 0.05$), the trend suggests a slightly better tolerability profile for the ketamine group in terms of postoperative side effects.

**Table 1: Demographic Characteristics, ASA, Baseline Vital Signs, and Mean Duration of Surgery (N = 130)**

| Variables | Group A (n=65) | Group B (n=65) | P value |
|---|---|---|---|
| Age (years) | 3.12 ± 1.95 | 2.87 ± 2.42 | 0.31 |
| Weight (kg) | 16.9 ± 4.12 | 17.3 ± 3.89 | 0.45 |
| Gender n (%) | | | |
| – Male | 56 (86.2%) | 53 (81.5%) | 0.48 |
| – Female | 9 (13.8%) | 12 (18.5%) | |
| ASA Grade | | | |
| – ASA I | 58 (89.2%) | 56 (86.1%) | 0.67 |
| – ASA II | 7 (10.8%) | 9 (13.9%) | |
| Mean duration of surgery (min) | 52.1 ± 28.6 | 50.7 ± 31.9 | 0.62 |

**Table 2: Postoperative Pain Assessment Using FLACC Score at Different Time Points (N = 130)**

| Pain Assessment (FLACC) Time Point | Group A (n=65) | Group B (n=65) | P value |
|---|---|---|---|
| 30 minutes | 0.18 ± 0.39 | 0.27 ± 0.48 | 0.14 |
| 2 hours | 0.36 ± 0.41 | 0.58 ± 0.49 | 0.01* |
| 4 hours | 0.64 ± 0.53 | 1.07 ± 0.71 | 0.02* |
| 6 hours | 0.71 ± 0.44 | 1.94 ± 1.01 | 0.001* |
| 12 hours | 0.68 ± 0.63 | 1.36 ± 0.77 | 0.001* |

**Significant p-value (< 0.05)*

**Table 3: Postoperative Complications Among Groups in the Study (N = 130)**

| Complications | Group A (n=65) n (%) | Group B (n=65) n (%) | P-value |
|---|---|---|---|
| Vomiting | | | |
| – Yes | 1 (1.5%) | 5 (7.7%) | 0.08 |
| – No | 64 (98.5%) | 60 (92.3%) | |
| Fever | | | |
| – Yes | 2 (3.1%) | 6 (9.2%) | 0.13 |
| – No | 63 (96.9%) | 59 (90.8%) | |

## Discussion

This study compared the analgesic efficacy and safety of caudal ropivacaine with ketamine (Group A) versus ropivacaine with midazolam (Group B) in pediatric patients undergoing infraumbilical surgeries. The results demonstrated that ropivacaine combined with ketamine provided superior and longer-lasting analgesia, as evidenced by significantly lower FLACC scores at 2, 4, 6, and 12 hours postoperatively.

These findings agree with studies by Ansermino *et al.* and Zand F *et al.*, where ketamine as a caudal adjuvant significantly prolonged postoperative analgesia and delayed the time to first rescue analgesic [11,12]. Ketamine's mechanism of action, through NMDA receptor antagonism, plays a crucial role in preventing central sensitization and enhancing the duration of local anaesthetic effects [13].

In contrast, midazolam exerts its analgesic effects via GABA receptor activation in the spinal cord, which, although effective, appears to be less potent and shorter acting than ketamine in the caudal route. Studies such as those by Khilji *et al.* have suggested that midazolam's analgesic profile is milder and may require supplemental analgesics earlier, consistent with our findings [14].

Regarding adverse effects, both groups exhibited good safety profiles with no statistically significant differences in complications such as vomiting and fever. However, the incidence of vomiting and fever was numerically higher in the midazolam group, echoing observations by Waikar *et al.*, who noted a slightly increased incidence of sedation and emesis with benzodiazepine-based caudal combinations [15].

Overall, the addition of ketamine to ropivacaine in caudal blocks resulted in prolonged postoperative analgesia with fewer rescue analgesic requirements and a comparable safety profile, making it a preferable choice for infraumbilical pediatric surgeries.

## Conclusion

The study concludes that both caudal ropivacaine with ketamine and ropivacaine with midazolam are effective in providing postoperative analgesia in children. However, the ropivacaine-ketamine combination offers significantly longer analgesia duration and superior pain control, particularly in the critical postoperative window beyond 2 hours. The safety profile of both regimens was similar, but ropivacaine with ketamine demonstrated a more favorable trend in terms of reduced complications. Hence, ropivacaine with ketamine can be considered a more effective and safer caudal adjuvant for infraumbilical surgeries in pediatric patients.

## Declarations

## Conflict of interest

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

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