

To Study and Compare Efficacy of Ropivacaine and Bupivacaine for Caudal Analgesia in Paediatric Patients

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Abstract

Aims and objectives: The aim of the study was to compare quality and duration of intra and post operative analgesia and need of rescue analgesia of 0.5 ml/kg of 0.25% Bupivacaine. and 0.5 ml/kg of 0.2% Ropivacaine. **Methodology:** We conducted a prospective, randomized, double blind study, in which 60 paediatric patients undergoing lower abdominal and genitourinary surgeries. Group A received 0.5 ml/kg of 0.25% Bupivacaine and Group B received 0.5 ml/kg of 0.2% Ropivacaine. Quality and duration of motor block, Adjunct to general anaesthesia, Margin of safety of ropivacaine over Bupivacaine was assessed. **Results:** Both the drugs provided post-operative analgesia Mean duration of post-operative analgesia is 344.5±29.37 min in group A & that In group B is 346.3±10.66 min (paired) two tailed p value is 0.749 which is comparable & statistically not significant. Mean duration of motor block in group A is 176.6±21.02 min and in group B was 103.8±11.79 min with P value of 0.0001 which is statistically significant. The incidence of the side effect between the two groups is not statistically significant. **Conclusion:** Caudal block with 0.2% Ropivacaine resulted in equal duration of analgesia with less duration of motor block as compared with 0.25% caudal Bupivacaine, without an increase in incidence of side effects when administered pre-operatively in a volume of 0.5 ml/kg to children undergoing lower abdominal and urogenital surgeries.

Keywords: Ropivacaine; Bupivacaine; Abdominal and urogenital surgeries.

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Introduction

Pain is by far one of the most common and distressing effects of disease and all medical persons regard its relief as one of their main duties. An acute pain service must act as a research vehicle while anaesthesiologists remain crucial contributors in the fascinating field of pain management. If pain is agony, relieving pain

is ecstasy. "Failure to relieve pain is morally and ethically unacceptable". Adequate pain relief is considered as basic human right. Whether it is by drug, nerve injection, surgery or any other means, every patient want desperately to be relieved by pain. The history of pain management in children is rather described as under diagnosis, misinterpreted. It was misbelieved that children do not suffer from the pain they don't feel it, they

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tolerate the discomfort well, they don't respond to the pain as adult do. Therefore paediatric pain management is challenging and one of the frontiers of modern anaesthesiology.

The post-operative pain has equal importance as that of operative analgesia, Relief of post-operative pain is a challenge for all anaesthesiologists. Expressions of gratitude from patients, free of pain can contribute to feelings of self-esteem and job satisfaction.

In the last 15 years, the use of innovative techniques for the management pain, the awareness of severe complications connected with insufficient pain relief, the neurohormonalsequelae connected with pain, created new philosophy due to which at present there is no reason why neonates, infants and children should be denied of adequate analgesia.

There are many reasons for surgical encounter of the little-angels in the early childhood, lower abdominal surgeries being the most common. They are associated with considerable post operative pain which results in restlessness, agitation, bleeding and psychological stress in children. Insufficient pain relief in early post-operative period also leads to delay in full recovery, prolonged hospital stay, discouraged ambulation, behavioural and psychological problems and parental agony. Caudal epidural block being prescribed by many as the "Wonder Technique" for analgesia has a definitive place in the post-operative pain relief protocols in many hospitals. Caudal epidural block is the most commonly used regional technique for post-operative analgesia in children.

In order to maximize post-operative analgesia, a number of agents been tried by epidural and spinal route. Epidural and spinal opioids have been used but the associated major side effects like sedation; itching, urinary retention, nausea, and vomiting, respiratory depression have limited widespread use. Ropivacaine which is newer and long-acting amide local anaesthetic with a potentially improved safety profile when compared to bupivacaine [1,2]. Ropivacaine being less lipophilic, it is less likely to penetrate in large myelinated motor fibres as compared to bupivacaine, resulting in a relatively earlier recovery from motor blockade without compromising duration of sensory blockade. This property of ropivacaine is helpful in earlier diagnosis of nerve injury which can occur during reduction and fixation of upper limb fractures. Ropivacaine has selective action on the pain-transmitting A δ and C nerves rather than A β fibres, which are involved in motor function. Many comparative studies between ropivacaine and bupivacaine proved that

ropivacaine produces less cardiac as well as central nervous system toxic effects, less motor block and a similar duration of action of sensory analgesia as bupivacaine [3,4].

Because of the side effects of bupivacaine which include motor weakness, cardiovascular and central nervous system toxicity, this study was conducted to compare duration of analgesia, motor block, incidence of side effects with single shot caudal block with either 0.2% Ropivacaine or 0.25% Bupivacaine.

Aims and Objectives

1. To compare quality and duration of intra and post operative analgesia and need of rescue analgesia
2. To compare quality and duration of motor block
3. As an adjunct to general anaesthesia
4. To compare margin of safety of ropivacaine over Bupivacaine.

Material and Methods

The present randomized prospective study titled "To study and compare efficacy of Ropivacaine and Bupivacaine for caudal analgesia in paediatric patients." was carried out; after obtaining the local ethical committee approval. 60 patients of either sex requiring GA with Caudal block for lower abdominal surgeries and genitourinary surgeries were selected after fulfilling following inclusion and exclusion criteria. Patient of ASA class I between 1 year to 10 years of age Patient of both sexes undergoing only elective lower abdominal surgery, genitourinary surgeries were included in the study.

Patients with neurological diseases, bleeding disorders, local infection at the site and patients with obvious skeletal deformities were excluded from the study and patients with upper respiratory tract infections, cardiorespiratory diseases, systemic Problems, meningocele and myelocelwere excluded.

Each patient was examined and interviewed (parents also) on the evening prior to operation. Detailed history about previous illness and treatment was elicited. Thorough physical examination was carried out and patients weight was recorded. Investigations like haemoglobin estimation, urine analysis for albumin and sugar, TLC and DLC were done.

All the parents were informed regarding the procedures of anaesthesia and surgery and a written consent of the parents was obtained.

The children were kept nil by mouth for at least 4 hours before surgery and mothers were informed to give glucose water in the morning 4 hours before the scheduled time of surgery. Oral Midazolam 0.5 mg/kg 30 minutes before scheduled time of surgery was given.

After taking patient on operating table, the standard intra operative monitors i.e. ECG, NIBP, pulse oximeter & temperature probe were applied. Intravenous cannulation was done with 22G or 24G cannula and crystalloid (ringer lactate) infusion was started according to Holiday Segar formula.

Preoxygenation with 100% oxygen by mask was done for 3 minutes. Premedication was done with iv inj. Glycopyrrolate (0.004 mg/kg), inj. Ondansetron (0.08 mg/kg) excluding opioid analgesics. Anaesthesia was induced with injpropofol (2 mg/kg) iv & inj atracurium (0.5 mg/kg) iv was given after checking mask ventilation. Endo tracheal intubation was performed after 3 minutes. Anaesthesia was maintained with O₂ + N₂O + isoflurane through Jackson-Rees paediatric circuit with controlled ventilation.

Then the child was placed in the lateral position with the hips and knees flexed and caudal block was performed. The sacral region was prepared with betadine and spirit solution and following identification of sacral cornua, a 23G needle was inserted into the skin overlying the sacral hiatus. The epidural space was identified by the loss of resistance when the needle pierced the sacrococcygeal ligament. The needle was made parallel to the back and inserted into the canal 2-3 mm more. After the negative aspiration for blood or CSF, the drug was injected.

Group A - 0.5 ml/kg of 0.25% Bupivacaine

Group B - 0.5 ml/kg of 0.2% Ropivacaine

Continuous ECG, B.P, heart rate, pulseoximetric measurements were recorded. After the block (any of the two), patients were placed in supine position and Surgery was carried out. anaesthesia was maintained with oxygen (40%), nitrous oxide (60%), Isoflurane (1-1.5%) and top ups of muscle relaxant. Heart rate (ECG), NIBP & oxygen saturation (SpO₂) was monitored intraoperatively for every 5 mins for first 15 minutes & thereafter every 15 mins till the end of surgery. At the end of surgery, residual neuromuscular blockade was reversed with iv inj. Neostigmine (0.05 mg/kg) & Glycopyrrolate (0.008 mg /kg) & Thorough oropharyngeal and

endotracheal suction was done and patient was extubated after return of reflexes.

Post operatively Heart rate, NIBP & oxygen saturation (SpO₂), pain score & motor blockade was monitored at 15 min, 30 min, 60 min, 90 min, 120 min, 3 hr, 4 hr, 5 hr, 6 hr after surgery. Pain was assessed by mCHEOPS score. Inj paracetamol 20 mg/kg was given iv when mCHEOPS score was greater than 4. The time from caudal block to first post op rescue analgesic administration was the end point of study. Finally assessment of the duration of effective analgesia was done by comparing time from caudal block to administration of first analgesic. Degree of motor blockade was assessed by motor power scale. Other adverse effects like nausea, vomiting, facial flushing, fever were noted. Both groups were comparable in respect to mean age, sex, weight and duration of surgery.

Results

Both groups were comparable in respect to mean age, sex, weight and duration of surgery. The mean duration of surgery in group A is 58±21.51 min. and of group (B) is 53.33±16.78 min. The difference is not statistically significant. Mean total duration of surgery is more or less same in both the groups.

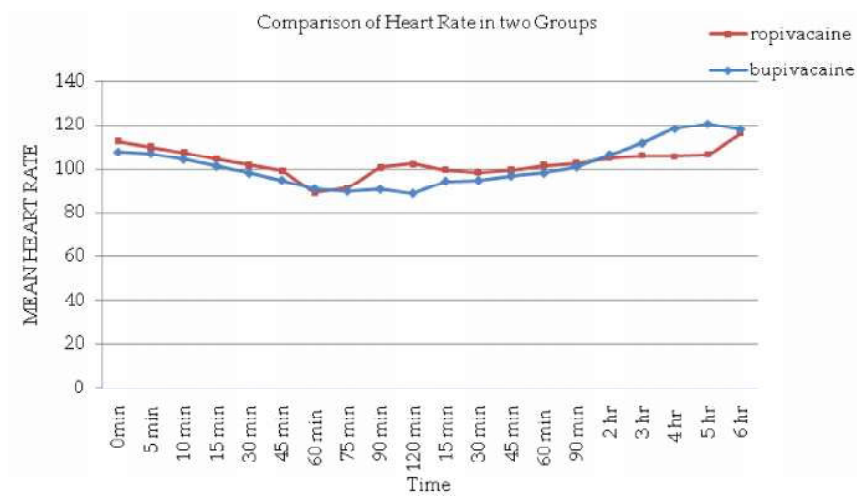
In this study group the mean pulse rate in group A is 107.77±13.942 /min, in group B is 112.67±16.647/min in preoperative period, this is comparable. The difference is not statistically significant. The pulse rate remained stable throughout intra operative period in both the groups. In post operative period, pulse rate remained stable up to 2 hours in both group A and group B. There is slight increase in pulse rate seen after 3 hours post operative in group A, while in group B it is stable (Table 1).

In this the mean preoperative systolic blood pressure is 103.13±6.532 mm of Hg in group A and in group B is 101.87±6.033 mm of Hg which is comparable and the difference is not statistically significant. The systolic blood pressure remained stable and comparable in both the groups throughout the intra operative period. In post operative period, systolic blood pressure remained stable up to 2 hours in both group A and group B. There is slight increase in systolic blood pressure seen after 3 hours post operative in group A, while in group B it is stable (Table 2).

In this the mean preoperative diastolic blood pressure is 53.8±4.881 mm of Hg in group A and in group B is 54.4±6.134 mm of Hg which is comparable and the difference is not statistically significant.

Table 1: Comparison of Changes in the Pulse Rate in two Groups

Mean		Bupivacaine A		Ropivacaine B		P value	Significance
		Std. Deviation	Mean	Std. Deviation	Mean		
Pre-op	0 min	107.77	13.942	112.67	16.647	0.221	Not significant
Intra-op	5 min	106.93	13.196	109.77	16.644	0.468	Not significant
	10 min	104.33	12.704	107.23	15.456	0.43	Not significant
	15 min	101.27	12.889	104.47	15.793	0.393	Not significant
	30 min	98.07	14.263	101.57	15.776	0.371	Not significant
	45 min	94.76	13.185	99.17	16	0.254	Not significant
	60 min	90.65	12	88.88	11.057	0.663	Not significant
	75 min	89.63	10.849	90.75	11.354	0.871	Not significant
Post-op	90 min	90.4	12.522	100.5	2.121	0.332	Not significant
	120 min	88.5	14.849	102	2.3	0.593	Not significant
	15 min	94.27	11.753	99.2	15.314	0.167	Not significant
	30 min	94.67	10.466	98.23	13.733	0.263	Not significant
	45 min	96.83	9.502	99.37	14.308	0.422	Not significant
	60 min	98	8.781	101.27	13.235	0.265	Not significant
	90 min	100.97	7.289	102.4	13.014	0.601	Not significant
	2 hour	106.5	7.291	104.87	13.994	0.573	Not significant
	3 hour	111.83	6.783	105.93	14.125	0.044	Significant
	4 hour	118.4	7.546	105.6	14.265	0.01	Significant
5 hour	120.68	8.41	106.32	13.94	0.01	Significant	

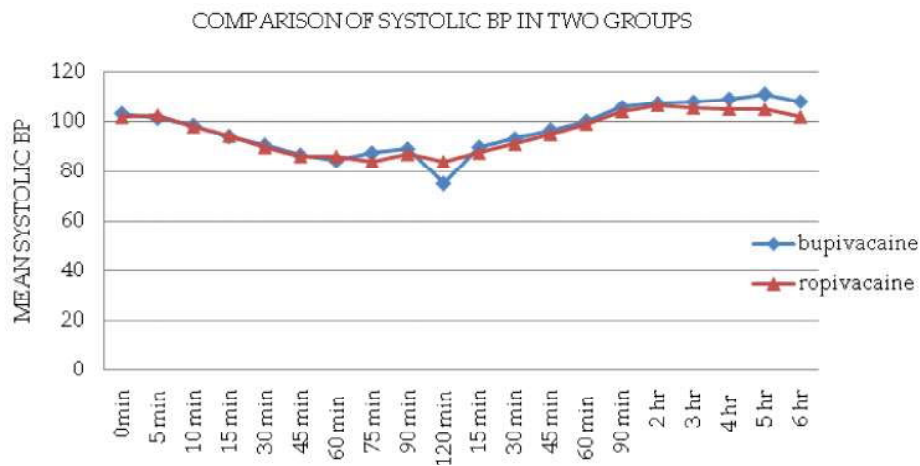


Graph 1:

Table 2: Comparison of Changes in the Systolic B.P.

Mean		Bupivacaine A		Ropivacaine B		P value	Significance
		Std. Deviation	Mean	Std. Deviation	Mean		
Pre-op	0 min	103.13	6.532	101.87	6.033	0.438	Not Significant
Intra-op	5 min	101.2	5.448	102.73	6.528	0.327	Not Significant
	10 min	98.33	6.83	97.8	7.034	0.767	Not Significant
	15 min	93.87	8.565	94.33	7.862	0.827	Not Significant
	30 min	90.33	7.915	89.87	8.959	0.831	Not Significant
	45 min	86.48	7.609	86.27	9.032	0.921	Not Significant
	60 min	84.35	6.901	86.13	8.747	0.522	Not Significant
	75 min	87.25	9.794	84	4.899	0.552	Not Significant
	90 min	88.8	13.084	87	4.243	0.863	Not Significant
	120 min	75	4.243	84	4.63	0.333	Not Significant

Post-op	15 min	89.53	6.383	87.53	7.838	0.283	Not Significant
	30 min	92.87	5.649	91	7.423	0.278	Not Significant
	45 min	96.41	5.11	95.07	6.028	0.359	Not Significant
	60 min	100.07	4.441	99.13	4.918	0.444	Not Significant
	90 min	105.73	3.269	104.2	3.295	0.076	Not Significant
	2 hour	107.33	2.591	106.73	2.377	0.354	Not Significant
	3 hour	107.93	3.503	105.67	5.228	0.053	Significant
	4 hour	109.13	5.002	105.2	4.221	0.002	Significant
	5 hour	111.12	4.729	105.14	3.979	0.001	Significant



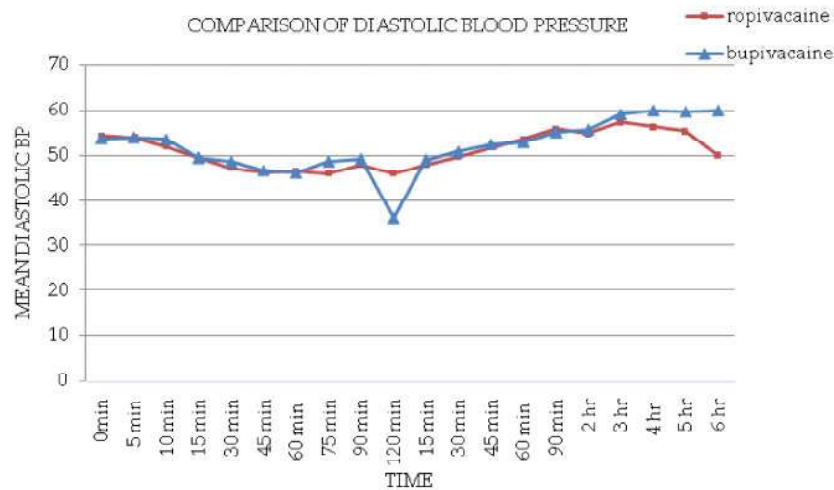
Graph 2:

Table 3: Comparison of Changes in the Diastolic B.P.

Mean	Bupivacaine A		Ropivacaine B		P value	Significance	
	Std. Deviation	Mean	Std. Deviation	Mean			
Pre-op	0 min	53.8	4.881	54.4	6.134	0.677	Not Significant
Intra-op	5 min	54.07	3.463	54.07	5.078	1	Not Significant
	10 min	53.6	4.994	52.07	4.712	0.226	Not Significant
	15 min	49.53	5.164	49.4	5.308	0.922	Not Significant
	30 min	48.6	6.871	47.2	5.671	0.393	Not Significant
	45 min	46.69	6.217	46.2	6.088	0.761	Not Significant
	60 min	46.12	4.029	46.63	5.965	0.775	Not Significant
	75 min	48.75	5.849	45	5.774	0.318	Not Significant
	90 min	49.2	9.121	48	2.828	0.869	Not Significant
	120 min	36	5.657	46	2.57	0.386	Not Significant
Post-op	15 min	49.07	5.552	47.93	6.528	0.472	Not Significant
	30 min	50.87	5.77	49.87	6.516	0.532	Not Significant
	45 min	52.53	4.953	51.87	6.642	0.661	Not Significant
	60 min	53	5.401	53.6	4.082	0.629	Not Significant
	90 min	55.33	4.678	55.87	5.198	0.678	Not Significant
	2 hour	55.87	4.297	54.93	5.959	0.489	Not Significant
	3 hour	59.2	4.597	57.47	4.783	0.158	Not Significant
	4 hour	60.07	6.443	56.47	5.244	0.021	Significant
5 hour	59.84	6.656	55.36	4.961	0.007	Significant	

The diastolic blood pressure remained stable and comparable in both the groups throughout the intra operative period. In post operative period, diastolic blood pressure remained stable up to 3 hours in both group A and group B. There is slight increase in diastolic blood pressure seen after 4 hours post operative in group A, while in group B it is stable (Table 3).

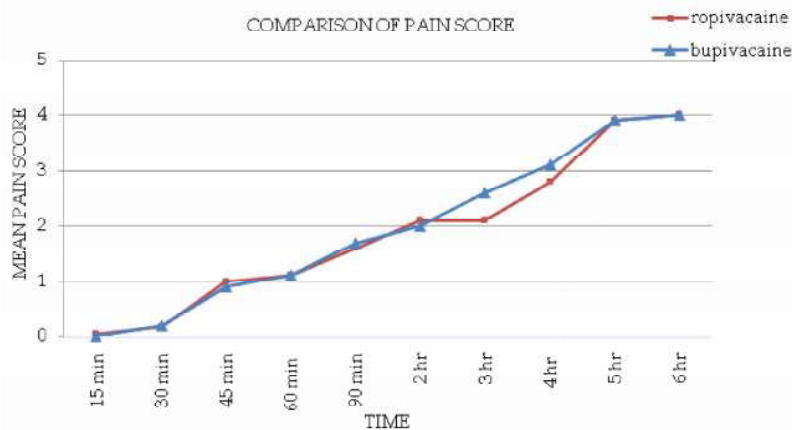
Mean pain score in both groups are more or less same up to 2 hours, and the difference is statistically not significant. After this, in 3rd and 4th post operative period mean pain score in group A is more than mean pain score in group B, and the difference is statistically significant. In 5th post operative hour, most of the patients in both groups required rescue analgesia (Table 4).



Graph 3:

Table 4: Comparison of Changes in Pain Score

	Mean	Bupivacaine A		Ropivacaine B		P value	Significance
		Std. Deviation	Mean	Std. Deviation	Mean		
Post-op	15 min	0	0	0.03	0.183	0.321	Not Significant
	30 min	0.2	0.407	0.17	0.461	0.768	Not Significant
	45 min	0.93	0.254	1.03	0.32	0.185	Not Significant
	60 min	1.13	0.346	1.17	0.379	0.723	Not Significant
	90 min	1.73	0.45	1.63	0.49	0.414	Not Significant
	2 hour	2.07	0.254	2.1	0.305	0.647	Not Significant
	3 hour	2.67	0.479	2.13	0.346	0	Significant
	4 hour	3.17	0.379	2.8	0.551	0.004	Significant
	5 hour	3.96	0.2	3.96	0.189	0.936	Not Significant



Graph 4:

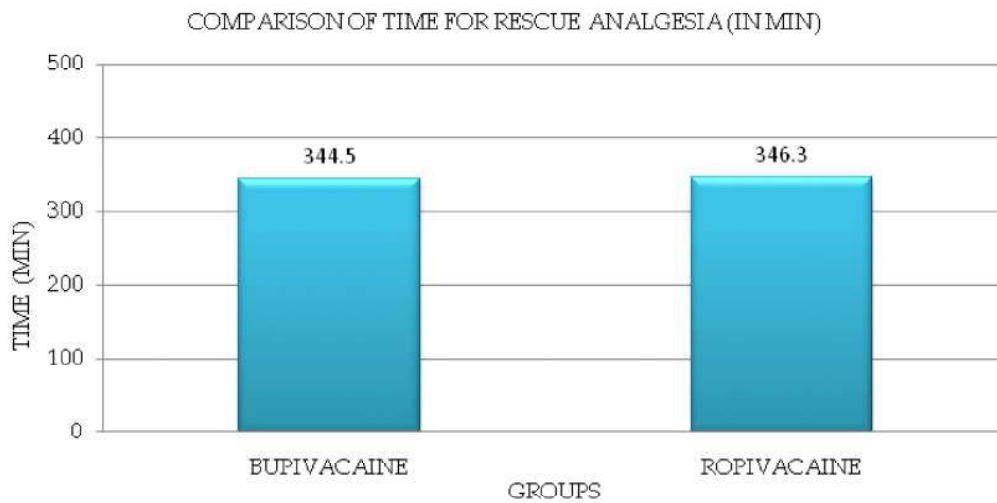
Mean time for rescue analgesia between two groups is statistically not significant (Table 5).

Mean duration of motor block in group A is 176.6 ±21.02 min and in group B is 103.8±11.79 min with p value of 0.000 which is statistically significant.

In group A, side effects are seen in 5 out of 30 patients (Flushing =2, Nausea vomiting= 3) In group B, side effects are seen in 5 out of 30 patients (Flushing = 3, Nausea vomiting= 2). p value is 1 and the difference is statistically not significant (Table 6).

Table 5: Comparison of Time for Rescue Analgesia

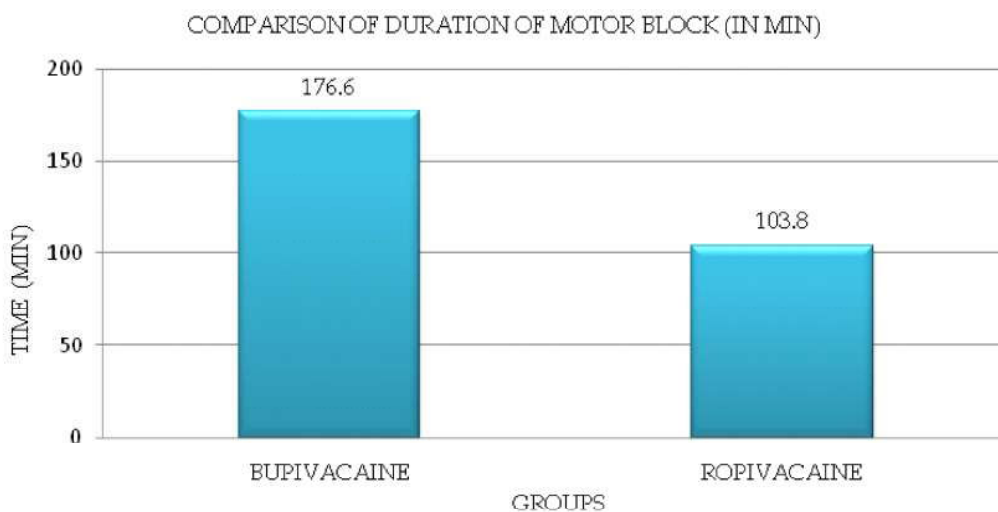
	Group	N	Mean	Std. Deviation	Std. Error Mean	P value	Significance
DOA	Bupivacaine A	30	344.5	29.37	5.36	0.749	Not Significant
	Ropivacaine B	30	346.3	10.66	1.94		



Graph 5:

Table 6: Comparison of Duration of Motor Block

	Group	N	Mean	Std. Deviation	Std. Error Mean	P value	Significance
DOMB	Bupivacaine A	30	176.6	21.02	3.83	0.000	Significant
	Ropivacaine B	30	103.8	11.79	2.15		



Graph 5:

Discussion

Post-operative pain is an acute pain, which starts with surgical trauma and usually ends with tissue healing. Post-operative analgesia has been neglected for a long time whereas post-operative pain has been considered an inevitable cost of operations. Post-operative pain, apart from causing discomfort and distress, has got deleterious effects on body mechanisms.

The caudal block is most accepted method of analgesia in children undergoing inguino-genital operations, used for providing both surgical and postoperative analgesia. Caudal epidural block, advocated by Kay B (1974) [5] using 0.5% bupivacaine with 1 : 200000 Adrenaline at dose rate of 0.5 ml/year of age is an effective and simple method. They proposed that the identification of the landmarks of the blocks i.e. sacrococcygeal hiatus is extremely easy in children and block application is rapid and easy with minimal failure. It requires lateral or prone positioning. This block has produced satisfactory operative anaesthesia and post-operative analgesia.

Trend of changes in the pulse rate-

In this study group the mean pulse rate in group A is 107.77 ± 13.942 /min, in group B is 112.67 ± 16.647 /min. the pulse rate remained stable throughout intraoperative period in both the groups. In post-operative period pulse rate remained stable up to 2 hours in both groups. There is slight increase in pulse rate seen after 3 hours post operative in group A while in group B it is stable. This time correlate with the time when mean pain score in group A is more than that in group B, leading to increase in the pulse rate and group B did not have pain at this time leading to stable pulse rate. This finding correlated well with the study performed by Conceicao et al., (1998) [6]. Similarly in the study conducted by Rosemary Hickey et al (1991) [7] did not observe at significant variation in the mean pulse rate and systolic blood pressure between 0.5% ropivacaine and 0.5% bupivacaine at different time intervals.

Trend of changes in the blood pressure-

In this study mean preoperative blood pressure both systolic and diastolic is comparable and the difference is not statistically significant. Blood pressure remained stable and comparable in both the groups throughout the intraoperative period. But in the postoperative period the BP showed

slight increase in group A with statistically significant difference. Similarly as the patient had tachycardia they also showed increase in the blood pressure due to pain. This finding correlated well with the study performed by Conceicao et al., (1998) [6]. Similarly in the study conducted by Rosemary Hickey et al. (1991)[7] did not observe at significant variation in the mean systolic blood pressure between 0.5% ropivacaine and 0.5% bupivacaine at different time intervals.

Trend of changes in pain score-

In this study mean pain score in both groups are more or less similar up to 2 hours post operative. The difference is statistically not significant. After this in 3rd & 4th post operative period mean pain score in group A is 2.670.479 and 3.170.379, while in group B is 2.130.346 and 2.80.551 respectively. The difference is statistically significant. In 5th post operative hour, most of the patients in both groups required rescue analgesia. This finding correlated well with the study performed by Conceicao et al., (1998) [6].

Comparison of duration of analgesia-

The duration of adequate post-operative analgesia or pain free period was taken as time from caudal analgesic till the pain score ≥ 4 was observed at which time rescue analgesic was given. In group A the mean duration of analgesia is 344.5 ± 29.37 min while that in group B is 346.3 ± 10.66 min. (paired) two tailed p value 0.749 which is statistically not significant. The mean duration of post-operative pain relief (or pain free period) between the two groups is not significant. This finding correlated well with the study performed by Conceicao et al., (1998) [6]. Studied done by Hickey R, Candido (1990) [7], Casati A, Fanelli G (1999) [8] also showed duration of analgesia with ropivacaine was 11-14 hrs while with bupivacaine it was 10-12 hrs which was not statistically significant.

Comparison of duration of motor block-

Mean duration of motor block in group A is 176.6 ± 21.02 min and in group B is 103.8 ± 11.79 min with P value of 0.000 which is statistically significant. This finding correlated well with the study performed by Conceicao et al., (1998) [6]. Similarly in the study conducted by Surendra Raikwar et al., Onset of sensory & motor blockade was 12.9 ± 2.8 minutes and 13.2 ± 1.99 minutes in Ropivacaine and for bupivacaine it was 15.9 ± 2.8 minutes and 20.2 ± 3.22 minutes which was found to be significant for group R ($p < 0.05$) [9].

Comparison of side effects-

In group A, side effects are seen in 5 out of 30 patients. In group B, side effects are seen in 5 out of 30 patients p value is 1 and the difference is statistically not significant. This finding correlated well with the study performed by Conceicao et al., (1998) [6].

Conclusion

Caudal block with 0.2% Ropivacaine resulted in equal duration of analgesia with less duration of motor block as compared with 0.25% caudal Bupivacaine, without an increase in incidence of side effects when administered pre-operatively in a volume of 0.5 ml/kg to children undergoing lower abdominal and urogenital surgeries.

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