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Comparative Evaluation of Caudal Block Using Bupivacaine and Ropivacaine in Children Poster for Infra Umbilical Surgeries.

R Immanuel Nargunanathan J, and B Sangeetha*

Department of Anaesthesiology, Sree Balaji Medical College & Hospitals, Bharath University, Chrompet, Chennai -44, Tamil Nadu, India.

ABSTRACT

Caudal anaesthesia is a useful adjunct to General Anaesthesia for infra umbilical surgeries in children as it provides post-operative analgesia and reduces perioperative narcotic requirements. In randomized single blinded case control study evaluating caudal block in children using Bupivacaine and Ropivacaine in 75 children posted for infra umbilical surgeries concluded that caudal Ropivacaine provided reliable post-operative analgesia similar to Bupivacaine in quality and duration of pain relief, motor, sensory effects and time for first micturition in our study children. Because it is less cardio toxic, it may be safer.

Keywords: Caudal Block, Ropivacaine, Bupivacaine, Infra umbilical surgeries

**Corresponding author*

INTRODUCTION

Caudal epidural block is one of the most common regional techniques used in paediatric anaesthesia. In recent years it has gained popularity especially for short infra umbilical surgical procedures, as it is a simple, safe and reliable technique.

Ropivacaine is the *s*-enantiomer of amide local anaesthetic, which has been extensively evaluated in adults and older children. Recently it has been used in younger children and several studies have reported its clinical efficacy and safety.

When administered for caudal epidural analgesia, for lumbar epidural, for peripheral nerve block and as a continuous epidural infusion.

- Ropivacaine has several properties which may be useful in pediatric practice namely the potential to produce differential neural blockade with less motor block and reduced cardio-vascular and neurological toxicity.
- These features are particularly attractive for day care surgery in children, which is more common nowadays.

Caudal analgesia is a relatively simple technique with a predictable level of blockade and provides excellent post operative analgesia. It most popular regional technique used in pediatric surgeries such as lower abdominal, urologic and lower limb surgeries. This long standing regional anaesthesia technique provides analgesia beyond the duration of surgery with a smooth recovery period and good post operative pain control and therefore reduces analgesic requirements and facilitates early discharge.

Long acting anaesthetics such as Bupivacaine have had a well defined role in regional anaesthesia and analgesia for many years. Since the report of several cases of systemic toxic reactions after accidental intra venous injections of bupivacaine, the need for an effective long acting, local anaesthetic with high therapeutic ratio has prompted researchers to develop new local anaesthetics.

Ropivacaine with a good safety profile may become an ideal alternative to bupivacaine for post-operative analgesia.

MATERIALS AND METHODS

Inclusion Criterion

- Children between 1-10 years
- Posted for infra Umbilical Surgeries
- Physical status ASA I

Exclusion Criterion

- Parental unwillingness
- Body weight more than 25 KGs
- Children with pre existing neurological or spinal disease, cardiovascular, respiratory, renal, hepatic or any other systemic disease
- Bleeding diathesis
- Infection at the site of block
- Abnormalities of the sacrum
- Allergic to local anaesthetics

After institutional approval and parental written inform consent were obtained healthy boys and girls aged 1-10 years with physical status ASA I posted for elective perennial lower abdominal or lower extremities surgeries were allocated a random number table to receive caudal anaesthesia with either bupivacaine or ropivacaine after induction of general anaesthesia.

Anaesthetic Procedure

After induction of general anaesthesia child is made to lie in left lateral position, the caudal injection of propivacaine or bupivacaine, 0.25%, 1 ml/kg was administered using 22 gauge needles.

Post operatively,

- Quality of the pain relief was recorded using hanallah pain score
- The duration of pain relief (time from caudal placement till the first dose of post operative analgesic)
- Motor power and reflexes
- Sensory level and sensory recovery
- Time to first micturition

Sample size calculation to compare the effect of bupivacaine with ropivacaine on pain score, motor power, reflexes and sensation was performed. Pain was assessed based on the Hanallah pain Score (**Table 1**).

Table 1: Hanallah pain score

S.No.	Observation	Criterion	Points
1	Arterial Pressure	> 10% pre op	0
		> 20% pre op	1
		> 30% pre op	2
2	Crying	No Crying	0
		Crying respond to tender love in care	1
		Crying not responding to tender love in care	2
3	Movement	None	0
		Restless	1
		Thrashing	2
4	Agitation	Asleep/Calm	0
		Mild	1
		Histerical	2
5	Posture	No special posture	0
		Flexing legs and thighs	1
		Holding groin	2
6	Complains of pain	Asleep/ No Pain	0
		Cannot localize	1
		Can localize	2

This analysis was based on the 2 sample t tests with a P < 0.05, 80% power and the following assumptions: Detection of mean difference in pain score of 1.5 with a SD 1.5, mean difference I n motor power of 1.0 with SD of 1.5 and mean difference in reflex score of 1.0 with SD of 1.0. It was also assumed that the time from caudal placement to sensory recovery will differ by 30 minutes and SD will be 20 minutes in both groups.

OBSERVATION AND RESULTS

Although 81 children were randomly allocated to medication, the caudal block could not be placed in two older children, and four children (two younger than 1 year and two older than 10 year) were eliminated to decrease the age range. Therefore, 75 children, aged 1-10 years, comprised the study population, and all were included in the analysis. They had urologic, lower abdominal, or lower extremity operations, and the type of surgery did not differ between the two groups.

39 children received bupivacaine and 36 children received Ropivacaine as mentioned in Table 2. There were no differences between the two groups in age; weight; gender; ASA physical status; baseline blood pressure or heart rate; or durations of anaesthesia, surgery, awakening time, and post-operative ward stay

duration as mentioned in Table 3. After surgical incision, the two groups did not differ in intra operative vital signs Table 4.

None of the children developed a hemodynamic problem, respiratory difficulty, or any other adverse effect.

Table 2: Type of surgeries

Type Of Surgery	Bupivacaine	Ropivacaine
Hypospadiasis repair	6	3
Hydrocoelectomy	5	2
Circumcision	16	17
Orchidopexy	6	7
Inguinal Hernioraphy	5	5
Lower Lim surgeries	1	2
Total	39	36

Table 3: Patient Characteristics and Clinical Parameter

Variables	Bupivacaine (n=39)	Ropivacaine E(n=36)
Age (Months)	40 ± 33	35 ± 30
Weight (Kg.)	15 ± 8	13 ± 9
Gender (Male %)	37 (95)	35 (97)
Caudal Placement to surgery start (min)	10 ± 5	9 ± 4
Anaesthesia Duration (min)	66 ± 39	57 ± 24
Surgery Duration (min)	43 ± 39	39 ± 22
End of anaesthesia to awakening (min)	34 ± 21	34 ± 21
Duration of postop ward stay (min)	80 ± 30	89 ± 39

Values are mean plus or minus standard deviation.

Table 4: Statistical values

Time	Bupivacaine			Ropivacaine		
	N	Mean BP (mmHg)	HR (per Minute)	N	Mean BP (mmHg)	HR (per Minute)
Baseline	37	60 ± 15	125 ± 27	42	57 ± 10	127 ± 26
5	37	56 ± 10	134 ± 20	42	57 ± 9	136 ± 24
10	37	58 ± 9	135 ± 20	42	55 ± 10	136 ± 22
15	36	56 ± 8	130 ± 25	42	54 ± 11	135 ± 24
20	31	60 ± 5	130 ± 20	40	54 ± 11	131 ± 24
25	26	56 ± 8	130 ± 20	34	54 ± 11	132 ± 25
30	20	57 ± 10	131 ± 18	27	53 ± 10	125 ± 26
35	20	56 ± 10	133 ± 16	24	53 ± 12	126 ± 26
40	17	54 ± 8	135 ± 18	20	52 ± 11	125 ± 26
45	25	54 ± 10	128 ± 16	17	52 ± 12	124 ± 28
50	11	57 ± 9	126 ± 16	15	51 ± 8	127 ± 25
55	8	57 ± 11	124 ± 16	14	51 ± 9	128 ± 26
60	5	50 ± 6	120 ± 7	13	52 ± 11	125 ± 20
120	0	N/A	N/A	3	53 ± 8	112 ± 34

Pain Relief

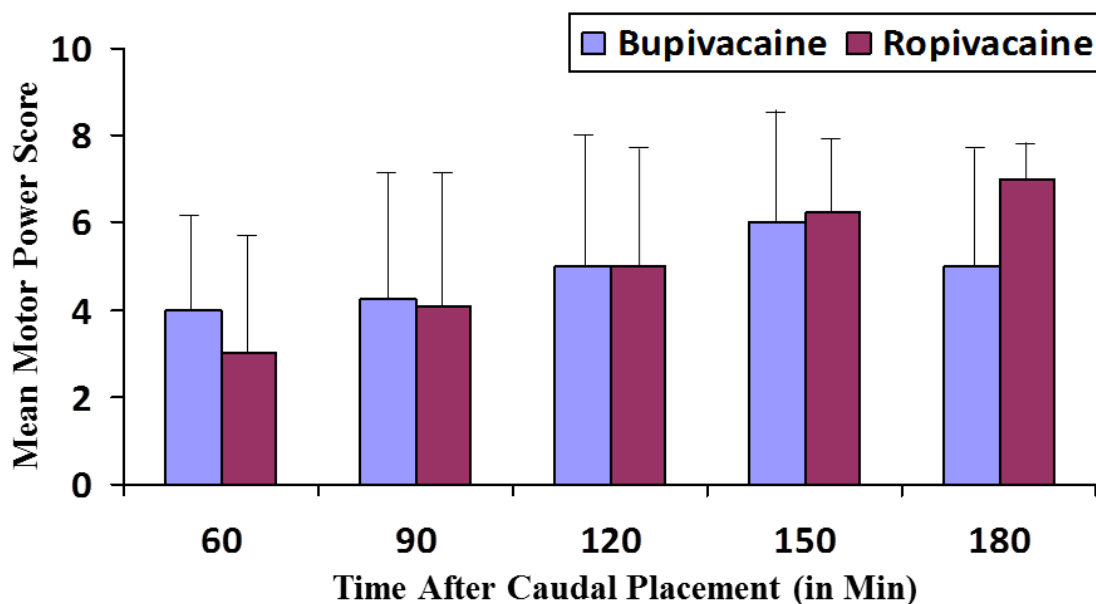
The quality and duration of post operative pain relief did not differ between the two groups. 36% of children in the bupivacaine group and 33% in the ropivacaine group required no additional pain medication during the 24 hour study period. Six children (one given bupivacaine; five given ropivacaine) were given fentanyl 1g/Kg, at the start of the surgery because they responded to the initial incision (P = 0.2). Three of 36 patients receiving bupivacaine and two of 39 receiving ropivacaine required intravenous paracetamol infusion in the recovery room. Oral paracetamol and Brufen combination drugs were given at post operative ward to 23 and 26 children in bupivacaine and ropivacaine groups respectively. The median time for caudal placement to the first administration of pain medication was 680 min for both treatment groups. The 25th percentile was

375 min for bupivacaine and 465 min for ropivacaine. The 75th percentile was 1440 min (24 hours) for both groups. There was no correlation between pain score (or need for analgesia) and regression of sensory or motor blockade.

Motor Power and Reflex Recovery

None of the study children had complete motor power recovery (Svore 10) within 3 hours after placement of caudal block (Figure1); the highest observed score within 3 hours was 8 for both the groups. Most patients were sent to post operative ward with a score of 8.

Figure 1: Degree of Motor Blockade



Micturition Time

There was no difference between the two groups in mean time to first micturition (254 ± 140 min for bupivacaine and 321 ± 164 min for ropivacaine ;) No child required catheterization.

DISCUSSION

Our study substantiates that a single caudal injection of ropivacaine after induction of anaesthesia provides reliable and long standing analgesia in children having ambulatory surgery similar to that studies shown by Vani et al [7] and Da Conceicao et al [8], it resembles Bupivacaine. Similar to earlier adult studies with ropivacaine [9, 10] we used 0.25% solution for both anaesthetics. In 1998 it was reported that 2mg/kg of 0.2% ropivacaine is sufficient to obtain a sensory block for infra umbilical surgeries in children aged 1-9 years. [7] Placing the block before the surgical incision provide intra operative pain relief reduces the general anaesthetic requirement, [6] affords earlier recovery of airway reflexes and contributes to the comfortable awakening.

In our study, children receiving fentanyl were not equally divided between the two treatment groups, which may have caused us to overestimate the effectiveness and duration of analgesia in the ropivacaine group. However, we expect fentanyl 1mcg/kg to “wear off” within 30 minutes, and the mean period for surgery start time to awakening time was not longer in the ropivacaine group. None of these six children receiving fentanyl required additional intra operative fentanyl and halothane requirement was reduced from 1.2% to 0.6%. In the recovery room all children demonstrated signs of motor block and all had adequate sensory levels.

Our median time from caudal placement to first dose of post op analgesia was 11 hours for both treatment groups. A similar pediatric trial [8] using 0.375% bupivacaine or ropivacaine, 1ml/kg, showed that post operative analgesia was required at a mean time of 5 hours for both drugs. In contrast, Ivani et al [7] reported a significant difference between the two drugs in the mean time to requirement of additional analgesia (253 minutes for bupivacaine and 520 minutes for ropivacaine, $P < 0.05$)

Similar to previous studies [7, 8, and 11] we included children scheduled for genital operations having lumbosacral innervations (low procedures) or operations in locations having lower thoracic innervations (high procedures); the number of low or high procedures did not differ between our two treatment groups. Previously, Wolf et al [1] demonstrated that 0.75 ml/kg of 0.25% or 0.125% bupivacaine was adequate for high procedures for children. We administered 1ml/kg for both drugs.

In the recovery room, all of our study children demonstrated signs of motor block and there was early resolution of motor block when compared with the recovery pattern for sensory block.

Most adult clinical trials to date, and our pediatric trial have shown no significant differences in the quality or duration of sensory blockade between 2 equal doses and concentration of bupivacaine and ropivacaine. [12-14]. However our studies have reported differences in the duration of sensory block [15-17].

Few pharmacokinetic studies of ropivacaine in children have been published. Habre et al [19] reported that 1ml/kg of ropivacaine, 2.5mg/ml, by caudal block produced a maximal venous plasma concentration of 0.72 ± 0.24 mg/l at 2 hours, which is much later than that reported for bupivacaine in children (29 ± 3.1 min) [20] and considerably lower than the maximal tolerated venous plasma concentration of ropivacaine in 12 adult volunteers (2.2 ± 0.8 mg/l) [21]

SUMMARY

This is a randomized single blinded case control study evaluating caudal block in children using bupivacaine and ropivacaine in 75 children posted for infra umbilical surgeries. The deduction from these studies were,

- Two groups did not differ in intra operative vital signs throughout the surgeries
- 2 mg/kg of 0.2% ropivacaine is sufficient to obtain a sensory block for infra umbilical surgeries in children. Placing the block before the surgical incision provides intra operative pain relief, reduces the general anaesthetic requirement.
- It aids earlier recovery of airway reflexes and contributes to a comfortable awakening.
- In the recovery room all of our study children demonstrated signs of motor blockade and there was early resolution of motor block when compared with the recovery pattern for sensory block.
- There was no difference between the two groups in mean time to first micturition, no child required catheterization.

CONCLUSION

Caudal ropivacaine provided reliable post operative analgesia similar to bupivacaine in quality and duration of pain relief, motor and sensory effects and time to first micturition in our study children. Because it is less cardio toxic, it may be safer.

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