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EFFICACY OF CAUDAL ROPIVACAINE WITH KETAMINE VERSUS ROPIVACAINE WITH MIDAZOLAM FOR ANALGESIA IN PEDIATRIC INFRAUMBILICAL SURGERY

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ABSTRACT: Aim: This study aimed to compare the analgesic efficacy of caudal ropivacaine and ketamine with ropivacaine and midazolam in paediatric patients undergoing infraumbilical surgery. **Material and Methods:** A study was conducted involving a group of 100 paediatric patients who underwent infraumbilical surgery. The study participants were divided into two groups: Group A received 1.0 ml/kg of 0.15% ropivacaine with 0.3 mg/kg of ketamine, while Group B received 1.0 ml/kg of 0.15% ropivacaine with 0.03 mg/kg of midazolam. The duration of the surgery, the duration of anaesthesia, the use of inhalation agents, and any complications were carefully documented. **Results:** The TTFAR for groups A and B were 14.5±3.50 hours and 12.26±4.12 hours, respectively. There was a significant difference in values between groups A and B ($p \leq 0.05$). The mean total fentanyl acetaminophen consumption in 24 hours was 101.79±79.14 mg for group A and 117.50±97.50 mg for group B. After the surgery, there was a noticeable difference in the FLACC pain scores between the two groups at various time intervals. **Conclusion:** The combination of Ropivacaine and ketamine showed better results in terms of the duration of postoperative analgesia and time for the first request of analgesic compared to the combination of Ropivacaine and midazolam.

INTRODUCTION: Regional anaesthesia in children has been gaining popularity over the past few decades due to its ability to reduce the use of unknown drugs and provide improved stability. The caudal block is a widely used regional anaesthetic procedure in paediatric patients for surgeries below the umbilicus. It is highly regarded and commonly performed by medical professionals. There are two ways to administer the block: a single-shot injection or a continuous infusion through a caudal epidural catheter.

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When it comes to continuous infusion, using a caudal catheter is generally not recommended because there is a high risk of catheter contamination from faecal soiling [1]. Minimal haemodynamic changes are observed following caudal block in children, as compared to adults. The reasons for this condition involve the widening of blood vessels throughout the body and a decrease in blood volume in the legs and splanchnic system [2].

In the past, there has been a tendency to not provide adequate treatment for pain and painful procedures in children. Since, its initial description by Campbell in 1933, the caudal epidural block has undergone significant advancements and is now widely recognised as the preferred regional anaesthetic technique for managing pain during and after surgery in children, particularly since the

1980s [3]. The caudal block is considered one of the most straightforward and easily mastered techniques among all regional anaesthetic procedures [4, 5]. One significant drawback of this technique is that the pain relief it provides after surgery is not long-lasting, even when using long-acting local anaesthetics. Various adjuvants have been used to prolong analgesia with the caudal technique, with opioids being the most commonly used medication.

Opioids were frequently utilized as adjuncts to extend the duration of pain relief. Regrettably, there have been reports of various side effects linked to caudal opioids. These symptoms include nausea, vomiting, itching, difficulty urinating, and shallow breathing. Respiratory depression can be a result of opioids spreading to the medullary respiratory centre, causing a decrease in respiratory function [6, 7]. After caudal opioids are administered, either alone or with local anaesthetics, it is important to closely monitor the patient for at least 24 hours following surgery. This is because the duration of time during which the child may be at risk of hypoventilation is uncertain [8]. Continuing research is being conducted to find the best combination of medications for caudal anaesthesia. Dexmedetomidine functions as a selective alpha-2 receptor agonist. It possesses pain-relieving and anxiety-reducing properties with minimal side effects. Midazolam is a benzodiazepine that possesses anxiolytic, sedative, and anticonvulsant properties. The analgesic effects of this substance are mediated by receptors in spinal cord [9]. Ropivacaine, an amide local anaesthetic, is well-suited for day-care surgery in children due to its ability to produce targeted neural blockade while minimising motor blockade, cardiovascular issues, and neurological toxicity. Various additives have been studied to prolong the duration of post-operative analgesia provided by the 'single shot' caudal technique. These include tramadol, ketamine, ephedrine, morphine, fentanyl, and clonidine, which have been combined with local anaesthetics [10].

Midazolam is thought to prolong the analgesic effects when used as an adjunct in the caudal block. There is a lack of research that compares the effectiveness, sedative properties, and potential side effects of midazolam and dexmedetomidine when used alongside ropivacaine in caudal blocks. For children undergoing infraumbilical surgeries, it is important to investigate the use of these adjuvants alongside caudal ropivacaine [11, 12]. Single-shot blocks have a duration of action that is limited and influenced by the volume and concentration of the drug administered. There are ways to extend the duration of action, such as adding additives or using catheters for continuous analgesia. This study aimed to compare the analgesic efficacy of caudal ropivacaine and ketamine with ropivacaine and midazolam in paediatric patients undergoing infraumbilical surgery.

MATERIAL AND METHODS: A study was conducted at a Department of Anaesthesia Tertiary Care Teaching Institute in India from May 2023 to January 2024. A study was conducted with a group of 100 paediatric patients who underwent infraumbilical surgery. The study includes 50 patients in each group, aged between one and seven years of any gender, weighing between 8 and 25 kg, and classified as ASA I to III. Exclusion criteria for the study included patients with a previous infection at the back, drug allergies, bleeding or coagulation disorders, developmental delays, sepsis, pre-existing neurological or spinal diseases, and allergies to the study drugs.

Children underwent monitoring for ECG, NIBP, SpO2, temperature, and EtCO2. A dose of 0.004 mg/kg of glycopyrrolate was administered as a premedication through an intravenous injection. The anaesthesia induction involved the use of inhalation method with 100% oxygen and Sevoflurane ranging from 2 to 7%. The insertion of the I-gel was made easier with the administration of 2 mg/kg of succinyl choline. The anaesthesia was maintained using a combination of 50% oxygen and 50% nitrous oxide, along with Sevoflurane at a concentration of 1 to 2%. Additionally, an injection of atracurium at a dose of 0.5 mg/kg was administered. Random selections were made using a closed envelope method. The caudal epidural procedure was carried out using a 22-gauze epidural needle, ensuring complete aseptic precautions were taken, while the child was positioned on their left side. Once the confirmation was made and blood and CSF aspiration came back negative, the study drugs were administered.

The study participants were divided into two groups: Group A received 1.0 ml/kg of 0.15% ropivacaine with 0.3 mg/kg of ketamine, while Group B received 1.0 ml/kg of 0.15% ropivacaine with 0.03 mg/kg of midazolam. During the surgical procedure, the medical team ensured that peripheral venous access was established and vital parameter monitors, including heart rate, electrocardiogram, blood pressure, and pulse oximeter, were properly attached. The co-induction agent was prepared in a 5 ml syringe by a separate Anaesthesiologist or Anaesthetic assistant who was not involved in the study.

No additional pain relief was provided during the surgery. The perioperative haemodynamic parameters including NIBP, heart rate, SpO2, and EtCO2 were consistently monitored and recorded every 15 minutes until the conclusion of the surgery. During surgery, the assessment of sufficient pain relief was determined by monitoring changes in haemodynamics and the need for sevoflurane concentration. If the heart rate and systolic blood pressure rise after 15 to 20 minutes of caudal block, it is seen as a failure of caudal anaesthesia. After the surgery, the neuromuscular blockade was reversed using neostigmine at a dose of 0.05 mg/kg and glycopyrrolate at a dose of 0.008 mg/kg. The surgery duration, anaesthesia duration, use of inhalation agent, and occurrence of complications such as bradycardia, tachycardia, hypotension, hypertension, vomiting, and delayed motor recovery were all carefully documented. The evaluation of postoperative pain involved the use of the FLACC score, which has a maximum score of 10. This assessment was conducted at one-hour intervals for the first three hours, and then every two hours until the score exceeded three for a total of 24 hours. In cases where the score was higher than three, a rescue analgesic was administered.

Statistical Analysis: The data was compiled and entered into a spreadsheet computer program (Microsoft Excel 2019) and then exported to the data editor page of SPSS version 19 (SPSS Inc., Chicago, Illinois, USA). Quantitative variables were reported using measures such as means and standard deviations or median and interquartile range, depending on their distribution. The qualitative variables were displayed as counts and percentages. Confidence level and level of significance were set at 95% and 5% respectively for all tests.

RESULTS: The patients' demographics, ASA classifications, and mean duration of surgery in the groups were similar **Table 1.**

Based on the surgeries performed, it was found that in group A, 25 patients (50%) underwent herniotomy, 20 patients (40%) underwent orchidopexy, and 5 patients (10%) underwent hypospadias repair. Group B consisted of 26 patients (52%) who underwent herniotomy, 15 patients (30%) who had orchidopexy, and 8 patients (16%) who underwent hypospadias repair.

The TTFAR for groups A and B were 14.5±3.50 hours and 12.26±4.12 hours, respectively. There was a significant difference in values between groups A and B ($p \leq 0.05$). In the 24-hour period following surgery, the average fentanyl consumption was 17.45±5.35 µg for group A and 17.78±6.10 µg for group B. As for acetaminophen, group A had an average consumption of 101.79±79.14 mg, while group B had an average consumption of 117.50±97.50 mg. After analysing the data, it was found that there was a significant difference in paracetamol consumption between groups A and B (p0.05). In **Table 2**, the mean FLACC pain scores at 30 minutes, 2, 4, 6, and 12 hours after surgery are presented. The p values for these time points indicate a significant difference in pain scores between the two groups. The results were statistically significant ($p \leq 0.05$).

TABLE 1: DEMOGRAPHIC CHARACTERISTICS, ASA, BASELINE VITAL SIGNS AND MEAN DURATION OF SURGERY (N=100)

Variables	Group A (n=50)	Group B (n=50)	P value
Age (years)	2.95±2.12	2.78±2.55	0.25
Weight (kg)	17.2±4.47	16.8±3.76	
Gender n (%)			
Male	44 (88)	42 (84)	
Female	6 (12)	8 (16)	0.09

ASA Grade			
ASA I	45 (90)	44 (88)	0.08
ASA II	5 (10)	6 (12)	
Mean duration of surgery in minutes	51.05±34.10	50.67±29.06	0.12

Statistically significance at p≤0.05

TABLE 2: POSTOPERATIVE PAIN ASSESSMENT USING FLACC SCORE AT DIFFERENT TIME POINTS (N=100)

Pain assessment (FLACC)	Group A (n=50)	Group B (n=50)	P value
30 minutes	0.12±0.44	0.29±0.50	0.10
2 hours	0.31±0.51	0.49±0.22	0.001*
4 hours	0.52±0.65	1.01±0.80	0.02*
6 hours	0.59±0.24	1.89±1.06	0.05*
12 hours	0.61±0.58	1.29±0.61	0.001*

TABLE 3: POSTOPERATIVE COMPLICATIONS AMONG GROUPS IN THE STUDY (N=100)

Complications	Group A (n=50) n (%)	Group B (n=50) n (%)	P-value
Vomiting			
Yes	0	3 (6)	0.22
No	50 (100)	47 (94)	
Fever			
Yes	0	5 (10)	0.09
No	50 (100)	45 (90)	

DISCUSSION: According to this study, the combination of ketamine and caudal ropivacaine in children undergoing ambulatory groin surgery has been found to significantly increase the duration of pain relief and reduce the need for pain medication in the first 24 hours after the operation. Caudal blockade is a widely used regional technique in children. This method is both simple and safe, providing effective pain relief before and after surgery with a high rate of success [13, 14]. After the surgery, group A had a mean FLACC score of less than three, which was lower than group B. Ropivacaine is a recently developed amide local anaesthetic that shares a similar profile to equipotent doses of bupivacaine. It offers exceptional pain relief after surgery through either an epidural or perineural method. With lower intrinsic toxicity, this local anaesthetic offers an increased margin of safety compared to others [15, 16]. Comparing the use of ketamine added to local anaesthetics versus other adjuvants added to local anaesthetics. Adding ketamine to local anaesthetics for a caudal block to control children's postoperative pain has emerged as a recent trend, when compared to other adjuvants like dexamethasone, fentanyl, morphine, and adrenaline. When neostigmine, midazolam, and ketamine are combined with bupivacaine for caudal block in children, the need for additional pain relief is significantly reduced. There was a delay in administering the initial rescue analgesic in the group using pure ropivacaine, but this did not result in any significant differences in complications during the first 24 hours after surgery among the four study groups.

In a recent study, researchers found that ketamine outperformed fentanyl when combined with ropivacaine for caudal block in children undergoing infraumbilical surgery. Not only did ketamine provide a longer duration of pain relief, but it also effectively reduced the neuroendocrine stress response. What's more, ketamine achieved these results without any notable side effects. These findings highlight the potential benefits of using ketamine in pediatric anesthesia [17, 18].

The TTFAR for groups A and B were 14.5±3.50 hours and 12.26±4.12 hours, respectively. There was a significant difference in values between groups A and B (p≤0.05). In the 24-hour period following surgery, groups A and B had average fentanyl consumptions of 17.45±5.35 µg and 17.78±6.10 µg, respectively. The average acetaminophen consumption in the same timeframe was 101.79±79.14 mg for group A and 117.50±97.50 mg for group B. In group A, a significantly longer TTFAR was found compared to group B. Nevertheless, both groups experienced minimal adverse effects.

When a local anesthetic is used without adjuvants, its duration of action is limited and it can cause side effects that depend on the dose. The findings align with a study that examined the use of dexmedetomidine as an adjuvant with 0.25% ropivacaine caudally [19]. The study observed that the group receiving the ropivacaine-dexmedetomidine mixture experienced a significantly longer duration of analgesia compared to the group receiving ropivacaine alone [20].

In another study, dexmedetomidine and clonidine were administered caudally as adjuvants with 0.25% bupivacaine, both at a dose of 2 μg/kg [21]. In a recent study, Soujanya U *et al* [22] examined the effectiveness of different local anaesthetics for postoperative pain relief in children aged 2-10 years undergoing caudal anaesthesia. The researchers compared the use of equal volumes of 0.25% Levobupivacaine, Ropivacaine, and Bupivacaine at a dosage of 1ml/kg. The authors found that there was no significant difference in the mean FLACC Score at recovery from anaesthesia and at 30 minutes, as indicated by a P value greater than 0.05. The Mean FLACC Score showed statistical significance ($p < 0.05$) at 60 minutes, 120 minutes, and 240 minutes. In the early hours, the results of our study showed significant findings at the 1st, 3rd, and 4th hour, with a p-value of less than 0.05.

Group B had the shortest duration of analgesia and achieved a pain score of ≥4 earliest, when compared to groups A and B. Nevertheless, the study conducted by Xiang *et al.* did not account for the potential impacts of ketamine. In this study, it is important to note that Ketamine was not given to the subjects in order to avoid any confounding variables. In this study, a dose of 1.0 ml/kg, 0.15% ropivacaine was administered [23]. Although the dosage used in the study by Goyal et al. was higher at 1.0 ml/kg with 0.15% ropivacaine, the postoperative analgesic durations are similar [24].

It is clear that Kumar *et al.* made an interesting observation regarding the use of 70% nitrous oxide and a higher dose of 1.0 ml/kg, 0.15% ropivacaine combined with 50 μg/kg midazolam [25]. It is worth noting that in the study conducted by Gulec *et al.*, they found that the group of patients who received ropivacaine and midazolam experienced prolonged sedation. This finding could potentially explain why they also observed a longer duration of pain relief, as sedation can effectively substitute for analgesia in nonverbal children [26]. In a study conducted by Veeravalli S *et al,* the postoperative analgesic efficacy of caudal Levobupivacaine was compared with Ropivacaine in paediatric patients [27]. They have divided 80 patients, ranging from 1 to 10 years old, into two groups. Both Group A and Group B were administered 1ml/kg of 0.25% caudal Levobupivacaine and Ropivacaine, respectively.

The postoperative pain was evaluated using the CHIPPS Score for patients under 6 years old and a numerical scale for those over 6 years old. The analysis showed no significant variation in the standard deviation between the groups (p value > 0.05), indicating that the postoperative pain scores were similar for both groups. Group A's reduced total analgesic consumption aligns with the findings of Salama *et al* [28]. Although Baris *et al.* found no difference in analgesic requirement among the groups in their study, they did acknowledge the benefits of using ropivacaine with an adjuvant combination compared to ketamine alone for more painful surgeries during caudal block [29]. One patient in Group B experienced vomiting and fever, occurring 5 hours after the operation, according to this study. The patient showed positive results with the use of tepid water sponging and paracetamol treatment.

In a related study, Himabindu *et al.* found a higher incidence (18%) of vomiting, which is likely due to the use of nitrous oxide [30]. In a study conducted by Locatelli B *et al.,* it was found that both Levobupivacaine and Ropivacaine resulted in an equal proportion of patients experiencing nausea or vomiting after surgery [31]. The difference was not statistically significant, mirroring our study. In a study conducted by Soujanya U *et al* [22], three different types of anaesthetics were compared.

The researchers used an equal volume of 1ml/kg of 0.25% Levobupivacaine, 0.25% Ropivacaine, and 0.25% Bupivacaine. No cases of postoperative complications such as nausea and vomiting were reported in either of the groups, mirroring the findings of our study. It is important to consider using ultrasound guidance for caudal block

administration in cases where detecting sacral anatomy is challenging, particularly through palpation. This can help overcome limitations in the study.

CONCLUSION: The duration of postoperative analgesia along with time for first request of analgesic was comparitavely superior in Ropivacaine and ketamine combination rather than Ropivacaine and midazolam combination without significant adverse effects or derangement in haemodynamic parameters. Despite unanswered questions exist, ketamine can be safely used as an adjuvant for caudal block in pediatrics for postoperative pain management to extend analgesic duration provided by local anesthetics alone with rare side effects. This adjuvant also decreases postoperative opioid consumption by prolonging the first analgesic requirement time.

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