Section: Anaesthesiology

Original Research Article

COMPARATIVE STUDY OF CAUDAL BLOCK BETWEEN ROPIVACAINE AND ROPIVACAINE WITH KETAMINE IN PAEDIATRIC AGE GROUP FOR INFRA UMBILICAL SURGICAL PROCEDURES

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ABSTRACT

Background: Children are more susceptible for pain during Intra Operative and Immediate Post-operative period. Most of the surgical procedures in children are carried out in General Anaesthesia. Caudal anaesthesia is supplemented to ensure Intra operative and Post-operative analgesia in the children who were posted for Infra Umbilical Surgical Procedures. **Materials and Methods:** Children of age group between 0ne to 10 years are taken up for the study. These children are posted for Umbilical and Infra Umbilical Surgical procedures under General Anaesthesia with Endo Tracheal gases. Comparative study was done with Inj. Ropivacaine 0.2% (1 ml/kg) for Group R and Inj. Ropivacaine 0.2%+Ketamine (0.2mg/kg) for Group RK for intra operative Hemodynamic changes and Post-Operative analgesia. The severity of pain was assessed with the Face, Legs, Activity, Cry, and Consolability scale or FLACC scale at 0 hours, 4 hours, 8 hours, 12 hours, 16 hours, 20 hours, and 24 hours. Motor blockade was measured with a Bromage scale at 0 hours, 1hour, and 2hours.Rescue analgesia was given when the FLACC scale score exceeded 3. Time of the first rescue analgesia was recorded. Any complications in Post-operative period are noted**. Results:** The duration of action of caudal analgesia is significantly higher in Group RK. At 4 and 8 hours, group RK showed significantly lower pain score than group RK indicating that the combination of Ropivacaine and Ketamine provided superior analgesia during early post-operative period. However, the pain scores at 24 hours post operatively is comparable between both groups, with p value of 0.33 suggesting no significant difference in pain levels at this time point. **Conclusion:** The addition of ketamine to Ropivacaine enhances post-operative pain relief and reduces analgesic requirements in children undergoing infra umbilical surgeries.

INTRODUCTION

Pain relief in children post-operatively is of much importance as the emotional part of pain is quite strong in them. Since pain is usually difficult to assess in the pediatric population, it is commonly under treated in them.[1] The assessment of pain in children is linked to their level of development. Children of the same age have different levels of perception of pain and the level of tolerance differs. If left unaddressed, chronic pain can affect children emotionally and psychologically, leaving them with scars that can affect their future healthcare choices.

The caudal regional block provides safe and effective analgesia. It is a commonly used procedure in children. A simple, reliable technique can be used with general anesthesia for providing intra and postoperative analgesia in patients coming for umbilical and sub-umbilical surgeries within the distribution of T10 –S5 dermatomes. The major drawback however is the short duration of action after a single injection of local anesthetic drugs.[3]

A single dose of caudal levo bupivacaine or Ropivacaine can provide effective analgesia for 4 to 8 hours, with a high success rate and minimal risk of adverse effects. Adding certain additives to local anesthetics has been shown to extend the duration of

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caudal analgesia.[2] The most commonly used additives were Clonidine, Ketamine, Opioids, Adrenaline, and Midazolam. Ropivacaine has been demonstrated to be an extremely effective agent for caudal analgesia but its use in combination with Ketamine has not previously been reported. This study is designed to determine if preservative free [4]Ketamine is added to lower concentration of Ropivacaine (0.2%) is as effective as Ropivacaine 0.2% alone for caudal anesthesia in children undergoing umbilical and sub-umbilical surgeries.

Aims and Objectives

The primary objectives is to compare the duration of analgesia between the two Groups using the FLACC score, the time taken for both groups to start rescue analgesia and to assess the duration of motor block in both groups as measured by Bromage scale.

The secondary objectives is to,[5] compare intra operative pain between the two groups by analyzing hemodynamic parameters, such as heart rate and oxygen saturation, at various

Intervals.

MATERIALS AND METHODS

The study design was a Randomized, single-blinded, interventional conducted at the tertiary care hospital. The Institutional Ethics Committee approved the study (vide approval number 110/IECAMC/ MAY2023) for 14months from October 2022 to April 2024 with 14 months of data collection following the principles of the Declaration of Helsinki (2013) and Good Clinical Practice guidelines. Written informed consent was obtained from all patients participating in the study, with permission to use the data for research and educational purposes. The study was randomized as patients were randomly allotted into either of two groups by computer-generated software. (ASA) physical status I/II, aged 1-10 years, of both genders, scheduled for infra umbilical surgeries under general anesthesia were assessed for eligibility. Patients with age more than 12 years, patients with infection at the site, bleeding disorders, patients who are on anticoagulant therapy, congenital anomalies of the spinal cord, patients allergic to anesthetic drugs, surgeries extending more than 90 minutes, surgeries requiring anesthesia above t10 level, patients' guardians who refused consent are excluded. The study protocol was discussed with patient's guardians and those who consented were subsequently enrolled. FLACC score (where Face, Legs, Activity, Cry, and Consolability) was explained to the patients and they were randomized into two groups, including 6Ropivacaine caudal block (group R, n=30) and Ropivacaine and Ketamine adjuvant (group RK, n=30), using computer generated codes [using statistical package for the social sciences (SPSS) statistics software version 1.5 kept in serially arranged sealed envelopes in a wide container. The envelope was picked by an independent investigator who did not participate further in patient management.

After transferring the patient into the operating room, the standard ASA monitors were attached and baseline readings of heart rate (HR), oxygen saturation (SpO2), systolic blood pressure (SBP), and diastolic blood pressure (DBP) were obtained. Patients were induced with a gas mixture of nitrous oxide, oxygen, and sevoflurane, and intravenous access was achieved. Fentanyl 0.2 mg/kg and Propofol 2 mg/kg body weight were given and the patient's airway secured with reusable endotracheal tube of appropriate size.

After inducing general anesthesia, each child was placed in the left lateral position, and the skin was aseptically prepared and draped. The sacral hiatus was located by identifying the apex of an equilateral triangle, with the base formed by a line connecting the two posterior superior iliac spines, and confirmed by palpating the sacral cornua. A 22 or 23-gauge sterile disposable hypodermic needle was inserted at a 60-degree angle to the skin for the caudal injection. Once the needle passed through the sacrococcygeal ligament with a characteristic "pop," the angle was reduced to 30 degrees, and the needle was advanced 0.5 cm further into the sacral canal. A syringe containing the calculated dose of the study drug for each group was then attached to the needle hub, and gentle aspiration was performed. The injection of the study drug (either Inj. Ropivacaine 0.2% 1 ml/kg for Group R or Inj. Ropivacaine 0.2%+Ketamine 0.2mg/kg for Group RK) was initiated. Correct needle placement in the caudal space was confirmed using tests such as the "whoosh test," where air injection produces a whoosh sound, or the "swoosh test," where a swoosh sound indicates proper needle positioning during the injection. Monitoring blood pressure and heart rate during the injection was crucial to prevent complications. Injecting too quickly could lead to a higher block and respiratory issues, while injecting too slowly might result in lateralization of the block or a lower level of anesthesia. The anesthesiologist responsible for preparing the study agents followed standard written instructions and had no further contact with the patient. After completing the procedure, the puncture site was covered with an antiseptic dressing, and the patient was turned supine. Intra-operatively pulse rate and oxygen saturation were noted at 1min,5min, 10min, 15min,30 min,45 min, and 60 min. No other analgesics were given. At the end of the surgery, sevoflurane was discontinued; ETT was removed and there after suctioning of the oral cavity was done. Post-operatively patients were observed in the post-anesthesia care unit (PACU) for 24 hours. The severity of pain was assessed with the Face, Legs, Activity, Cry, and Consolability scale or FLACC scale at 0 hours, 4 hours, 8 hours, 12 hours, 16 hours, 20 hours, and 24 hours. Motor blockade was measured with a Bromage scale at 0 hours, 1hour, and 2hours.Rescue analgesia was given when the FLACC scale score exceeded 3. Time of the first rescue

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analgesia was recorded. Any complications in Post-operative period are noted.

RESULTS

The demographic profiles of all patients were comparable between the two groups. Table 1 provides the comparable data. The average age was 7 with mean age of 7.166 years for group R and mean age of 7.066 years. There are no significant variances in both group and the t value was 0.13 with a p value of 0.8996. Concerning gender distribution, both groups had no notable differences. The Ropivacaine(R) group comprised 3.3% males and 56.65 females while the Ropivacaine with Ketamine (RK) group consisted of 46.6% females and 53.3 % females. The Chi-square was calculated to be 0.0673 and the 2-tailed p Value was 0.7952. The distribution of the patients by ASA grading is similar with no difference in representation of the ASA grades 1 and 2 between both groups with 65% study population falling under grade1and 60%of the population falling under grade 2. The p-value was 0.17595.

Table 2 compares the post-operative pain score (measured using FLACC scale) measured immediately post-extubation, after 4 hours, 8 hours, 16 hours, and 24 hours respectively. As a primary outcome measure, the duration of action of caudal analgesia is significantly higher in Group RK. At 4 and 8 hours, group RK showed significantly lower pain score with p values of 0.3087, 0.3098, and 0.00 than group RK indicating that the combination of Ropivacaine and Ketamine provided superior analgesia during early post-operative period. However, the pain scores at 24 hours postoperatively is comparable between both groups, withpvalueof0.33suggesting no significant difference in pain levels at this time point.

Table 3 demonstrates the time duration till rescue analgesia is required. An extremely significant difference with p value=0.0001exists between the two groups regarding the time of administration of rescue analgesics according to the FLACC score.

Patients in Group R reportedly had a lesser duration of analgesia and were in need of rescue analgesia earlier than group RK with the mean for Group R being 8.4 +0.85hours and that of Group RKwas10.9+1.1 hours.

Table 1: Demographic data

Variable	Group Ropivacaine		Group Ropivacaine with Ketamine		P value
	Mean	SD	Mean	SD	
Age	7.166	3.2598	7.066	2.8398	0.8996

Table 2: FLACC SCORE–analgesia efficacy

FLACC	Group R		Group RK		p Value
	Mean	SD	Mean	SD	
Immediate Post op	1.5333	0.5074	1.4000	0.4983	0.3087
4hrs post op	1.5667	0.5040	1.4333	0.5040	0.3098
8hrs post op	4.0667	0.8683	1.4333	0.5040	0.0000
16hrs post op	3.8333	0.9129	4.0667	0.7849	0.2928
24hrs post op	3.9000	0.7589	4.1000	0.8449	0.3387

Table 3: Time of rescue analgesia

Group	Obs	Mean	Variance	Std Dev
Group R	30	8.4	0.723	0.8503
Group RK	30	10.9	1.223	1.1059

DISCUSSION

The study aimed to assess and compare the analgesic efficacy and duration till requirement of rescue analgesia of caudal Ropivacaine versus Ropivacaine combined with Ketamine in children undergoing infra umbilical surgeries. The results showed that the addition of Ketamine to Ropivacaine provided superior analgesic efficacy in the early postoperative period, as evidenced by a lower FLACC score in this group compared to the control group, with a reduced need for rescue analgesics. However, the difference is not statistically significant after 16 hours and remains almost similar at the 24-hour mark. Ketamine-local anesthetics combinations have been shown to increase the speed of the onset and prolong the duration of caudal analgesia while reducing the incidence of ineffective analgesia compared with local anesthetics alone. Addition of Ketamine with local anesthetics is studied widely due to its analgesic properties, particularly its ability to block central sensitization by antagonizing NMDA receptors which likely accounts for the reduced pain scores observed in Group RK. Most studies assessed the impact of Ketamine on the effectiveness of local anesthetics by measuring the duration of postoperative analgesia or the time to the first analgesic request. S (+)-Ketamine has twice the anesthetic potency of the racemic mixture because it has a three-fold greater affinity for the N-methyl-D-aspartate (NMDA) receptor. However, this increased affinity does not seem to result in differences in clinical effectiveness. The study results corroborate

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with the studies suggesting that Ketamine can be a better adjuvant in children for caudal blocks.

The motor block was assessed too using a Bromage scale which showed no significant difference in both groups. Almost all of the patients in Group RK (83.33%) recovered motor activity within one hour and only 56.66% of patients in Group R had motor activity in 1st hour. However, that difference is not so significant when compared overall. Ropivacaine has similar sensory effects to bupivacaine; however, its motor block duration is shorter. The current findings align with the studies conducted by Elsafty O et al., who used 0.375% Ropivacaine and 0.375% bupivacaine (1 ml/kg) to compare motor recovery. They reported that Ropivacaine resulted in significantly less motor block than bupivacaine. Similarly, Ray et al. compared,[7] caudal bupivacaine and Ropivacaine at a 0.25% concentration and 0.75 ml/kg, concluding that caudal Ropivacaine provides effective analgesia comparable to bupivacaine but with less motor blockade.

Although both groups are associated with mild nausea and vomiting, no significant differences in adverse effects were found. It was found that the addition of Ketamine to Ropivacaine did not increase the incidence of side effects.[8] Spinal neurotoxicity has also been reported following continuous intrathecal infusion of racemic Ketamine over three weeks for terminal cancer-related pain. Due to the controversy surrounding the risk-benefit ratio of neuraxial Ketamine, only preservative-free S (+)-Ketamine should be used for neuraxial anesthesia. The risk of spinal toxicity is highest with prolonged subdural administration for cancer pain. Physiological NMDA receptor activity is essential for cell survival and cerebral function, and prolonged NMDA receptor blockade by Ketamine can lead to apoptosis of central neurons in the immature rat brain. Although no permanent neurological injury has been reported from single-shot caudal Ketamine use, caution is still warranted.

The lack of significant differences at 24 hours postoperatively suggests that the [9]analgesic effects of Ropivacaine alone and with an adjuvant can wear off over time. The addition of Ketamine may prolong the effect, but the benefits might not be as apparent beyond the early postoperative period.

CONCLUSION

The study in conclusion provides evidence that the addition of Ketamine to Ropivacaine enhances post-operative pain relief and reduces analgesic requirements in children undergoing infra umbilical surgeries. However, further studies are needed to assess the long-term efficacy and safety of these combinations, especially in children under going more complex or painful procedures.

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