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A randomized double-blinded comparative study of 0.25% Ropivacaine and 0.25% Bupivacaine by Caudal epidural for Paediatric sub-umbilical surgeries

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Abstract

Background & Objectives: Bupivacaine is the most frequently used local anaesthetic for caudal anaesthesia in children. Ropivacaine provides pain relief similar to bupivacaine with lesser motor blockade and cardiotoxicity. To compare caudal 0.25% ropivacaine and 0.25% bupivacaine in terms of the quality and duration of analgesia, motor and sensory block for sub-umbilical surgeries in children.

Materials & Methods: In a double-blinded randomized comparative study, 60 children aged 3-8 years were randomly allocated to receive a presurgical caudal injection of 0.75ml/kg of either 0.25% Ropivacaine (Group R) or 0.25% Bupivacaine (Group B) after induction of general anaesthesia. Apart from monitoring the vital parameters, all children were assessed for postoperative analgesia by Hannallah pain scale and for motor blockade by Motor power score. The time for full sensory recovery was also observed.

Results: The groups were comparable for age, sex, weight, height, vital signs, duration and type of surgery. The duration of postoperative pain relief did not differ between the two groups (338.83±44.75 min (group R) Vs 346.67±51.06 min (group B). The motor blockade recovered quickly in group R (113.50±10.18 min) than in group B (128.50±17.48 min) P<0.001. The time for full sensory recovery was similar for both the groups (77.50±2.67 min in group R vs 80.00±7.19 min in group B).

Conclusion: Caudal 0.25% ropivacaine provided good quality of analgesia with significantly faster motor recovery than 0.25% bupivacaine, allowing the children to be discharged earlier.

Keywords: Caudal epidural, Ropivacaine, Bupivacaine, Hannallah pain score, Motor block, Post-op analgesia

Introduction

Regional anaesthesia, especially caudal epidural plays an important role in providing pain relief both in the intra-operative and post-operative periods in paediatrics. Bupivacaine is a long-acting amide local anaesthetic that has provided reliable anaesthesia and analgesia with differential motor-sensory blockade for more than 40 years.[1,2]

In response to the problem of increased cardiac toxicity of racemic mixtures of bupivacaine, single enantiomers were developed and Ropivacaine is the first local anaesthetic to be prepared as a pure S-enantiomer that is less cardio-toxic.[3] The sensory block provided by ropivacaine is similar to that produced by an equivalent dose of bupivacaine in epidural and peripheral nerve block whereas the motor block produced by ropivacaine is slower in onset, less intense and shorter in duration than bupivacaine.[3] Hence, this study was undertaken to compare the effectiveness of ropivacaine with bupivacaine for caudal anaesthesia in children.

Materials and Methods

After obtaining Institutional Ethical Committee clearance, this, prospective double blinded randomized comparative study was conducted in our hospital from April 2015 to September 2015. After obtaining informed consent from parents, sixty ASA I-II children aged 3-8 years undergoing lower abdominal surgeries were randomized by computer generated randomization table into two groups of thirty each – Group B and Group R. The randomization sequence was prepared in double-blinded cancelled manner. The study solution was prepared by a final year post-graduate student who was not associated with the study. The caudal block was performed by the fourth author whereas the observations were done by the first author. The study blinding was broken after the statistical analysis. The children in group B received 0.75ml/kg of 0.25% Bupivacaine (0.5% solution diluted in equal volumes of sterile water) whereas those in group R received 0.75ml/kg of 0.25% Ropivacaine (0.5% solution diluted in equal volumes of sterile water) through the caudal route. Those children with local infection, pre-existing neuromuscular disease, bleeding diathesis were excluded from the study.

The children were fasted for 6 hours for solids and 2 hours for clear liquids. All children were premedicated with intranasal Midazolam 0.2mg/kg[4] 15-20 min before surgery. They were brought into the operation theatre and intravenous access was secured with appropriate size intravenous canula. Maintenance infusion was started with Isolyte-P (4-2-1 rule)[5] and Inj. Atropine 0.02mg/kg i.v. was given. Standard Monitors like pulse oximeter, blood pressure, ECG, temperature probe, precordial stethoscope were placed and baseline values recorded. Then the children were pre-oxygenated with 100% O_2 for 3 minutes and induced with Inj.Propofol 2.5mg/kg i.v. After administering Inj. Atracurium 0.5 mg/kg i.v., the

children were mask ventilated with $N_2O:O_2$ (3L:3L) and 2% Sevoflurane mixture for 3 minutes and intubated with the appropriate size endotracheal tube. The children were then placed in left lateral position and under sterile aseptic precautions, caudal epidural injection was given with 0.75 ml/kg of either 0.25% bupivacaine or 0.25% ropivacaine depending upon the group. Then the patients were placed in supine position and anaesthesia was maintained with N2O:O2 (4:2), 1% Sevoflurane and top-up doses of Inj. Atracurium (0.1mg/kg). The incision was made 10 min after caudal block.

An independent blinded Observer (the first author) recorded heart rate, BP, SpO2 just before and after surgical incision and then every 5 min interval till the end of surgery. If the patient responded to the incision with a greater than 15% increase in Systolic BP or Heart rate, Inj. Fentanyl 1 µg/kg i.v. was administered and these children were excluded from the study. Significant bradycardia was defined as greater than 20% decrease from baseline and significant hypotension requiring treatment was defined as more than 20% fall of Systolic blood pressure from baseline. At the end of the surgery, residual neuromuscular blockade was reversed with Inj. Neostigmine 0.05mg/kg i.v. and Inj. Atropine 0.02mg/kg i.v. and the child was extubated awake. The child was then shifted to the recovery room for observation.

Post-operatively, apart from monitoring PR, BP, SpO_2, the quality of analgesia was assessed by Hannallah Objective Pain Scale[6] (Table 1) every 15 min for the first two hours and every 30 min for the next 8 hours. The time between the caudal block and administration of the first rescue analgesic drug was noted. Diclofenac rectal suppository 1mg/kg[7] was given as rescue analgesic when the pain score equals or exceeds 4.

Table 1: Hannallah Objective Pain Scale (OPS)

No	Observation	Criteria	Points
1.	Systolic Blood pressure	+ 10% pre op	0
		> 20% pre op	1
		> 30% pre op	2
2.	Crying	No crying	0
		Crying responding to tender loving care	1
		Crying not responding to tender loving care	2
3.	Movement	None	0
		Restless	1
		Thrashing	2
4.	Agitation	Asleep/calm	0
		Mild	1
		Hysterical	2
5.	Posture	No special posture	0
		Flexing legs and thighs	1
		Holding groin	2
6.	Verbalisation of Pain	Asleep/states no pain	0
		Vague/Can`t localize	1
		Can localize pain	2

Motor power was assessed by Motor power scale (Table 2) every 15 min for the first two hours and every 30 min for the next eight hours. The time of attaining full motor recovery (Score = 10) was noted. The level of sensory block was assessed by pin-prick test every 15 min interval till the patients regained complete sensory recovery. The time to first micturition and any adverse events or complications were noted.

Table 2: Motor power scale

1.	Muscle Tone	Flaccid 0	Hypotonia 1	Normal 2
	Muscle Power(Flexion)	Unable	Partial	Normal
2.	Ankle	0	1	2
3.	Knee	0	1	2
4.	Thigh	0	1	2
5.	Ability to stand	0	1	2

Statistical Analysis: Data are expressed as mean ± standard deviation. Quantitative analysis was compared with Independent sample student`s t-test for continuous variables; Chi-square test with Yates correction was used for discrete variables like sex, types of surgery. When using the above statistical tests to compare the mean among the two groups, a p-value of less than or equal to 0.05 was taken as significant. All analyses were done using SPSS version 11.5 statistical software. All values were rounded off to a maximum of two decimals.

Results

Demographic variables like age, sex, weight, height, duration of surgery were comparable between the two groups (Table 3). Of the 60 children, 17 children in each group underwent surgeries involving thoraco-lumbar dermatomes (Herniotomy, PV sac ligation, Orchidopexy) that required a maximum level of T10 whereas the remaining 36 surgeries of both groups involved the sacral dermatomes (Circumcision, Urethroplasty, Foreign body foot).

Table 3: Demographic variables, duration of surgery

Variable	Group R		Group B		P-value	Standard Error difference	Confidence intervals of difference 95%	
	Mean	SD	Mean	SD			Lower	Upper
Age (years)	4.93	1.82	4.83	1.82	0.83*	0.47	-0.84	1.04
Weight (kg)	14.13	3.00	14.07	3.96	0.94*	0.91	-1.75	1.88
Height (cm)	111.73	5.79	111.63	6.43	0.95*	1.58	-3.06	3.26
Duration of surgery	32.67	10.06	32.83	9.62	0.95*	2.54	-5.26	4.92

There was no significant bradycardia or hypotension (>20% fall) in any of the children. The mean heart rates (Fig. 1), systolic & diastolic BP (Fig. 2) at 5 min intervals up to the completion of surgery did not differ significantly between the two groups.

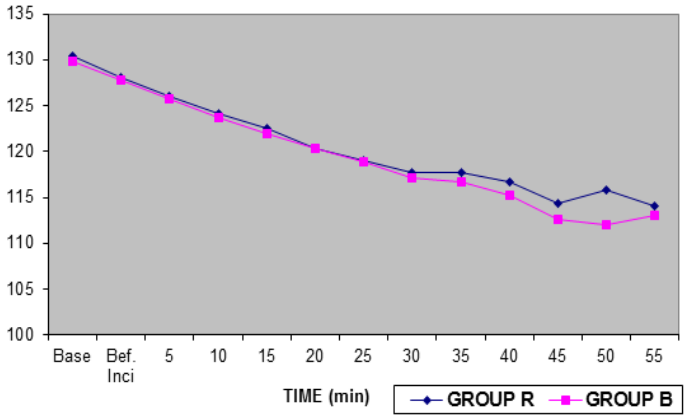

Fig. 1: Heart Rate Variability

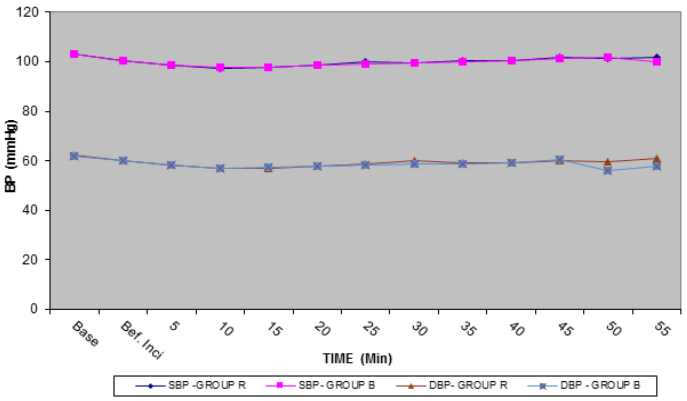

Fig. 2: Systolic (SBP) and Diastolic (DBP) blood pressure variability

All the blocks were successful with none of the children responding to the skin incision with an increase in heart rate or systolic blood pressure. There was no need for supplementation with Inj.Fentanyl intra-operatively. Only one child in group B was given diclofenac suppository at the end of 3 hours whereas none in group R required supplementary analgesia during the same time period (Fig. 3). But by the end of 5 hours, only 18 children in group B had received diclofenac suppository in contrast to 21 children in group R though the difference was statistically insignificant. But, all children required rescue analgesia by the end of 7 hours.

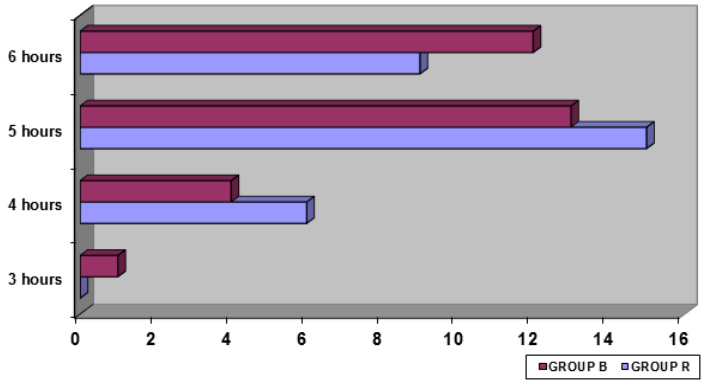

Fig. 3: No. of patients requiring rescue analgesia

Post-operatively, the quality and duration of analgesia did not differ between the two groups. The Hannallah pain scores did not differ significantly at 0, 1, 2, 3 hours post-operatively between the two groups (Table 4). But the mean scores were slightly less in group R than in Group B after 6 hours, though they were statistically insignificant. The mean time from caudal placement to the first administration of rescue analgesic was 338.83±44.75 min in group R and 346.67±51.06 min in group B, the difference being statistically insignificant (P=0.53) (Table 5).

Table 4: Hannallah Objective Pain Score

Time	Group R		Group B		
	N	Mean±SD	N	Mean±SD	p-value
1 hour	30	0.93±0.25	30	0.70±0.65	0.08
2 hours	30	1.93±0.25	30	2.00±0.53	0.09
3 hours	30	2.43±0.50	30	2.63±0.67	0.48
4 hours	30	3.10±0.40	30	3.10±0.61	0.36
5 hours	30	3.57±0.57	30	3.53±0.82	0.83
6 hours	30	4.00±0.59	30	3.87±0.86	0.71
7 hours	30	4.30±0.54	30	4.40±0.81	0.46
8 hours	30	4.30±0.47	30	4.53±0.57	0.09
9 hours	30	4.40±0.50	30	4.63±0.62	0.11
10 hours	30	4.40±0.50	30	4.53±0.63	0.37

Table 5: Time of rescue analgesia, Full motor recovery, Full sensory recovery, time to first micturition

	Group R		Group B		P-value	S.E.D.	C.I. of diff. 95%	
	Mean	SD	Mean	SD			Lower	Upper
Time of first Analgesia (Min)	338.83	44.75	346.67	51.06	0.53*	12.39	-32.65	16.98
Full motor recovery	113.50	10.18	128.50	17.48	0.001	3.69	-22.39	-7.61
Full sensory recovery	77.50	2.67	80.00	7.19	1.49*	1.67	-5.82	0.85
Time to first micturition	326.88	41.88	330.00	32.62	0.30*	10.57	-24.38	18.13

Fifteen children in group R had full motor power (score =10) at the end of 105 min after surgery whereas only 4 children had full motor power in group B. At the end of 120 min, only one out of the total 30 children in group R did not have full motor recovery whereas 12 out of the 30 children in group B were having mild motor weakness. All children had regained full motor power by the end of two and half hours in both the groups. But, the mean time for full motor recovery in group R was 113.50±10.18 min compared to 128.50±17.48 min in group B the difference being highly significant (P=0.001). (Table 6)

Table 6: Motor Power Score

Time	Group R		Group B		
	N	Mean±SD	N	Mean±SD	p-value
0 Minutes	30	2.33±0.48	30	2.03±0.18	0.003
30 Minutes	30	3.30±0.75	30	2.63±0.56	0.002
60 Minutes	30	5.03±0.85	30	4.13±1.01	0.001
90 Minutes	30	7.80±0.93	30	6.73±1.05	0.001
105 Minutes	30	9.17±0.95	30	8.20±0.85	0.001
120 Minutes	30	9.97±0.18	30	9.47±0.73	0.001
150 Minutes	30	10.00±0.00	30	10.00±0.00	-

There was no difference statistically in the time for resolution of sensory blockade between the two groups (Table 5). Apart from the 10 children who underwent urethroplasty, there was no difference in the time to first micturition between group R (326.88±41.88 min) and B (330.00±32.62 min). No child required catheterization postoperatively due to retention.

Postoperatively, there were no adverse hemodynamic alterations without any significant difference in the Pulse rate, Blood pressure and the Oxygen saturation between the two groups.

Discussion

Our study showed that a single pre-surgical caudal injection of ropivacaine after induction of anaesthesia provided good quality analgesia of sufficient duration following lower abdominal and perineal surgeries.

Ropivacaine has been used in different concentrations for caudal block with varying efficacy. Da Conceicao et al[8] used ropivacaine 0.375% for caudal block and found that it produces sufficient analgesia for lower abdominal surgery in children. But, Ivani et al[9,10] in two different studies observed that 0.2% ropivacaine given through the caudal route in children is sufficient to provide sensory blockade for infra-umbilical surgeries. In our study, we used 0.25% ropivacaine that provided reliable and long duration analgesia. This finding is in conjunction with previous studies.[11,12]

We included children who underwent surgeries involving lumbosacral (low) as well as lower thoracic (high) innervations but the number of low and high procedures did not differ between the two groups. Wolf et al[13] demonstrated that 0.75ml/kg of 0.25% or 0.125% bupivacaine with epinephrine caused adequate sensory blockade for high procedures involving 13 dermatomes in children. In our study, we used 0.75ml/kg volume for caudal injection that was adequate for both thoracolumbar as well as sacral surgeries. But, other studies[10,12,14] have used 1ml/kg of local anaesthetic for thoracolumbar surgeries.

Many workers[9,10] had observed that 1ml/kg of 0.2% ropivacaine and 0.25% bupivacaine by caudal block had similar onset and duration. They compared these concentrations in order to achieve equal volumes and to maintain blindness of the study. But, we used equal volumes of 0.25% concentration of both ropivacaine and bupivacaine, thereby achieving study blinding as done by Khalil et al[12] and others.[11]

In our study, the mean time from caudal block to first dose of diclofenac administration was comparable for both the groups with the average being slightly less than 6 hours. A similar trial[12] using 0.25% bupivacaine or 0.25% ropivacaine showed that postoperative analgesia was required at a mean time of 11hours for both drugs whereas another study[8] using 0.375% bupivacaine or ropivacaine revealed that the mean time for first analgesia was around 5 hours in both drugs. On the contrary, Ivani et al[10] compared 0.2% ropivacaine with 0.25% bupivacaine and observed that first requirement of rescue analgesia was 253 and 520 min for bupivacaine and ropivacaine groups respectively($P<0.05$). But this finding was not replicated by other studies.[9,11,12]

Our study showed that significant motor block was demonstrated in all our study children in the recovery room, with the ropivacaine group having a statistically significant greater motor power score than bupivacaine group. This faster resolution of motor blockade in the ropivacaine group continued in the post-operative ward also. This is in conjunction with other studies[11] that recorded quicker motor recovery with 0.25% ropivacaine than 0.25% bupivacaine. Khalil et al[12] also found delayed motor recovery in both the groups and found that those who received 0.25% ropivacaine had slightly higher mean motor score at the end of 3 hours than those who had received 0.25% bupivacaine. Da Conceicao et al[8] used a higher concentration (0.375%) of ropivacaine and bupivacaine and observed that there was significant difference between ropivacaine and bupivacaine groups in motor block postoperatively with lesser blockade in the former. This quicker motor recovery in ropivacaine group may be due to its less lipid solubility as determined by the N-heptane/buffer partition coefficient of 2.9 as against that of 10 for bupivacaine.[3] This low lipid solubility and high pKa (8.1) of ropivacaine causes blockade of A – delta and C fibers supplying pain and touch sensation to a greater extent than that of the A-α and A-β fibers supplying motor sensation.

Other workers[11,12] had observed that there were no significant differences in the quality or duration of

sensory blockade between equal doses and concentrations of bupivacaine and ropivacaine and reported that sensory block resolved earlier than motor block. Our study also supported their views.

In our study, there was a delay in micturition of around five and half hours in both the groups with no significant difference between them. This was supported by others[12] who did not find any difference in the time to first micturition between ropivacaine and bupivacaine. This delay may be due to the blockade of the sacral fibres caused by caudal block that prevents voiding of urine.

Only one child in ropivacaine and 2 children in bupivacaine group had vomiting postoperatively that was treated with Inj. Ondansentron 0.01mg/kg i.v. This may be due to the effects of general anaesthestics.

Due to the smaller study group, we did not encounter any instance of intravenous or intraosseous injections that could have resulted in local anaesthetic toxicity, thereby conferring an added advantage for ropivacaine in terms of increased safety profile.

Others[9,10,12] have compared the effects of caudal ropivacaine and bupivacaine when administered along with volatile anaesthetics intraoperatively. Pablo M. Ingelmo et al[15] in their study observed that without the effects of volatile anaesthetics, 0.2% ropivacaine is less effective during surgical stimulation than 0.2% bupivacaine and 0.2% levobupivacaine when used for caudal block. They reasoned out this finding based on the observation that all volatile anaesthetics depress the spinal alpha-motor neuron activity and may potentiate caudal ropivacaine. But they too observed that there was no difference in the analgesic onset times or residual analgesia indicating ropivacaine is an effective local anaesthetic.

Conclusion

Caudal Ropivacaine 0.25%, 0.75ml/kg provided reliable and long lasting analgesia similar to 0.75ml/kg of 0.25% bupivacaine in children undergoing sub-umbilical surgeries. ropivacaine caused less motor blockade than bupivacaine with similar time for sensory recovery. These along with the lower intrinsic toxicity of ropivacaine make it an effective and safe drug for day case surgery in paediatric patients.

Conflict of Interest: Nil

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