Section: Anaesthesiology

Original Research Article

A COMPARATIVE STUDY OF 0.25% BUPIVACAINE AND 0.25% ROPIVACAINE FOR CAUDAL BLOCK IN PAEDIATRIC AGE GROUP FOR INFRAUMBILICAL SURGERIES

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Abstract

Background: There is limited data comparing ropivacaine and bupivacaine in paediatric patients. This study evaluated the caudal effectiveness of all two drugs in paediatric patients undergoing infraumbilical surgeries and associated complications with these drugs. **Materials and Methods:** Patients were randomly allocated to 1 of the two groups (n = 29) by using a random number table to receive caudal block with either Inj Bupivacaine (0.25%) 1ml/kg (Group I) or Inj. Ropivacaine (0.25%) 1ml/kg (Group II). In the postoperative period, the caudal block was assessed using FLACC (Face, Legs, Activity, Cry, Consolability) pain score, duration of absolute analgesia, time for first rescue analgesia and motor blockage. **Result:** The mean age, weight, gender distribution and surgery duration were comparable in both groups. The hemodynamic parameters were also reported to be comparable in both groups. The mean motor blockage was statistically significant ($p<0.05$) in group 1 compared to group 2. The mean FLACC score between the two groups in various time intervals in the postoperative period was comparable. The mean duration of absolute analgesia in group 1 was 237 ± 40.7, and in group 2 was 232 ± 43.72. Two patients in both Groups had nausea and vomiting, and one patient in both Groups had urinary retention. **Conclusion:** We conclude that ropivacaine is equally potent as bupivacaine in terms of intraoperative quality assessed in hemodynamic stability, FLACC score, duration of analgesia, and safety profile. However, ropivacaine demonstrated a shorter duration of motor blockage throughout the perioperative period.

INTRODUCTION

Pain is a discomforting sensation that can impact one's well-being. Pain is a universal phenomenon; even infants and young children can sense pain, potentially impeding their healing process. Furthermore, an apt quote highlighting children's pain experiences states, "The inability to express pain verbally does not invalidate the likelihood that an individual is undergoing pain and requires suitable pain-relieving intervention". Pain is inherently a subjective experience.[1]

Regional anaesthesia plays a significant role in pain relief during intra-operative and postoperative phases of paediatric day care procedures. Administering a caudal block before incision under general anaesthesia has the benefit of reducing the requirement for sedative opioids for pain management and diminishing the need for volatile anaesthetics for intraoperative maintenance.[2] However, the caudal route of regional anaesthesia presents a drawback in the residual motor block, which might cause discomfort to children after surgery.[3] The caudal route involves using local anaesthetics alone or with additives. Commonly employed medications include lignocaine, bupivacaine, and ropivacaine. Nonetheless, it is important to note that no single drug is without drawbacks, as each has its own set of advantages and disadvantages.

Bupivacaine falls within the amide group of long-acting local anaesthetics, offering anaesthesia and analgesia through a distinct motor-sensory blockade. Most cases of drug-related toxicity stem from procedural issues rather than the inherent nature of the drug itself. Toxicity typically arises from unintended intravascular or intrathecal injection of bupivacaine, resulting in severe neurological and cardiovascular depression and sometimes fatal outcomes. As a result, research has focused on

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investigating the cardiotoxic effects of local anaesthetics and exploring alternatives with reduced cardiotoxicity.[4,5] Commercially, bupivacaine is available as a racemic mixture of its R and S enantiomers. Its mechanism of action involves blocking sodium and potassium channels, with this channel blockade being stereo-selective when the channels are in the inactivated state, where R-bupivacaine exhibits greater potency than S-bupivacaine.[6]

In response to the heightened cardiac toxicity linked to racemic blends of bupivacaine, efforts created single enantiomers. Ropivacaine emerged as the initial local anaesthetic agent manufactured as a pure S-enantiomer.[7] Research findings indicate that ropivacaine demonstrates lower cardiotoxicity and neurotoxicity levels than bupivacaine. Its sensory block effects in epidural and peripheral nerve blocks resemble bupivacaine. However, the motor block induced by ropivacaine exhibits a slower onset, reduced intensity, and shorter duration than that caused by bupivacaine. Notably, ropivacaine boasts a diminished cardiotoxic and neurotoxic profile when contrasted with racemic bupivacaine.[8,9]

These attributes, alongside reduced cardiovascular and neurological risks, render ropivacaine highly valuable in paediatric healthcare, particularly for the growing prevalence of day-case surgeries. Thus, the present study aimed to assess and compare the efficacy of ropivacaine and bupivacaine for caudal anaesthesia in paediatric patients.

MATERIALS AND METHODS

The present randomised controlled trial study was conducted in the Department of Anaesthesiology, Thanjavur Medical College and Hospital (Tertiary Care Centre), Thanjavur, after getting approval from the Institutional Ethical Committee.

Inclusion Criteria

Patients of both sexes, aged three months to 7 years of age with American Society of Anaesthesiologists (ASA) physical class I and II, and patients with elective infra umbilical surgeries of less than 90 minutes were included.

Exclusion Criteria

Children with allergy or hypersensitivity to Bupivacaine or Ropivacaine, ASA physical class greater than three and with Local site infection. Patients with bleeding tendency, congenital spinal anomaly, neurological diseases, renal, hepatic, lung or cardiac diseases. Patients with surgery duration greater than 90 minutes, ineffective caudal analgesia- if mean hemodynamic data at the 15th-minute post procedure rise above 25% or 30% at 45th-minute post-procedure and denied consent of child's attendees were excluded.

Methodology

The heart rate (HR), non-invasive blood pressure (NIBP), and arterial oxygen saturation were recorded using a multiparameter monitor. Preinduction hemodynamic parameters were considered baseline parameters. Children were premedicated with Glycopyrrolate 10 mcg/kg intravenously, Midazolam 0.05 mg/kg. Anaesthesia induction was done in both groups with Thiopentone 5 mg/kg. Orotracheal intubation was done with Succinylcholine 2 mg/kg. Anaesthesia was maintained with 50% nitrous oxide, oxygen, sevoflurane, and vecuronium.

All 58 patients were randomly allocated into two groups, Group 1 and Group 2 of 29. All subjects were placed in the left lateral position, and a single dosage of local anaesthetic was administered under sterile conditions using 22 Gauze hypodermic needles. Group 1 (n=29) – received 1ml/kg of 0.25% bupivacaine caudally. Group 2 (n=29) – received 1ml/kg of 0.25% ropivacaine caudally.

Surgery was permitted 15 mins after giving the supine position to the subjects. Intraoperative analgesia was interpreted by measuring hemodynamic stability. Heart rate, mean arterial pressure and oxygen saturation were measured every 5 minutes for the first 15 minutes and every 15 minutes after that till the end of the surgery and hourly for the first four hours in the postoperative period. Caudal analgesia was considered ineffective if the mean hemodynamic data at the 15th-minute post-procedure time was above 25% or 30% at the 45-minute post-procedure. It was excluded from the study and was treated with 2 micrograms/kg of fentanyl intravenously.

FLACC Scoring system:[10]

Score	Observation
Face	
0	No particular expression or smile occasional
1	grimace or frown, withdrawn and disoriented
2	Frequent to constant frown, quivering chin and clenched jaw
Legs	
0	Normal or relaxed position
2	Restless, tense, uneasy
3	Kicking or legs drawn up
Activity	
0	Lying quietly normal position moves easily.
1	Squirming, shifting forth and back, tense
2	Arched, rigid, jerking
Cry	
0	No cry
1	Moans
2	Crying steadily, screams or sobs
Consolabity	
0	Content, relaxed
1	Reassured by occasional touch, hugging, being talked to, distractile
2	Difficult to console or comfort

In the postoperative period, the caudal block was assessed using FLACC (Face, Legs, Activity, Cry, Consolability) pain score, duration of absolute analgesia, time for first rescue analgesia and motor blockage. The duration of absolute analgesia is taken as time from injection of local anaesthetic until the FLACC score is less than or equal to 6. Children were followed for 24 hours, and the time of need for rescue analgesia and side effects were noted. Inj

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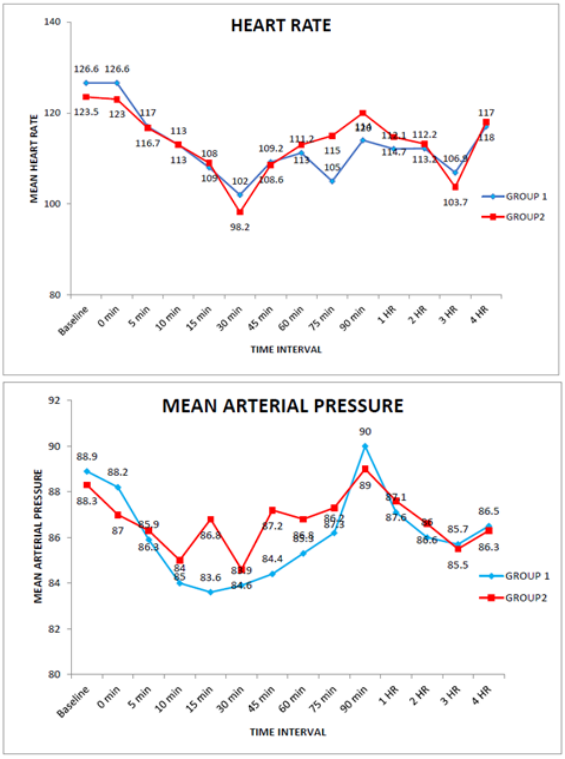
Paracetamol 15mg/kg i/v was used as rescue analgesia.

Statistical Analysis

Data collected was entered in Microsoft Excel and analysed using SPSS Version 19. Qualitative variables were expressed in percentage and proportion. Quantitative variables were expressed in Mean and standard deviation. The significance of a difference between two quantitative variables was calculated using the Chi-square test, and a p-value of less than 0.05 was considered significant.

RESULTS



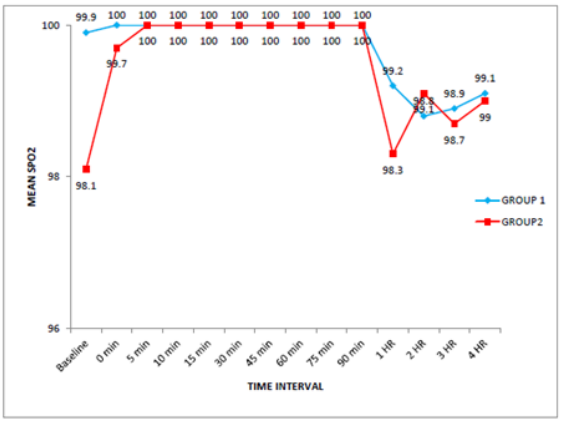


Figure 1: Observation of (A) mean HR, (B) MAP, and (c) Mean SpO2 amongst patients of both groups

The mean age, weight, gender distribution and surgery duration were comparable in both groups. The hemodynamic parameters like mean heart rate, mean arterial pressure (MAP) and mean SpO2 (from baseline to 4 hours) were also reported to be comparable in Group 1 (Bupivacaine) and Group 2 (Ropivacaine) patients [Table 1, Figure 1].

The mean motor blockage was found statistically significant ($p<0.05$) high in group 1 as compared to group 2 at 1, 2, 3 and 4 hour time points. The mean FLACC score in various time intervals in the postoperative period between Group 1 and Group 2 was comparable and was not significant statistically. The mean duration of absolute analgesia in Group 1 was 237 ± 40.7, and in Group 2 was 232 ± 43.72, which is not statistically significant [Table 1].

Two patients in both Groups had nausea and vomiting, and one had urinary retention. Hence, there is no statistical significance, and both drugs were equally safe. The mean time of need of first rescue analgesia in Group 1 was 547.7 ± 21.7, and in Group 2 was 538.9 ± 21.1 and was statistically insignificant [Table 2].

Table 1: Observation of different evaluation variables of patients in both groups

Parameters	Observation Frequency (%)		P-value
	Group 1 Bupivacaine	Group 2 Ropivacaine	
Age Group (Years)			
0 to 1	5 (17.2)	3 (10.3)	-
1-2	6 (20.6)	7 (24.1)	-
2-3	5 (17.2)	6 (20.6)	-
3-4	6 (20.6)	6 (20.6)	-
4-5	3 (10.3)	2 (0.06)	-
>5	4 (13.7)	5 (17.2)	-
Mean age (years) (Mean± SD)	2.9 ±1.9	3.2 ±1.8	>0.05
Gender			
Male	24± 82.8	16 ±55.2	>0.05
Female	5 ±17.2	13 ±44.8	
Weight (years) (mean± SD)	12.17 ± 4.28	14.76 ± 6.92	>0.05
Mean duration of surgery (min) (mean± SD)	48.6 ± 16.2	48.2 ± 15	>0.05
Duration of absolute analgesia (min) (mean± SD)	237.6 ± 40.7	232 ± 43.72	>0.05
Motor block (min) (mean± SD)			
1 hour	1.85 ±0.36	0.77 ±0.58	<0.05
2 hour	1.36 ± 0.62	0.04 ± 0.19	<0.05
3 hour	0.79 ± 0.68	0	<0.05
4 hour	0.27 ± 0.45	0	<0.05
FLACC score (mean± SD)			
1 hour	2. ± 1	2.7± 0.92	>0.05

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2 hour	3.46 ± 1.22	4 ± 0.9	>0.05
3 hour	4.9 ±1. 4	5.5 ± 0.8	>0.05
4 hour	5.8 ± 0.9	6.3 ± 0.7	>0.05

Table 2: Observation of side effects amongst patients in both groups

Side effects	Group 1 Bupivacaine	Group 2 Ropivacaine	P-value
Nausea and Vomiting	2 (6.89)	2 (6.89)	>0.05
Urinary retention	1 (3.44)	1 (3.44)	>0.05
Arrthymia	0	0	>0.05

DISCUSSION

Managing acute pain in the perioperative period is the responsibility of the attending anesthesiologist. This review focuses on the overview of acute pain management in children, with special emphasis on regional anaesthetic techniques like a caudal block to achieve the goal of optimal analgesia in the perioperative period.[1,2] Although the caudal block is one of the most cost-effective, relatively safe analgesia modalities, the overall quality of analgesia greatly relies on the local anaesthetic used in the single-shot caudal block.[3,4] Hence, this study was conducted to identify the ideal local anaesthetic agent and its concentration with a wide margin of safety, limited motor blockade and a prolonged period of analgesia.

The study population was divided into two groups. Group 1 received 1ml/kg of 0.25% bupivacaine, and Group 2 received 1ml/kg of 0.25% Ropivacaine caudally after induction of general anaesthesia. Each group comprised 29 patients. Both groups were comparable in terms of mean age, weight, gender and duration of surgery, and there were no biases. In this study, both Bupivacaine and Ropivacaine provided similar intraoperative quality with minimal hemodynamic variability demonstrated in terms of comparable mean heart rate, mean arterial pressure and saturation at various time intervals in the perioperative period. These findings in the present study follow earlier reported studies.[11,12]

The mean motor blockage was found statistically significant ($p<0.05$) high in group 1 as compared to group 2 at 1, 2, 3 and 4 hour time points. Hence, we conclude that ropivacaine produces significantly less motor blockade than bupivacaine. This result was comparable to a study by Ivani et al. on 60 sevoflurane anaesthetised children undergoing minor sub-umbilical surgeries who randomly received 1ml/kg of either 0.25% Bupivacaine or Ropivacaine or Levobupivacaine.[13] The study showed that using ropivacaine but not levobupivacaine was associated with less motor block during the first postoperative hour than racemic bupivacaine. This result was contrary to Khalil et al., who demonstrated no significant difference in motor blockade between Bupivacaine and Ropivacaine.[14]

FLACC score in both groups was similar and was not clinically significant. The duration of absolute analgesia in Group 1 was 237.6 ± 40.7, and in Group 2 was 232 ± 43.72. Though the Bupivacaine group demonstrated a slightly longer duration of absolute analgesia than ropivacaine, it was not clinically significant. The time of need of first rescue analgesia in Group 1 was 547.7 ± 21.7 minutes, and in Group 2 was 538.9 ± 21.1 minutes, which is not statistically significant. Hence, we conclude that ropivacaine was equally potent as bupivacaine in terms of duration and quality of analgesia.

This study was comparable to Chipde et al.'s study, which studied 50 patients aged 1 -10 years who underwent urogenital surgeries under general anaesthesia. Caudal block was given with either Bupivacaine 0.25% 1 ml/kg (Group 1) or Ropivacaine 0.25% 1 ml/kg (Group 2).[15] All the patients had adequate intraoperative analgesia. The duration of absolute analgesia was 276.8 min in Group 1 and 284.8 min in Group 2. The only significant difference was the motor-block score at the 2nd, 3rd and 4th hour after surgery, although the score was the same 1 hour post-operatively. Ropivacaine's and bupivacaine's efficacy is almost the same regarding the onset and duration of analgesia. The motor blockade caused by ropivacaine is less. This study was also supported by Ivani et al., which concluded that ropivacaine was as effective as bupivacaine for caudal analgesia in children.[13] This result is contrary to Sharma et al., which concluded that Levobupivacaine and Ropivacaine provided similar intraoperative quality with minimal hemodynamic variability and shorter duration of postoperative analgesia without any significant complications when compared with racemic Bupivacaine.[16]

When side effects were evaluated, nausea, vomiting, and urinary retention were noted in both groups, but there was no statistical significance among Bupivacaine and Ropivacaine groups. Toxic reactions to local anaesthetics would cause cardiovascular and neurological side effects. No such complications were encountered in our study population. Hence, we conclude that both drugs are equally safe, similar to the results of Breschan et al., which concluded that none of the two local anaesthetics was superior to the other regarding safety profile.[17]

CONCLUSION

We conclude that ropivacaine is equally potent as bupivacaine in terms of intraoperative quality assessed in hemodynamic stability, FLACC score, duration of analgesia, and safety profile. However, ropivacaine showed a lesser duration of motor

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blockade in the perioperative period when compared to bupivacaine.

REFERENCES

1. Merskey H, Bogduk N. Part III: pain terms, a current list with definitions and notes on usage. Classification of chronic pain. 2nd ed. Seattle: IASP Task Force on Taxonomy IASP Press 1994:209-14.
2. Dalens B, Hasnaoui A. Caudal anaesthesia in pediatric surgery: success rates and adverse effects in 750 consecutive patients. Anesth Analg 1989;68:83-9.
3. Murat I, Delleur MM, Esteve C, Egu JF, Raynaud P, Saint-Maurice C. Continuous extradural anaesthesia in children. Br J Anaesth 1987;59:1441–50.
4. Albright GA. Cardiac arrest following regional anesthesia with etidocaine or bupivacaine. Anesthesiology 1979;51:285–7.
5. Marx GF. Cardiotoxicity of local anesthetics-the plot thickens. Anesthesiology 1984;60:3-5
6. Valenzuela C, Delpón E, Tamkun MM, Tamargo J, Snyders DJ. Stereoselective block of a human cardiac potassium channel (Kv1.5) by bupivacaine enantiomers. Biophys J 1995;69:418–27.
7. McClure J. Ropivacaine. Br J Anaesth 1996;76: 300-7.
8. Knudsen K, Beckman Suurküla M, Blomberg S, Sjövall J, Edvardsson N. Central nervous and cardiovascular effects of i.v. infusions of ropivacaine, bupivacaine and placebo in volunteers. Br J Anaesth 1997;78:507–14.
9. Scott DB, Lee A, Fagan D, Bowler GM, Bloomfield P, Lundh R. Acute toxicity of ropivacaine compared with that of bupivacaine. Anesth Analg 1989;69:563-9.
10. Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S. The FLACC: A behavioural scale for scoring postoperative pain in young children. Pediatr Nurs 1997; 23:293-7.
11. Ala-Kokko TI, Paranen A, Karinen J, Kiviluoma K, Alahuhta S. Pharmacokinetics of 0.2% ropivacaine and 0.2% bupivacaine following caudal blocks in children. Acta Anaesthesiol Scand 2000;44:1099-1102
12. Da Conceicao MJ, Coelho L. Caudal anaesthesia with 0.375% ropivacaine or 0.375% bupivacaine in paediatric patients. Br J Anaesth 1998;80:507–8.
13. Ivani G, Denegri P, Conio A, Grossetti R, Vitale P, Vercellino C, et al. Comparison of racemic bupivacaine, ropivacaine, and levo-bupivacaine for pediatric caudal anesthesia: Effects on postoperative analgesia and motor block☆. Reg Anesth Pain Med 2002;27:157–61.
14. Khalil S, Campos C, Farag AM, Vije H, Ritchey M, Chuang A. Caudal Block in children, ropivacaine compared with bupivacaine. Anesthesiology 1999;91:1279-84.
15. Chipde SS, Banjare M, Arora KK, Saraswat M. Prospective randomised controlled comparison of caudal bupivacaine and ropivacaine in pediatric patients. Ann Med Health Sci Res. 2014;4(Suppl 2):S115-8.
16. Sharma J, Gupta R, Kumari A, Mahajan L, Singh J. A Comparative Study of 0.25% Levobupivacaine, 0.25% Ropivacaine, and 0.25% Bupivacaine in Paediatric Single Shot Caudal Block. Anesthesiol Res Pract. 2018;2018:1486261
17. Breschan C, Jost R, Krumpholz R, Schaumberger F, Stettner H, Marhofer P, et al. A prospective study comparing the analgesic efficacy of levobupivacaine, ropivacaine and bupivacaine in pediatric patients undergoing caudal blockade. Paediatr Anaesth 2005;15:301–6.

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