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Comparative evaluation of caudal block administration of ropivacaine, levobupivacaine and bupivacaine in pediatric patients undergoing lower-abdominal surgeries

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Abstract--Aim: The purpose of the present research was to assess and compare the efficacy of Ropivacaine, Levobupivacaine and Bupivacaine in paediatric patients as an anaesthetic in caudal block undergoing various lower abdominal surgeries. Methodology: This was a prospective randomized controlled study including 50 consecutive patients in the age group of 1-10 years, who underwent urogenital surgeries under general anesthesia. Study was performed at Dr. Moopen's Medical College, Wayanad, Kerala. India and duration was from January 2022 to September 2022. Caudal block was given with either bupivacaine (0.25%) 1 ml/kg (Group I) or ropivacaine (0.25%) 1 ml/kg (Group II) or levobupivacaine 0.25% 1 mL /kg (Group III). Heart rate (HR) and systolic blood pressure (SBP) were recorded as a baseline, before the anesthesia induction and then at 30, 60 and 90 min after incision. Pain scores were assessed post-operatively by a single observer at 30 min and then at 2, 4, 8 and 12 hour with a 5-point observer pain score (OPS). Patients and observer were blinded to the medication given. The duration of absolute analgesia was

defined as the time from caudal injection until the pain score was >2 . Motor block was assessed by modified Bromage scale. Statistical analysis was performed with Chi-square test, Student's t-test and log-rank test. $P < 0.05$ were considered as significant. Results: HR and SBP measured at a specific time intervals showed no significant difference. All the patients had adequate intraoperative analgesia. Mean OPS (observer pain score) were comparable between these three groups. Duration of absolute analgesia was 276.8 (11) min in Group I, 284.8 (12) min for Group II and 285 (13) min for Group III. The only significant difference was the motor-block score at 2, 3 and 4 hours after surgery, although the score was same 1 hour post-operatively. Conclusion: The efficacy of both ropivacaine, bupivacaine and Levobupivacaine is almost same in terms of onset and duration of analgesia. Therefore, the motor blockade caused by Ropivacaine is less; there is no significant difference in cardiovascular events.

Keywords--analgesia, bupivacaine, caudal block, motor block, pediatric patients.

Introduction

In pediatric surgery, caudal anesthesia is commonly combined with general anesthesia since it suppresses neurohumoral response to surgery, accelerates recovery and enhances postoperative pain control. Because of decreased perioperative and postoperative analgesic requirements, which are the most important advantages of this technique, caudal anesthesia is commonly used in pediatric surgery for urological and lower abdominal procedures.¹ Caudal anesthesia is a simpler regional block technique with fewer complications compared to other central block techniques, but there is still no ideal local anesthetic defined, which should be used for this technique. The most preferred local anesthetic in pediatrics is racemic bupivacaine and its most important advantage is that it has a long duration of action. Ropivacaine is the analogue of bupivacaine having fewer cardiotoxic and neurotoxic side effects compared to bupivacaine.^{2,3}

The analgesic effectiveness of ropivacaine is weaker than bupivacaine in adults.⁴ Whereas in infants, the analgesic effectiveness of ropivacaine is equal to that of bupivacaine, even in lower doses.⁵ The injection of local anesthetics into infants causes competitive decrease in dependent plasma proteins and increase of free local anesthetic amounts. Therefore, infants are more susceptible to local anesthetic toxicity.^{6,7} Previously a dosage of 0.175% ropivacaine administered via caudal route was proven to have sufficient analgesic effects without increased motor block frequency.⁸ Bupivacaine has a narrower therapeutic index and cardiac and CNS complications may occur. Ropivacaine, the N-propyl homologue of bupivacaine, a long-acting aminoamide local anaesthetic provides similar type of pain relief with less intense and shorter duration of motor blockade.⁹ As it is safer than bupivacaine, with less risk for CNS and cardiac toxicity it has been extensively used for regional anaesthesia in both adults and children. It may be more suitable for caudal epidural analgesia especially following day care surgery

as it has a quicker onset of action and provides more prolonged postoperative analgesia.¹⁰ Levobupivacaine is the most recent local anaesthetic introduced into clinical practice.¹¹ It is the S(-) -enantiomer of bupivacaine. Whereas both the R(+)- and S(-)-enantiomers of bupivacaine have anaesthetic activity, preclinical studies suggested that the S(-)-enantiomer may be less toxic than the racemic mixture.¹²

Aim of the present study

The purpose of the present research was to assess and compare the efficacy of Ropivacaine, Levobupivacaine and Bupivacaine in paediatric patients as an anaesthetic in caudal block undergoing various lower abdominal surgeries.

Methodology

This is a prospective randomized study including 50 consecutive patients in the age group of 1-10 years, who underwent elective unilateral inguinal herniotomy or urogenital surgeries. Study was performed on Dr. Moopen's Medical College, Wayanad, Kerala, India and duration was from January 2022 to September 2022. The study was approved by the local ethics committee and written informed parental consent was obtained for each subject. All patients were American Society of Anesthesiologists (ASA) grade I. Patients were randomly allocated to one of the two groups by using a random number table, to receive caudal block with either bupivacaine (Group I) or ropivacaine (Group II) and Levobupivacaine (Group III). Patients and observer were blinded to the medication given. Patients having coagulopathy, spinal deformities, infection at the injection site or allergy to amide local anaesthetics were excluded from the study. Premedication was done with intravenous (i.v.) glycopyrolate (0.01 mg/kg) and all procedures were performed under general anaesthesia. Induction was done with i.v. propofol 2 mg/kg and i.v. atracurium 0.5 mg/kg, followed by oro-tracheal intubation.

Anaesthesia was maintained with 60% of nitrous oxide in oxygen, isoflurane 0.2-0.4% and atracurium. Patients received caudal block with either bupivacaine (0.25%) 1 ml/kg or ropivacaine (0.25%) 1 ml/kg or levobupivacaine 0.25% 1 mL/kg in left lateral position using a 23-gauge short-bevel needle (Dispovan, Ballabgarh, India) under aseptic condition. Neither sedatives nor opioids were administered intra-operatively. Heart rate (HR) and systolic blood pressure (SBP) were recorded as a baseline, before the anesthesia induction and then at 30, 60 and 90 min after incision. An intraoperative decrease of SBP or HR by >30% was defined as hypotension or bradycardia, respectively and was treated by fluid bolus, ephedrine, or atropine, as necessary. Each patient was observed for 4 hours in the recovery room before being transferred to the ward. Heart rate and oxygen saturation (SpO₂) and SBP were monitored every 30 min. Pain scores were assessed post-operatively by a single person at 30 min and then at 2, 4, 8 and 12 hours with a 5-point observer pain score (OPS): 1 = asleep or awake and laughing; 2 = awake, but no pain; 3 = mild pain (irritable/restless); 4 = moderate pain (crying, grimacing restless but consolable); and 5 = severe pain (crying/screaming/inconsolable). The duration of absolute analgesia was defined as the time from caudal injection until the pain score was > 2.

Rescue analgesic was given for a pain score of 4 in the form of paracetamol suppository (20 mg/kg), if necessary. Motor block was assessed on awakening by using a modified Bromage scale that consisted of 4 points: 0 = full motor strength (flexion of knees and feet), 1 = flexion of knees, 2 = little movement of feet only, 3 = no movement of knees or feet. The sample size was determined with a target to have a power of 0.80 and P value of 0.05. All the statistical analysis was performed by SPSS 25.0 software (Chicago Inc. Illinois, USA). Data were expressed as mean (standard deviation). Analysis was performed with Chi-square test, Student's t test and log-rank test. P values of less than 0.05 were considered as significant.

Results

All patients had adequate intraoperative analgesia. Fentanyl was required in 4 patients of Group I and 5 patients of Group II (P = 0.12). There was no episode of severe hypotension or bradycardia in any patient. Mean OPS (observer pain score) at different time intervals post-operatively, was comparable for the three groups without a significant difference. Duration of absolute analgesia (OPS < 2) was 276.8 (11) min in Group I, 284.8 (12) min for Group II (P = 0.23) and 285 (13) mins in Group III. (Table 1) The only significantly different finding between three groups was motor block score on the Bromage scale after 2, 3 and 4 hours after surgery, although the score was same 1 hour post-operatively in both groups (P = 0.23, 0.04, 0.02, 0.01 at 1, 2, 3, 4 hours post-operatively). There was no adverse effect such as nausea, vomiting and pruritus between the groups. (Table 1)

Discussion

Post-operative pain relief in pediatric patients needs special attention due to their inability to express the severity and type of pain. Therefore, a pragmatic practical approach of pediatric pain management has been used in recent years with the introduction of safe and effective techniques.¹³ Ropivacaine is increasingly used in the place of bupivacaine for the single shot caudal analgesia in children because of so called lower side-effects.^{14,15} Bupivacaine is commonly used in pediatric patients for caudal block. However, its cardiotoxic side effect, although rarely observed, limits the usage of the medicine and causes the search for new less toxic medicines. Ropivacaine has less cardiotoxic effect compared to bupivacaine and its sensorial and motor effectiveness is superior to bupivacaine.¹⁶ The 0.2% preparation of ropivacaine can be used in all ages. However, pharmacodynamic responses may vary depending on age. Caudal analgesia effectiveness is directly related to volume and concentration of the medicine used for the block.¹⁷ It is indicated that ropivacaine 0.175% and 0.2% concentrations have similar analgesia time and quality in neonatal and infants.⁸

Bosenberg et al. obtained the same analgesic effect with ropivacaine 0.175% and 0.2% in a study conducted on children aged over one year and that ropivacaine 0.175% caused even less motor block development.¹⁸ The use of epidural levobupivacaine for surgical anaesthesia has been investigated in several randomised, double-blinded studies and compared with bupivacaine.¹⁹ The anaesthetic and analgesic effects of levobupivacaine were similar to the same dose of bupivacaine, but time to complete regression of sensory block was significantly

longer with levobupivacaine. A recent study of Ivani and colleagues compared levobupivacaine with ropivacaine and bupivacaine by the caudal route in children undergoing minor surgery.²⁰ Levobupivacaine and bupivacaine were used in a concentration of 0.25% and ropivacaine in a concentration of 0.2%, but the same volume was administered for the three local anaesthetics.

In that study, no difference regarding time to first analgesic demand was found and the use of ropivacaine was associated with less motor block than bupivacaine. In the evidence based clinical update published by Dobereiner et al., statistical analysis was performed between seventeen RCTs.¹⁵ It was found that, the incidence of motor blockade was higher with bupivacaine, so they advised that this drug should be administered if motor block is desired and ropivacaine is preferred if motor block is to be minimized. On the contrary, Khalil et al. found that ropivacaine (0.25%, 1 ml/kg) provided adequate post-operative analgesia with no difference from bupivacaine (0.25%, 1 ml/kg) in motor and sensory effects. Ivani et al. performed a double-blind multicenter study involving 245 children and found no motor block in either group.²¹

Conclusion

This study confirms that ropivacaine is an effective local anesthetic when given by caudal route in pediatric patients. It produces sensory block similar to bupivacaine and levobupivacaine but motor block of shorter duration. This finding is useful for children for early post-operative recovery.

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Tables

Table 1
Surgical procedures performed in each group

Surgery	Group I (bupivacaine) (%)	Group II (ropivacaine) (%)	Group III (levobupivacaine) (%)
Inguinal hernia	10 (40)	10 (40)	10 (40)
Circumcision	6 (24)	5 (20)	4 (21)
Urethroplasty	5 (20)	6 (24)	2 (19)
Cystolithotomy	2 (8)	2 (8)	2(8)
Orchidopexy	2 (8)	2 (8)	2(8)

Table 2
Post-operative OPS at different time intervals

Post-operative duration (hours)	Mean OPS score			P value
	Group I (bupivacaine)	Group II (ropivacaine)	Group III (Levobupivacaine)	
0.5	1.35	1.25	1.52	0.06
2	1.56	1.45	1.69	0.07
4	2.24	1.97	2.71	0.07
8	3.12	2.99	3.55	0.08
12	4.12	4.02	4.20	0.09
24	5	4.84	5.03	0.08

*OPS- Observer pain score