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Efficacy of Caudal Ropivacaine Vs Bupivacaine in Paediatric Population

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Abstract

Introduction: Caudal anaesthesia has formed a "Corner Stone" in paediatric regional anaesthesia. Bupivacaine is commonly used for caudal analgesia. Newer drugs like Ropivacaine is more cardio-stable and produces less motor blockade hence safer in paediatric age group. *Methodology:* This study was conducted at a tertiary care setting on 60 ASA 1 & 2 children posted for elective sub-umbilical surgeries. After thorough pre-anaesthetic evaluation, General Anaesthesia was administered followed by Caudal procedure with administration of Ropivacaine (R) or Bupivacaine (B) 1 ml/kg of 0.25% each. Motor blockade and Pain Scores were assessed using Modified Bromage Scale and Objective Pain Score respectively. Rescue analgesics were supplemented accordingly. *Results:* Haemodynamic parameters, pain score and duration of caudal analgesia were comparable in the 2 groups. Motor blockade in the immediate post-recovery period had a mean value of 1.80 ± 0.66 in group R and 2.47 ± 0.51 in Group B with a $p<0.01$ and was statistically significant. At 4th hr post-operatively, Group R had no motor blockade whereas Group B had a score of 0.17 ± 0.38 with a $p<0.019$ and statistically significant. *Conclusion:* Caudal Ropivacaine offers less motor blockade compared to Bupivacaine and is safe for paediatric population.

Keywords: Caudal; paediatric; ropivacaine; bupivacaine; motor blockade.

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Introduction

Pain is an inevitable component after surgery. Discovering various methods of pain relief has been a constant human effort in the field of medicine. Various techniques and medications have been used to treat acute postoperative pain. Successful pain management depends on a thorough understanding of pain pathways. The pain pathways are well defined even in new born infants thus resulting in significant signs of distress due to any nociceptive stimulus [1]. It has been proved beyond doubt that the density of nociceptive nerve endings in these newborn infants is similar to or greater than that in adults [2,3]. Among the various techniques used, "Caudal Anaesthesia" is very popular and has become a corner-stone in paediatric regional anaesthesia.

Caudal Anaesthesia was first described in 1895 by Fernard Cathalin and Jean Anthanase Sicard. It was first described in paediatric urological intervention in 1933 [4]. It holds an important place as an effective analgesic during intra and post-operative period in paediatric sub-umbilical surgeries [5].

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Various drugs have been employed in caudal anaesthesia. These include local anaesthetics and various adjuvants. The drugs selected for caudal anaesthesia should be safe and devoid of any side effects. Bupivacaine, a long acting anaesthetic has been very popular for caudal anaesthesia. But it possess cardiac side effects and long duration of motor blockade. Ropivacaine, a pure S-enantiomer with similar structure, pharmacology, mechanism of action and physicochemical properties has fewer cardiac side effects and lesser motor blockade when compared to Bupivacaine [6,7].

This comparative study evaluates the efficacy of Ropivacaine (0.25%) with Bupivacaine (0.25%) administered caudally with regard to duration of sensory and motor blockade, quality of analgesia, cardiovascular side effects.

Materials and Methods

Sample size calculation—to ompare the effect of bupivacaine with ropivacaine on motor blockade, power analysis was performed. Mean difference in motor blockade of 1.2 with an SD of 1.0, a mean difference in time duration of analgesia of 7.0 with an SD 5.0, in both groups with 80% power and 95% confidence interval. Power analysis indicated that the minimum number of patients needed in each group should be 11. So 30 patients were selected in each group.

This study was conducted at a tertiary care hospital on 60 children of either sex aged 2 to 10 years, belonging to ASA I and II physical status posted for elective subumbilical surgeries like inguinal herniotomy, appendicectomy, circumcision, orchidopexy, perineal surgeries and urological surgeries. After obtaining institutional ethical committee clearance, an informed verbal and written consent was obtained from parents/ guardian. Children with documented allergy to local anaesthetics, spine/meningeal abnormality, infection at caudal region and coagulopathies were excluded from the study.

After a thorough pre-anaesthetic evaluation, routine investigations were performed. Standard fasting guidelines were ordered and fluid calculation was done based on Holiday and Segar formula and replaced.

On the day of surgery, all children were pre-medicated with oral midazolam 0.5 mg/kg 30 minutes prior to surgery in the pre-operative holding area after connecting to SpO_2 monitor.

On arrival into the operation theatre, all children were connected to standard monitors like pulse oximetry, ECG, NIBP and baseline parameters were noted. All children were induced with gas, O_2, sevoflurane. Appropriate size IV canula was secured. Inj. Glyco-P 0.01 mg/kg, Inj. Fentanyl 2 µg/kg iv were given, relaxed with Inj. Vecuronium 0.1 mg/kg iv, intubated with appropriate sized endotracheal tube. After securing the ETT, all children were put in left lateral semi-flexed position. They were randomly allocated into 2 groups by a computer generated randomization table. Group B received 0.25% Bupivacaine 1 ml/kg and Group R received 0.25% Ropivacaine 1 ml/kg through the caudal epidural route performed under strict aseptic precautions. After the caudal procedure, children were placed in the desired surgical position. Anaesthesia was maintained with O_2, N_2O, volatile agent and IPPV with intermittent dose of vecuronium. Towards the end of surgery, anaesthetic agents were discontinued. Children were reversed and extubated ones awake and adequate spontaneous ventilation was attained. The children were shifted to recovery room.

Haemodynamic parameters like Heart Rate (HR), Blood Pressure Systolic (SBP), Diastolic (DBP) and Mean Arterial Pressure (MAP) were recorded at 0, 5 10, 15, 30 minutes after administration of caudal and thereon every 15 minutes till the end of the procedure. Time of caudal injection, type and duration of surgery, duration of sensory and motor blockade, duration of caudal analgesia were noted.

Modified Bromage scale consisting of 4 points was used to assess motor blockade in older children.

0 - Full motor strength (flexion of knees and feet)

1 - Flexion of knees only

2 - Little movement of feet only

3 - No movement of knee or feet.

In younger children who were not able to move their legs on command, the legs and feet were tapped/stimulated and motor block was assessed.

In the postoperative period, pain scores were assessed by a person blinded to the study at 1, 2, 4, 8 and 12th hour using a 5-point Observer Pain Score (OPS).

1 - Asleep/Awake/Laughing

2 - Awake but not in pain

3 - Mild pain (Irritable/Restless)

4 - Moderate pain (crying/grimacing/restless but consolable)

5 - Severe pain (crying/screaming and inconsolable).

Rescue analgesics were supplemented when pain score was 4 and above with paracetamol and ibuprofen syrup.

Any side-effects like hypotension, nausea/ vomiting, urinary retention were noted.

Statistical Analysis

The results of continuous variables are given as mean ± SD and proportion as percentage. The difference between the two groups was assessed by student's T test and chi-square test. For all the tests a 'p' value of 0.05 or less was considered for statistical significance.

Results

Both groups were comparable with regard to age, sex and weight distribution as shown in Table 1, 2and 3. The type and duration of surgeries are as shown in Table 4 and Table 5. The heart rate, systolic, diastolic blood pressure and mean arterial pressure are as shown in Table 6, 7, 8, 9 and Graph 1, 2, 3, 4 respectively. There was no significant differences in the above parameters between the 2 groups with a $p>0.05$ which was not significant.

The pain score at various time interval in the post-operative period is shown in Table X with a p-value >0.05 which was not significant at any given time interval.

Motor blockade assessed as per the modified Bromage Scale was statistically significant at immediate post recovery with a mean value of 2.47±0.51 in Group B and 1.80±0.66 in group R with a $p<0.01$. On assessment of motor blockade at 4th hour postoperatively, Group B had a score of 0.17±0.38 whereas Group R has no motor blockade. This was statistically significant with a $p<0.019$ as shown in Table XI and Graph V respectively.

The duration of caudal analgesia was comparable in both the groups with mean duration of 276.50±15 minutes in group B and 272.33±0.81 in group R. The p value of 0.238 was statistically insignificant as shown in Table XII.

Urinary retention was noted in 2 patients in Group B and 3 patients in Group R. No other side effects were noted in either group.

Table 1: Age Distribution

Age in years	Bupivacaine		Ropivacaine	
	No	%	No	%
1-2	0	0.0	1	3.3
3-5	15	50.0	9	30.0
6-10	15	50.0	20	66.7
Total	30	100.0	30	100.0
Mean ± SD	5.70 ± 1.78		6.27 ± 2.12	

Samples are age matched with p=0.267

Table 2: Gender Distribution

Gender	Bupivacaine		Ropivacaine	
	No	%	No	%
Female	1	3.3	1	3.3
Male	29	96.7	29	96.7
Total	30	100.0	30	100.0

Samples are gender matched with P=0.103

Table 3: Weight (kg)

Weight (kg)	Bupivacaine		Ropivacaine	
	No	%	No	%
1-10	8	26.7	12	40.0
11-20	21	70.0	17	56.7
21-30	1	3.3	1	3.3
Total	30	100.0	30	100.0
Mean ± SD	12.30 ± 3.12		12.10 ± 3.98	

Samples are weight matched with p=0.829

Table 4: Types of surgical procedures

Surgery	Bupivacaine		Ropivacaine	
	No	%	No	%
Herniotomy	16	53.3	21	70.0
Circumcision	12	40.0	6	20.0
BL herniotomy	0	0.0	1	3.3
Femoral implant removal	0	0.0	1	3.3
Polypectomy	1	3.3	0	0.0
Urethroplasty	1	3.3	0	0.0
Vaginal laceration	0	0.0	1	3.3
Total	30	100.0	30	100.0

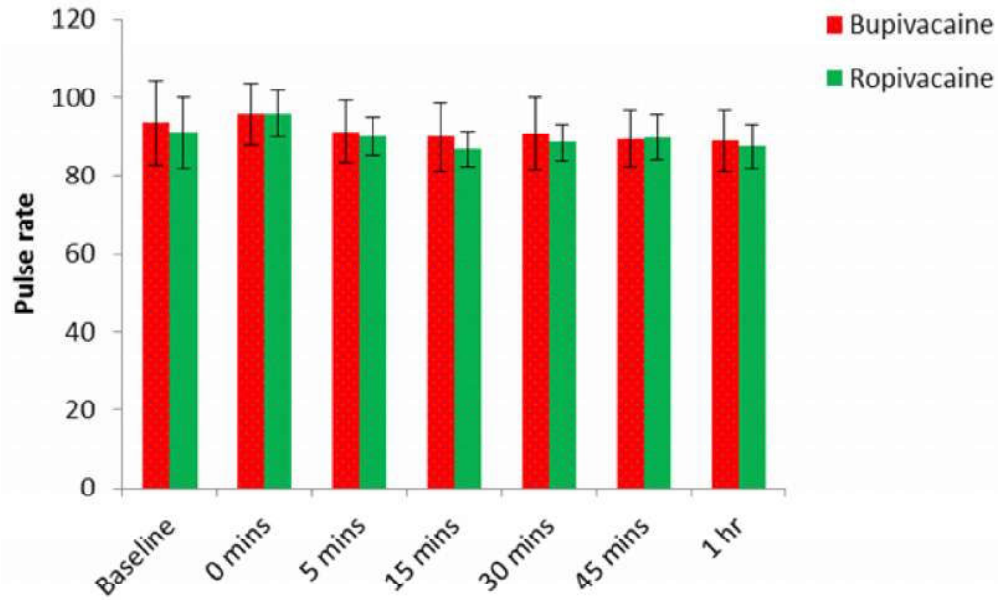
Table 5: Duration of Surgery (mins) in two groups of patients studied

Duration of Surgery (mins)	Bupivacaine		Ropivacaine	
	No	%	No	%
<30	12	40.0	7	23.3
30-50	15	50.0	19	63.3
>50	3	10.0	4	13.3
Total	30	100.0	30	100.0
Mean ± SD	39.00 ± 16.32		41.17 ± 13.04	

p=0.572, Not significant, Student t test

Table 6: Heart Rate

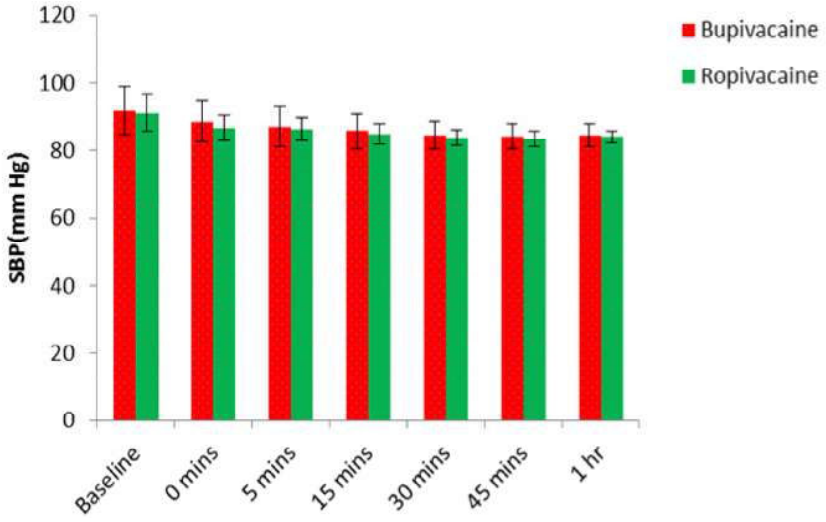
Heart rate	Bupivacaine	Ropivacaine	P value
Baseline	93.60±10.83	90.97±8.94	0.309
0 mins	95.63±7.88	95.80±6.00	0.927
5 mins	91.23±7.91	90.03±4.93	0.484
15 mins	89.87±8.57	86.80±4.64	0.090+
30 mins	90.77±9.21	88.43±4.78	0.223
45 mins	89.43±7.31	89.73±5.78	0.861
1 hr	89.00±7.88	87.60±5.62	0.431



Graph 1: Heart rate

Table 7: Comparison of SBP (Mm Hg) in two Groups of Patients Studied

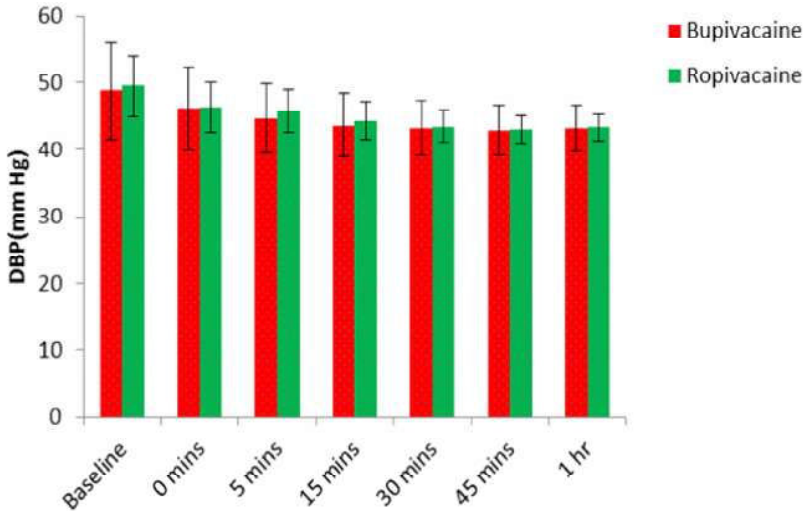
SBP (mm Hg)	Bupivacaine	Ropivacaine	p value
Baseline	91.90 ± 6.94	91.20 ± 5.45	0.666
0 mins	88.73 ± 6.20	86.83 ± 3.86	0.160
5 mins	87.23 ± 5.93	86.50 ± 3.43	0.560
15 mins	85.87 ± 5.21	85.03 ± 2.93	0.448
30 mins	84.53 ± 4.16	83.93 ± 2.24	0.489
5 mins	84.33 ± 3.80	83.67 ± 2.31	0.415
1 hr	84.53 ± 3.50	84.23 ± 1.77	0.677



Graph 2: Comparison of SBP (mm Hg) in two groups of patients studied

Table 8: Comparison of DBP (Mm Hg) in two Groups of Patients Studied

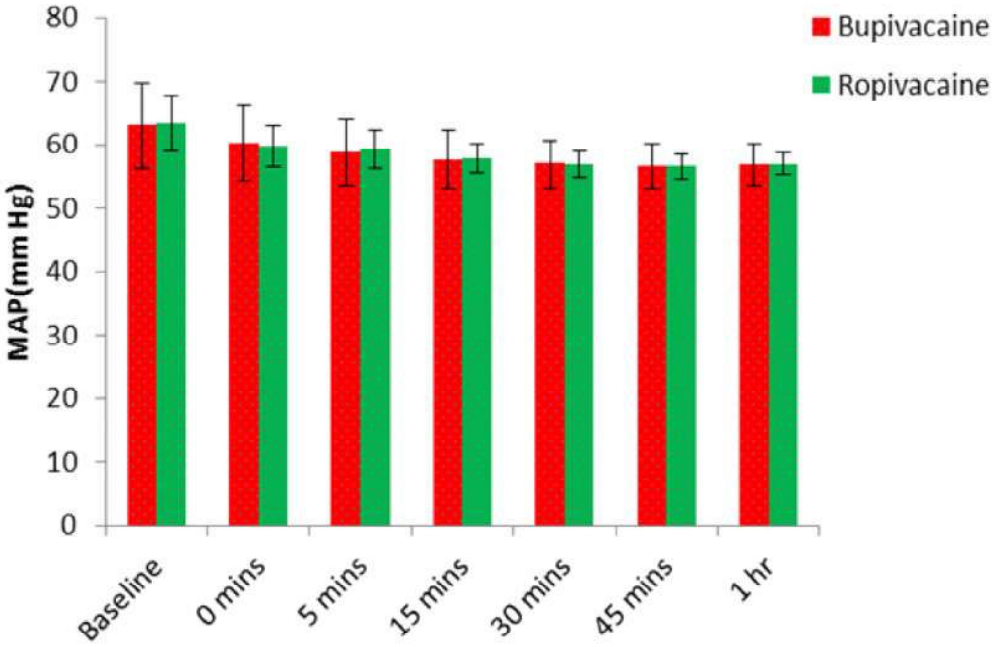
DBP (mm Hg)	Bupivacaine	Ropivacaine	p value
Baseline	48.77 ± 7.22	49.47 ± 4.52	0.655
0 mins	46.13 ± 6.23	46.27 ± 3.67	0.920
5 mins	44.67 ± 5.19	45.73 ± 3.18	0.341
15 mins	43.60 ± 4.70	44.30 ± 2.78	0.486
30 mins	43.23 ± 4.11	43.43 ± 2.34	0.818
45 mins	42.90 ± 3.67	43.07 ± 2.08	0.830
1 hr	43.20 ± 3.42	43.30 ± 1.93	0.890



Graph 3: Comparison of DBP (mm Hg) in two groups of patients studied

Table 9: Comparison of Map (Mm Hg) in two Groups of Patients Studied

MAP (mm Hg)	Bupivacaine	Ropivacaine	p value
Baseline	63.14 ± 6.75	63.38 ± 4.52	0.876
0 mins	60.33 ± 5.94	59.79 ± 3.29	0.662
5 mins	58.86 ± 5.10	59.32 ± 2.93	0.665
15 mins	57.69 ± 4.53	57.88 ± 2.38	0.840
30 mins	57.00 ± 3.74	56.93 ± 2.05	0.932
45 mins	56.71 ± 3.42	56.60 ± 1.97	0.878
1 hr	56.98 ± 3.22	56.94 ± 1.67	0.960



Graph 4: Comparison of MAP (mm Hg) in two groups of patients studied

Table 10: Pain Scale in two groups of patients studied

Pain Scale	Bupivacaine	Ropivacaine	p value
Immediate post recovery	1.00 ± 0.00	1.00 ± 0.00	-
1 hr	1.33 ± 0.48	1.23 ± 0.43	0.399
2 hr	2.00 ± 0.00	2.07 ± 0.25	0.155
3 hr	2.20 ± 0.41	2.23 ± 0.43	0.759
4 hr	3.07 ± 0.45	3.00 ± 0.37	0.534
8 hr	4.00 ± 0.59	3.93 ± 0.58	0.661
12 hr	4.33 ± 0.48	4.53 ± 0.57	0.147

Table 11: Motor blockade in two groups of patients studied

Motor blockade	Bupivacaine	Ropivacaine	p value
Immediate post recovery	2.47 ± 0.51	1.80 ± 0.66	<0.001**
1 hr	1.90 ± 0.48	1.67 ± 0.48	0.065+
2 hr	1.23 ± 0.43	1.10 ± 0.31	0.171
3 hr	0.80 ± 0.41	0.77 ± 0.43	0.759
4 hr	0.17 ± 0.38	0.00 ± 0.00	0.019**

** p value significant

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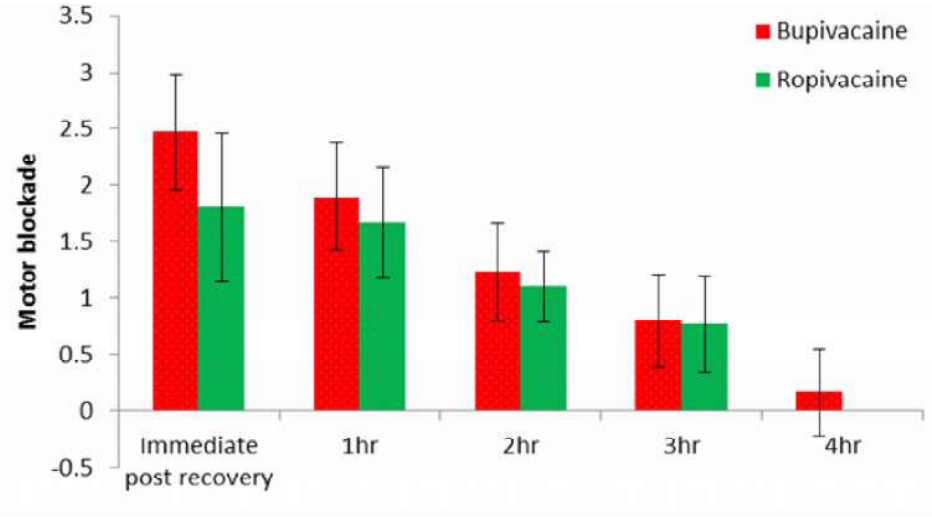

Graph 5: Motor blockade in two groups of patients studied

Table 12: Duration of caudal analgesia in two groups of patients studied

Duration of caudal analgesia	Bupivacaine		Ropivacaine	
	No	%	No	%
<250	4	13.3	1	3.3
250-290	22	73.3	28	93.3
>290	4	13.3	1	3.3
Total	30	100.0	30	100.0
Mean ± SD	276.50 ± 15.82		272.33 ± 10.81	

p=0.238, Not significant, Student t test

Discussion

Ropivacaine being a newer amide local anaesthetic is long-acting with various advantages like minimal cardio-toxicity and neurotoxicity. It has a unique characteristic separation of sensory and motor effects. This property has made Ropivacaine an alternative agent to be used in paediatric blocks [6,7].

Various parameters studied namely haemodynamic variables, pain score and duration of analgesia are comparable in both Ropivacaine and Bupivacaine groups. Studies by Reiz S and colleagues [8] showed lesser cardiovascular events with Ropivacaine than Bupivacaine. Koinig et al. [9], compared haemodynamic effects of the two drugs and found no difference between the two groups. The same is reported by Da Conceicao et al. [10], who studied heart rate and arterial pressure every 5 minutes after administering the twolocal anaesthetic agents.

The motor blockade was statistically significant in Bupivacaine group at immediate postoperative period and at 4th hour interval postoperatively. Dobereiner et al. [11], performed statistical analysis of 17 RCTs and published the report in the evidence based clinical update. They found higher incidence of motor blockade with Bupivacaine and are of the opinion that it should be administered only if motor blockade is desirable and Ropivacaine in conditions where motor block is to be minimized.

Ropivacaine has an intrinsic vasoconstrictive property which prolongs duration of analgesia [12,13,14]. In olden days, adrenaline was used with local anaesthetic agents to bring about this action. But with newer drugs having intrinsic vasoconstrictive property, use of adrenaline has almost become obsolete. Performance of any block for pain relief should aim at minimizing the side-effects, prolonging duration of analgesia and enhancing recovery. These characters are very important in today's era of Day Care Surgery. If the pain management technique provides all the above, it can be considered a Gold Standard.

Bosenberg AI et al. [15] evaluated the efficacy of 3 different doses of caudal Ropivacaine namely 1, 2 and 3 mg/kg and concluded that 2 mg/kg provided satisfactory pain relief. 1 mg/kg had lesser efficacy whereas 3 mg/kg had higher incidence of motor blockade with minimal

improvement in postoperative pain relief. Ivan G et al. [16] in his study reported that 2 mg/kg of 0.2% Ropivacaine is sufficient to obtain sensory block for lower abdominal or genitourinary surgeries in children.

The toxic effects of any local anaesthetic depends upon the maximal plasma concentration achieved after a particular dose, volume and concentration. According to various pharmacokinetic studies, a caudal injection with 1 ml/kg of 0.25% Ropivacaine attains a maximal plasma concentration of 0.72 ± 0.24 mg/lt which is much lower than the maximal tolerated plasma concentration of Ropivacaine 2.2 ± 0.8 mg/lt [17,18].

Conclusion

We conclude that caudal Ropivacaine is safer in paediatric postoperative pain management with lesser degree of motor blockade compared to Bupivacaine. However, the two drugs are comparable in terms of duration of analgesia and minimal cardiovascular effects.

Limitations

1. Small sample size owing to shorter duration of the study.
2. Only ASA I & II children were included. With inclusion of children with ASA 3 & 4, the cardiovascular effects might have been more pronounced owing to their basic pathophysiology.
3. USG was not used for performance of caudal procedure.

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