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Comparative Study of Caudal Blockade with 0.2% Ropivacaine Versus 0.2% Bupivacaine for Postoperative Analgesia in Children Undergoing Inguinal Herniotomy

Dr. Shabeer Ahmed Khan

Consultant Intensivist, Lalitha Super speciality Hospital, Kothapet, Guntur, Andhra Pradesh

Corresponding Author

Dr. Shabeer Ahmed Khan

Consultant Intensivist, Lalitha Super speciality Hospital, Kothapet, Guntur, Andhra Pradesh

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Abstract

Background: Bupivacaine provides reliable and long-lasting postoperative analgesia when given via caudal route. Ropivacaine is a newer long-acting local anesthetic agent. Preliminary reports suggest that it has less motor blockade and less cardiotoxicity than bupivacaine.

Aim of this study was to compare quality and duration of caudal block produced by ropivacaine and bupivacaine.

Methodology: This prospective, double-blind, randomized comparative study was conducted over 12 months at Narayana Health Institute and Mazumdar Shaw Cancer Centre, Bangalore, to evaluate the efficacy and safety of 0.75 ml/kg of 0.2% Ropivacaine vs. Bupivacaine for caudal epidural block in children aged 6 months to 6 years undergoing elective inguinal herniotomy among 60 patients 30 in each group. Group R (n=30): Received 0.2% Ropivacaine via caudal route and Group B (n=30): Received 0.2% Bupivacaine via caudal route to compare duration of analgesia, Assess the requirement and frequency of rescue analgesia, Evaluate the degree of motor block, Monitor and compare hemodynamic parameters (HR, BP) intra- and post-operatively and Assess postoperative sedation levels between the two groups. The study used a computer-generated randomization method to assign patients equally, ensuring double-blind allocation for unbiased comparison.

Results: The difference in Mean duration of analgesia, degree of Motor blockade, rescue analgesia requirement, post operative sedation, Hemodynamic parameters (heart rate, blood pressure) intraoperatively and post operatively between Ropivacaine & Bupivacaine are statistically not significant.

Conclusion: Caudal 0.75 ml/kg of 0.2% Ropivacaine or Bupivacaine provides effective and safe postoperative analgesia in paediatric inguinal herniotomy, with minimal motor blockade, stable hemodynamics, and no significant side effects—supporting rapid recovery and early ambulation.

Keywords: Ropivacaine, Bupivacaine, HR (Heart rate),SBP (systolic Blood Pressure), Diastolic Blood Pressure,Mean Arterial Pressure (MAP),Respiratory Rate (RR),SpO2

INTRODUCTION:

Pain is defined by the international association for study of pain as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage".[1]

The provision of adequate analgesia is necessary during perioperative period and it is all the more important in children.[2] There is a well-defined pathway for sensation in the new-born infant. Nociception is associated with signs of distress even in new-born.[3] The density of nociceptive nerve endings in the skin of new-born infants is similar to or greater than that in adults.[4,5]

Caudal anaesthesia was first described at the turn of last century by Fernand Cathelin and Jean Anthanase Sicard in year 1895. It was predated by lumbar approach to epidural block by almost a decade. Since its first description in 1933 for paediatric urological interventions, it has evolved to become the most popular regional anaesthetic technique for use in children.[6] It prides great analgesia during surgery as well as postoperatively in subumbilical surgeries in children.[7] It is a simple technique to perform and remains corner stone in paediatric regional anaesthesia.

Caudal epidural block is one of the most common regional anaesthetic techniques used in children. It is usually considered simple and safe technique with a predictable level of blockade used commonly with general anaesthesia for intraoperative and postoperative analgesia in patient undergoing lower abdominal, urological, and lower limb operations. Administration of bupivacaine for caudal analgesia is standard for pain relief but single shot injection of plain bupivacaine has only short duration of action.[8] Bupivacaine has been used in different concentrations but no difference in duration of postoperative analgesia was found.

The use of caudal catheters to administer repeated doses or infusions of local anaesthetic solution is not popular, partly because of concerns about infection. However, the merits of using a 'double-caudal' technique, whereby the caudal is `topped up' at the end of the procedure, have recently been advocated.[8] Prolongation of caudal analgesia using a 'single-shot' technique has also been achieved by the addition of various adjuvants like epinephrine, opioids, ketamine, tramadol and midazolam.[9]

Bupivacaine is a well-established local anaesthetic agent, first of long acting to be used. Ropivacaine is a pure S-enantiomer. Both the drugs possess similar structure, pharmacology, mechanism of action and physiochemical properties. However, Ropivacaine is believed to have lower incidence of clinical cardiac side effects than Bupivacaine[10] and also has lesser motor blockade compared to Bupivacaine.[11]

The potential use of a local anaesthetic agent that could produce equal or greater degree of analgesia with lesser toxicity has prompted the present study.

Aim:

Primary Objective:

1. To compare the degree of analgesia provided by caudal blockade with 0.75 ml/kg of 0.2% Ropivacaine versus 0.2% Bupivacaine in children aged 6 months to 6 years undergoing inguinal herniotomy, as assessed by postoperative pain scores.

Secondary Objectives:

2. To compare the duration of analgesia between the two groups.
3. To evaluate the requirement and frequency of rescue analgesia in each group.
4. To assess the degree of motor block produced by each drug.
5. To monitor and compare hemodynamic parameters (heart rate, blood pressure) during and after the procedure.
6. To evaluate the level of sedation postoperatively in both groups.

Methodology:

A Prospective Double Blind Randomized Comparative Study of Ropivacaine Versus Bupivacaine, 0.75 ml/Kg, 0.2% for Caudal Epidural Block in Children of 6 Months- 6 Years Undergoing Elective Inguinal Herniotomy in Paediatric Surgery Operation Theatre, Narayana Health Institute of Cardiac Sciences and Mazumdar Shaw Cancer Centre, Bangalore.

The study was approved by the institutional ethics committee. A written valid informed consent was taken from the respective parents or legal guardians of the patients undergoing the study.

STUDY POPULATION: A total of 60 children scheduled for inguinal herniotomy under general anaesthesia were enrolled.

INCLUSION CRITERIA

- ASA - I & II.
- Aged 6 months – 6 years.
- Weight of patient falling between 3rd- 80th percentiles of normal.
- Patient belonging to either sex.
- Patient posted for elective herniotomy
- Parent consenting for the studies.

EXCLUSION CRITERIA

- Children having any neurological disorder, renal or hepatic dysfunction.
- Children having any cardiac abnormalities, i.e., anatomical, functional, etc.
- Any surgery involving handling of the spinal cord.
- Pre-existing bleeding disorder.
- H/o hypersensitivity to any of the drugs.
- Local site skin infection.
- Sacral abnormalities.

STUDY GROUPS: Computer-generated table of random numbers was used for allotting equal number of patients in each group undergoing inguinal herniotomy, the study population was divided into 2 groups, viz:
Group R: Children received Ropivacaine 0.2%, 0.75 ml/kg via caudal epidural route (n= 30).
Group B: Children received Bupivacaine 0.2%, 0.75 ml/kg via caudal epidural route (n= 30).
Duration Of Study: 12 months.
SAMPLE SIZE: The number of participants required in each intervention group, n, is given

$$n = \frac{2(z(1-\square\square\square/2) + z(1-\square\square\square))^2}{\Delta^2}$$

A s per the study done by **SS Chipde et al in 2014**[12] the duration of analgesia for
Bupivacaine group: 276.8±11 minutes
Ropivacaine group: 284.8±12 minutes
S.D. of the total population: 11.51 minutes
Based on these values and for a significance level of 10% (confidence level of 90%) and a power of 80%, sample size for each group was calculated as 30 cases.
Total sample size = 2x30= 60 cases

SAMPLING PROCEDURE: All the children between the age group of 6months to 6 years, ASA Class- I & II who are undergoing elective inguinal herniotomies under Standardized General Anaesthesia who gave consent were enrolled till the required sample size of 60 is achieved. Allocation of cases to any one of the two groups will be done by double blinded randomization as follows:

Methodology:
Pre-anaesthetic check-up
All patients were evaluated one day prior to the surgery with a detailed general physical examination, systemic examination including airway and spine examination. Baseline parameters like heart rate were recorded. Routine laboratory investigations like complete blood picture, urine routine, bleeding and clotting time, HIV HBs Ag status and chest x-ray if needed. Informed consent for the procedure was acquired from the parent with clear fasting guidelines (solid foods stopped 6hrs before, milk 4 hours and water 2-3 hours prior to surgery).
Patients fulfilling the inclusion & exclusion criteria will be randomly allocated to Ropivacaine or Bupivacaine groups after informed consent.

Premedication
All children were pre-medicated with oral or nasal midazolam 0.5 mg/kg 30 minutes before surgery.On arrival into operation theatre, monitors viz. pulse oxymeter, ECG leads and NIBP cuff were connected and baseline parameters were noted.

Procedure
All subjects were induced with 8% sevoflurane and a mixture of 50% nitrous oxide and 50% oxygen till loss of consciousness is achieved, following which ASA standard monitors were attached and an iv line was secured. Heart rate, mean arterial pressure and oxygen saturation will be recorded. Inj. Fentanyl 5mcg/kg is given. After achieving appropriate depth of anaesthesia, Laryngeal Mask Airway (LMA) of appropriate size was inserted and patient was ventilated with O_2:N_2O in 50:50 proportions with isoflurane. After securing the airway, patients were given Left lateral position. Under all aseptic precautions, sacral hiatus and thence caudal epidural space was identified. Hence, caudal epidural block was given by the attending anesthesiologist. The study drug as per allocation by randomization chart for that serial number was given.

Caudal block
Child was put in lateral semi-flexed position. Vitals were recorded with child in spontaneous breathing under mask

ventilation. Under strict aseptic precautions, sacral hiatus was identified by running thumb from superior sacral spines towards coccyx. After identifying sacral hiatus, a 23G hypodermic needle with its bevel facing anteriorly was inserted at 45-70 degrees angle till sacrococcygeal membrane was pierced with a clear pop. Confirmation of needle position in epidural space is done with the 'whoosh' test. After negative aspiration to CSF and blood drug was injected. After injection, needle was removed, site of injection was wiped with betadine swab and child was placed in supine position. There on anaesthesia was maintained with Oxygen, Nitrous oxide and inhalational agent with patient on spontaneous ventilation throughout surgery.

Drug & dosage

Children were randomly divided into 2 groups of 30 each.

- **Group B, Bupivacaine** 0.2% 0.75ml/kg into caudal epidural space.
- **Group R, Ropivacaine** 0.2% 0.75ml/kg into caudal epidural space.

MONITORING: Following parameters were noted at the time of induction & every 5 minutes for first 30 minutes & thence every 10 minutes there after till the end of surgery:

- Heart Rate on ECG Monitor, recorded as beats/minute.
- Blood Pressure [BP] using NIBP monitor recorded as Systolic Blood Pressure [SBP], Diastolic Blood Pressure [DBP], & Mean Arterial Pressure [MAP] in mm Hg.
- SpO_2 in % on Pulse Oximeter.

Anaesthesia was maintained with O_2:N_2O in 50:50 proportions with Isoflurane.

Hemodynamic parameters: Child's heart rate, blood pressure and respiratory rate after administration of caudal block at 0, 5, 10, 15, 30 minutes and there on every 15 minutes till end of procedure were recorded.

Time of caudal injection, duration of anaesthesia, duration of sensory and motor blockade and time of first dose of rescue analgesia post-operatively were noted. Patient was observed postoperatively for:

- Pain by FLACC score.
- Motor blockade by Bromage score.
- Sedation by Ramsay score.
- Postoperative Nausea & Vomiting [PONV].
- Urinary retention.

PAIN ASSESSMENT: FLACC SCALE

CATEGORIES	**SCORING**		
	0	**1**	**2**
FACE	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
LEGS	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up.
ACTIVITY	Lying quietly, normal position moves easily	Squirming, shifting back and forth, tense.	Arched, rigid or jerking
CRY	No cry, (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
CONSOLABILITY	Content, relaxed	Reassured by occasional touching hugging or being talked to, distractible	Difficulty to console or comfort

Each of the 5 categories [F] Face, [L] Legs, [A] Activity, [C] Cry, [C] Consolability is scored from 0-2, which results in a score between 0 & 10. Pain score more than or equal to 4 is suggestive of rescue analgesic requirement.

RESCUE ANALGESIA

For the first 3 hours postoperatively, rescue analgesics was administered in the form of Inj. Fentanyl 0.25µg/kg i.v. with a lock out period of 30 minutes.

After 3 hours postoperatively, rescue analgesic given was Inj. Tramadol 1mg/kg i.v. with a lock out period of 4 hours. In this lock out period if pain persists, syrup Paracetamol 10mg/kg orally was given.

Bromage Scale for Motor Blockade

Grade	Criteria	Degree of block
I	Free movement of legs and feet	Nil (0%)
II	Just able to flex knees with free movement of feet	Partial (33%)
III	Unable to flex knees, but with free movement of feet	Almost complete (66%)
IV	Unable to move legs or feet	Complete (100%)

RAMSAY'S SEDATION SCORE

1. Agitated, Anxious or Restless.
2. Cooperative & Oriented.
3. Responds to Commands.
4. Asleep, but has brisk response to light Glabellar tap or Loud Auditory Stimuli.
5. Patient exhibits a sluggish response to light glabellar tap or loud auditory
6. Asleep has no response.

Statistical tools: The information collected regarding all the selected cases was recorded in a MS Excel sheet. Data analysis was done using **SPSS statistical package-Version 17.** A 'p' value less than 0.05 will denote significant relationship. The mean duration of analgesia was calculated and analyzed using Unpaired *'t'* test/Mann Whitney test as the data is skewed.

RESULTS:

The mean age of the cases in group R and B are 3.4 and 4 years respectively, there were no significant differences (p value 0.176) between the two groups with respect to age.

The mean weight of the cases in group R and B are 11.98 and 12.867 kgs respectively; there were no significant differences (p value 0.265) between the two groups with respect to weight.

Baseline and intraoperatively, values immediately after induction were recorded and considered as post- induction (PI) value. Time 0 min was considered as the time immediately after caudal block. After this, recordings were done at every 10 min. Both the groups were comparable in terms of haemodynamic parameters intraoperatively.

Hemodynamic parameters (heart rate, blood pressure) during and after the procedure:

The heart rate,systolic BP ,Diastolic BP,MAP,RR,SPO2 in both the groups R and B at various intervals (baseline, PI, 0 min, 10 min, 20 min, 30 min, 60 min,70 min, 80 min and 90min) intraoperatively and post operatively are statistically not significant.

Table: 1 Postoperative Duration of Analgesia

Parameter	**Group**				**Unpaired**	**"p" value**
	R (n= 30)	**SD**	**B (n= 30)**	**SD**	***'t'* value**	
	Mean		**Mean**			
Mean Analgesic Duration (min)	831.5	708.22	743.00	711.66	0.4828	0.6311

It was observed that there is no significant difference in the median duration of analgesia between Ropivacaine and Bupivacaine on applying unpaired t test.

Rescue Analgesia Requirement:
It was observed that when total requirement of rescue analgesia with Fentanyl /Tramadol / (Fentanyl + Tramadol) was compared, No significant difference was noted between the 2 groups.

Table: 2 Degree of Motor block (Bromage Score)

	Ropivacaine			Bupivacaine			Z	p value
	Percentile 25	Median	Percentile 75	Percentile 25	Median	Percentile 75		
BROMAGE 0min	1	1	1	1	1	1	-1.012	0.311
15 min	1	1	1	1	1	1	-0.358	0.72
30 min	1	1	1	1	1	1	-0.068	0.945
45 min	1	1	1	1	1	1	-0.068	0.945
1 hr	1	1	1	1	1	1	-0.626	0.531
2 hr	1	1	1	1	1	1	0	1
3 hr	1	1	1	1	1	1	0	1
POD- 1	1	1	1	1	1	1	0	1

As data had skewed distribution; majority had scores of 1, only scores of six patients of Group- R and three patients of Group- B at 0 min and of five patients of Group- R at 15 min were ≥ 2. Hence, their Median and Percentile 75 values were calculated and Mann- Whitney U test was applied. No significant difference was noted between the 2 groups.

Table: 3 Post operative sedation: Ramsay Score

	Ropivacaine			Bupivacaine			Z	p value
	Percentile 25	Median	Percentile 75	Percentile 25	Median	Percentile 75		
RAMSAY 0min	1	3	3	1	2.5	4	-0.237	0.813
15 min	1	3	3	1	3	3	-0.295	0.768
30 min	2	2	3	2	3	3	-0.494	0.621
45 min	2	2	3	2	2	3	-0.189	0.85
1 hr	2	2	3	2	2	3	-0.903	0.367
2 hr	2	2	2	2	2	2	-0.034	0.973
3 hr	2	2	2	2	2	2	-0.992	0.321
POD- 1	2	2	2	2	2	2	-1	0.317

On applying Mann Whitney test it was observed that statistically no significant difference was observed in the Ramsay sedation scores in both the groups Ropivacaine and Bupivacaine.

Discussion:
Postoperative pain is inevitable and often inadequately managed, especially in children who have historically been under-treated for acute pain. Caudal anaesthesia, first described in 1895 and adopted for paediatric use in 1933, has become a widely used and effective regional technique for providing intraoperative and postoperative analgesia in sub umbilical surgeries in children, such as inguinal herniotomy. Its simplicity, safety, and ability to provide smooth recovery make it ideal for ambulatory surgeries.

Bupivacaine, synthesized in 1963, is a long-acting local anaesthetic but carries a risk of cardiotoxicity due to the presence of the R-enantiomer. Ropivacaine, introduced later in 1993 (and in India in 2009), is a pure S-enantiomer with a safer pharmacological profile. It offers sensory-selective blockade with reduced motor block and lower cardiotoxic and CNS toxic risks compared to Bupivacaine, due to its lower lipophilicity and stereoselectivity. However, in neonates and young

infants (1–6 months), systemic exposure to Ropivacaine is higher due to a lower clearance rate, which must be considered when planning anaesthesia in this population.

This study compared the efficacy and safety of caudal Ropivacaine (0.2%) and Bupivacaine (0.2%) at 0.75 ml/kg in children aged 6 months to 6 years undergoing inguinal herniotomy, focusing on postoperative analgesia, motor blockade, and side effects.

Wulf et al[13]. and Hansen et al [14] observed higher systemic exposure to Ropivacaine in infants <6 months, thus such children were excluded.

Children above 6 years were also excluded due to changing anatomy affecting drug diffusion. A standardized protocol was used to eliminate selection, observer, and measurement bias.

In the present study the Mean duration of analgesia in Group Ropivacaine (R): 831.5 ± 708.22 min and Group Bupivacaine (B): 743.0 ± 711.66 min respectively. It was observed that there was no significant difference (p=0.6311) in the Mean duration of analgesia between thee 2 groups. In the present study it was observed that no significant difference in the motor blockade between the 2 groups.

Khalil et al[15] and Ivani et al[16] found similar durations of analgesia and minimal motor blockade with 0.2–0.25% Ropivacaine compared to Bupivacaine.
Locatelli et al [17] reported shorter motor block and similar analgesia with Ropivacaine, supporting its safety profile.
Koinig et al.[18] showed that higher concentrations of Ropivacaine (0.5%) prolong analgesia but increase motor blockade risk.

Da Conceicao et al[19]. showed significant motor block at higher concentrations (0.375%), which is undesirable.
Present study also includes children less than 1 year of age it will be difficult if degree of motor blockade is high so it was aimed at minimizing the duration of motor blockade while not compromising on the quality and duration of analgesia. Hence, a concentration of 0.2% of both Ropivacaine and Bupivacaine was chosen in the present study.

Pain Assessment Tool:
The **FLACC scale** (Face, Legs, Activity, Cry, Consolability) was used due to its **validated use in non-verbal children**, ensuring **objective and reliable** pain assessment.
In infants and young children, anatomical changes—particularly the fluid nature of the epidural fat pad—allow for better diffusion of drugs administered via caudal epidural injection. This favorable diffusion is typically observed up to six years of age. Beyond this age, ongoing spinal anatomical changes hinder consistent drug spread. Therefore, children above six years were excluded from the study to ensure reliability and uniformity of caudal drug distribution.

Rescue Analgesia:
Since children cannot reliably use the Visual Analog Scale (VAS) for pain, the FLACC scale—validated for children aged 2 months to 7 years—was used in this study to objectively measure postoperative pain and avoid measurement bias. The mean duration of analgesia observed using the FLACC scale was 831.5±708.22 minutes in the Ropivacaine group and 743.0±711.66 minutes in the Bupivacaine group, with no significant difference (p=0.6311). This finding was consistent with previous studies using different pain scales, where no major differences were found between the two drugs.

Regarding rescue analgesia, 43.33% of patients in the Ropivacaine group and 50% in the Bupivacaine group required additional pain relief, again with no significant difference (p=0.6048). For postoperative pain management, Fentanyl (0.25 µg/kg IV) was chosen in the PACU due to its rapid onset and availability. However, because of its potential for respiratory depression, Tramadol—safer with minimal respiratory and cardiovascular effects—was used in the ward. Rectal Paracetamol, used in other studies, was avoided due to delayed onset and poor acceptance in children post-anaesthesia.
Fentanyl (0.25 µg/kg) used in PACU due to fast onset and availability.

Tramadol used in the ward for its safety and minimal respiratory effects.
Morphine and rectal Paracetamol were avoided due to delayed onset, side effects, and acceptability issues.
In the present study, **Rescue analgesia** required in 43.33% (R) vs 50% (B); It was observed that there was no significant difference between thee 2 groups.

In the postoperative period, **Khalil et al** [15]used IV Morphine (0.05–0.1 mg/kg), which has a slow onset (15–30 min) and can cause hypotension, making it less common in the Indian context. Fentanyl, with a faster onset (1 min) and peak effect

at 5 minutes, is more readily available and was therefore selected in a low dose (0.25 µg/kg) as rescue analgesic in the PACU. However, due to the risk of respiratory depression from both Morphine and Fentanyl, they are unsuitable once the patient is shifted to the ward. While **Koinig and Ivani**[16] used rectal Paracetamol, its delayed onset and poor acceptance in children post-anesthesia limited its use. Instead, Tramadol was chosen in the ward for its milder effects and safety profile. In the present study it was observed that no significant **intraoperative or postoperative hemodynamic changes** found between the 2 groups.

In the present study it was observed that no significant **side effects** reported in either group.
Koinig et al[18] **and Da Conceicao et al**[19] found no significant differences in hemodynamic parameters between Ropivacaine and Bupivacaine groups, which aligns with our study's findings. All demographic variables were comparable, and no significant intraoperative or postoperative hemodynamic changes were observed. Like **Ivani et al**[16]**,** we noted no significant motor blockade. Due to general anesthesia and postoperative sedation, assessing sensory block onset and regression was not feasible. No significant side effects were encountered. Overall, caudal administration of 0.75 ml/kg of 0.2% Ropivacaine or Bupivacaine was effective and safe for inguinal herniotomy, with comparable analgesia and minimal side effects.

Conclusion
Caudal administration of 0.75 ml/kg of 0.2% Ropivacaine or Bupivacaine offers:

- Comparable postoperative analgesia
- Minimal motor blockade
- No significant side effects
- Stable hemodynamics

This makes both agents effective and safe for caudal anaesthesia in paediatric inguinal herniotomy, especially when aiming for rapid recovery and early ambulation.

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