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A Comparative Study Between Bupivacaine and Ropivacaine in Caudal Block in Paediatric Age Group (0 To 8 Years) in Unilateral Groin Surgeries

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Abstract

Introduction: Pain is an unpleasant subjective sensation which can only be experienced though not fully expressed especially in children.The regional anaesthetic techniques significantly decrease post operative pain and systemic analgesic requirements. Caudal route was chosen for this study as it is one of the simplest and safest techniques in paediatric anaesthesia with a high success rate. *Aim:* Aim of the study is to compare between 0.25% bupivacaine and 0.2% ropivacaine in caudal block in paediatric age group (0 to 8 years) in unilateral groin surgeries. *Materials and Methods*: It is a randomized controlled study comparing bupivacaine and ropivacaine in caudal epidural analgesia for lower abdominal and genital surgeries. Patients were allocated by random number table in two groups of 30 patients each to receive 0.25% Bupivacaine (Group B) 1ml/kg or 0.2% Ropivacaine (Group R) 1ml/kg for caudal block. *Results:* No significant differences were observed among haemodynamic parameters throughout intraoperative period. Mean pain scores were more in Bupivacaine group however the difference was not statistically significant. Motor power was low in both the groups in first hr postoperatively and significantly low in Bupivacaine group in second hour, low but comparable in 3rd hr i.e. Ropivacaine group attained full motor power by 3rd hr and Bupivacaine group by 4th hr. Mean duration of sensory block in Ropivacaine group was 86.6 ± 10.2 min and in Bupivacaine group was 90.96 ± 7.29 min-not statistically significant. Mean duration of analgesia in Ropivacaine group was 5.38 ± 0.71 hrs and Bupivacaine group was 5.01 ± 0.8 hrs –not statistically significant. *Conclusion:* Local anaesthetic Ropivacaine may prove to be a better alternative to Bupivacaine via caudal epidural route in Paediatric patients in urogenital surgeries.

Keywords: Caudal route; Paediatric anaesthesia; Ropivacaine; Bupivacaine

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Introduction

The concept of postoperative pain relief and its utilization in the paediatric age group has improved dramatically over the recent years. The various methods of providing pain relief have some side effects which prohibit their use in children for eg.,

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narcotics, because of their respiratory depression, the other analgesics which cannot be given for sometime after general anaesthesia due to the fear of vomiting and aspiration, the fear of needles in the case of parenterally administered analgesics.[1]

Caudal block is usually done after the introduction of general anaesthesia and is used as an adjunct to intraoperative anaesthesia as well as postoperative analgesia in children undergoing surgical procedures below the level of the umbilicus. Caudal analgesia can reduce the amount of inhaled and IV anaesthetic administration, attenuate the stress response to surgery, facilitate rapid, smooth recovery, and provides good immediate postoperative analgesia.[2] In order to

Decrease perioperative analgesic requirements after single shot caudal epidural blockade, various additives, such as morphine, fentanyl, clonidine and ketamine with local anaesthetics have been investigated.[4]

Materials and Methods

The present study is, a randomized controlled study comparing bupivacaine and ropivacaine in caudal epidural analgesia for lower abdominal and genital surgeries was undertaken at Gandhi hospital, Hyderabad. After obtaining approval for the study from Institutional Ethics Committee, written consent was obtained from all the patients.

Inclusion criteria: Patients selected for the study were between age groups 0 to 8 years, ASA grade I and II cases scheduled for urogenital operations such as urethroplasty, herniotomy, orchidopexy.

Exclusion criteria: Children with nuero muscular diseases, with skelet al deformity problems, local infections, mental retardation, allergy to the drugs used in the study, with suspected coagulopathy.

Patients were allocated by random number table in two groups of 30 patients each to receive 0.25% Bupivacaine (Group B) 1ml/kg or 0.2% Ropivacaine (Group R) 1ml/kg for caudal block.

A resting preanaesthestic pulse rate, blood pressure and respiratory rate were recorded. Patients were fasted for 4 hours and pre medicated with oral Midazolam 0.5mg/kg 30 minutes before surgery. After applying standard monitors, general anaesthesia was induced with Thiopentone 5 mg/kg , sevoflurane and Nitrous oxide in oxygen via mask. An intravenous cannula was secured and Lactate Ringers solution was infused to provide fluid during surgery. Injection Atropine 0.02mg/kg was administered intravenously as pre medicant. Endotracheal intubation was facilitated by administering injection vecuronium bromide 0.1 mg/kg intravenously. After securing Endotracheal tube, patients were placed in left lateral position.

Procedure: Under aseptic precautions, a short beveled 22 G needle was introduced in caudal epidural space, after conforming the space 1 ml/kg of local anaesthetic agents 0.25% Bupivacaine (Group B) or 0.2% Ropivacaine (Group R) was administered slowly. After deposition of the drug in epidural space, patients were placed in supine position and anaesthesia was maintained by 1% of Halothane, 60% of Nitrous oxide in oxygen and top up doses of vecuronium bromide ($1/5^{th}$ of the loading dose of 0.1mg/kg). Baseline heart rate ,mean arterial pressure recorded before incision and after incision at 5, 10, 20, 30, 60, and 90 min of surgery, residual neuromuscular blockade was reversed and patients were transferred to the post operative ward. Using the paediatric observations FLACC, pain scale with its 0-10 score range, each patients pain intensity was assessed at the end of surgery and then every 30 min interval until the patient became fit to discharge from postoperative ward.

If the FLACC, pain scale was 4 or more , rectal Paracetomol 20 mg/kg was administered. Motor block was assessed on awakening using a four point Bromage scale. Observations were continued for 24 hours.

Fig. 1. Performing Caudal Block

The Statistical software namely Open Graphpad was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc. Descriptive statistical analysis had been carried out in the present study. Results on continuous measurements were presented on Mean ± SD and results on categorical measurements were presented in Number (%). Significance was assessed at 5% level of significance.

Student t test (two tailed, independent) had been

used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven's test for homogeneity of variance had been performed to assess the homogeneity of variance. . Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. Significant (p value: $0.01 < p < 0.05$)

Results

Table 1 : Comparison of type of surgeries.

Name of Surgery	Group B	Group R
Hernia Repair	17	14
Orchidopexy	8	8
Hypospadias	5	8

Table 2: Patient characteristics and clinical parameters.

Variable (Mean +/- Stdev)	Group B	Group R	p Value
Age (In Years)	4.63+/-1.75	4+/-1.96	0.19
Weight (In Kg)	11.2+/-1.95	10.76+/-2.28	0.42
Gender M:F Ratio	26:4	25:5	1(Fischers Exact Test)
Baseline Heart Rate (Beat per min)	104.16+/-8.57	103.33+/-10.26	0.72
Baseline Map	70.73+/-4.98	69.03+/-5.27	0.20

Table 3: Haemodynamics during surgery.

	B Group				Standard deviation for R group		Standard deviation for B group		p Value	
	HR	MAP	HR	MAP	HR	MAP	HR	MAP	HR	MAP
Base line	103.33	69.03	104.16	70.73	10.26	5.27	8.57	4.98	0.19	0.72
After incision 5min	100	68.03	100.47	71.23	8.46	4.79	4.72	5.17	0.79	0.159
10 min	98.3	66.7	97.16	68.53	7.63	4.54	4.55	4.76	0.48	0.15
20 min	96.76	66	96.36	68.06	7.80	4.45	4.52	5.69	0.8	0.08
30 min	95.86	66.2	95.3	67.3	8.16	4.28	4.51	4.31	0.74	0.32
60 min	95.73	65.96	94.03	66.93	7.03	3.82	5.02	4.27	0.28	0.35
End of surgery	95.4	65.26	93.66	66.76	6.74	4.15	4.30	4.11	0.23	0.16

Table 4: Post operative pain scoring in two groups FLACC score.

Duration After Operation	Group R		Group B		p Value
	Mean	SD	Mean	SD	
O hour	0.1	0.30	0.13	0.34	0.71
2 hour	1.06	0.44	1.46	0.5	0.08
4 hour	2.56	0.77	2.7	0.65	0.44
6 hour	4.46	0.68	4.86	0.97	0.86
8 hour	6.16	1.23	6.2	0.92	0.88

The calculated p value is > 0.05, So this is statistically not significant. there were no differences between the two groups in age, gender, baseline blood pressure and heart rate (Table 2).

The p value calculated by student 't' test. p value is > 0.05, hence it is not statistically significant. The preoperative, intraoperative and postoperative haemodynamic changes between the groups were comparable and were not statistically significant and therapeutic interventions were not required (Table 3).

The quality and duration of postoperative pain relief did not differ significantly between the two groups ($p > 0.05$). Lack of analgesia was not found in any patients during surgery and there is no haemodynamic response to initial incision. Postoperative pain score was comparable in two groups. Average pain scores were less in group R but the difference was not significant (Fig. 2).

Patients showed some amount of motor weakness in both groups immediately after surgery. But after two hours almost normal motor power was recorded in Ropivacaine group. Motor

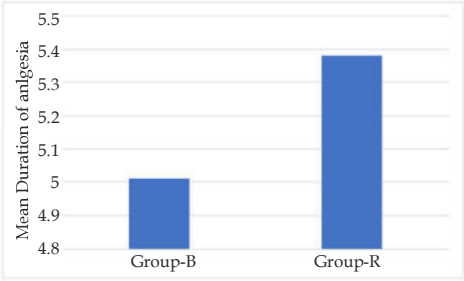

Fig. 2: Comparison of duration of analgesia

Table 5: Motor Power Scale in present study

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

Table 6: Assessed Motor Power in present study

Motor Power	Ohr	1hr	2hr	3hr	4hr
Group B	1 ± 0	1 ± 0	1.2 ± 0.4	1.9 ± 0.3	2 ± 0
Group R	1 ± 0	1.3 ± 0.46	1.4 ± 0.49	2 ± 0	2 ± 0
p Value		0.007	0.086	0.07	

recovery was significantly slow in Bupivacaine group in first 2hrs (Table 5).

No episodes of any clinically significant postoperative complications were recorded (Table 6).

Discussion

Children not only feel pain of same intensity as adults[1] but also, pain is associated with serious consequences, including harmful neuroendocrine responses, disrupted eating and sleep cycle and increased pain perception in subsequent painful experiences.[3,4] In addition, the invention of different pain scales has improved pain assessment in Paediatric patients and thereby, aiding in better Paediatric pain management. Control of postoperative pain is important in paediatric patients because poor pain control may result in increased morbidity and mortality. If acute pain is left untreated or not treated properly, it can also progress to chronic pain.[4] Caudal anaesthesia is the most common regional procedure to approach the extradural space in Paediatric group. It combines the advantages of being a fairly simple technique and high success rates.[35] Caudal block is usually placed after the induction of general anaesthesia and is used to provide adjunct intraoperative anaesthesia as well as postoperative analgesia in children undergoing surgical procedures below the level of the umbilicus. Caudal analgesia can reduce the amount of inhaled and IV anaesthetic administration, attenuate the stress response to surgery, facilitate a rapid, smooth recovery, and provide good immediate postoperative analgesia. Caudal block usually provide analgesia for approximately 4-6 hrs. Bupivacaine (an amide local anesthetic) has provided reliable anaesthesia and analgesia. Ropivacaine is also an amide local anaesthetic, and in adults it produces pain relief similar to that of bupivacaine with a motor block that is slower in onset, less intense, and shorter in duration. Moreover, animal studies have shown that ropivacaine appears to be less cardiotoxic than bupivacaine.[5]

Although bupivacaine is a racemic mixture of *R*-and *S*-enantiomers, ropivacaine is the first local anaesthetic to be prepared as a pure *S* -enantiomer.[1] It has been shown that block of the inactivated state of the cardiac sodium and potassium (hKv1.5) channels is stereoselective, with *R* - bupivacaine being more potent than *S* -bupivacaine. In clinical

practice, *S* -bupivacaine, which exhibits a lower affinity for sodium and potassium (hKv1.5) cardiac channels, may be a less cardiotoxic alternative to racemic bupivacaine.[6] Also, results of animal research have demonstrated that *R* -bupivacaine is more toxic than the *S* - enantiomer.[7] Bupivacaine provides reliable and long lasting post operative analgesia when given via caudal route but has more motor blockade and cardiotoxicity. Top priorities for successfully discharging patients of day care surgeries are the four A's: Alertness, Analgesia, Ambulation and Alimentation. Excessive pain, nausea and vomiting and fatigue will delay the discharge. The success of fast tracking depends on effective pain management by simple techniques.[8] Motor blockade resulting from caudal block is very distressful to children in the postoperative period and delays hospital discharge. Hence, Ropivacaine a more suitable agent for caudal epidural analgesia especially in day care surgery Pharmacokinetic studies by Khudsen et al.[9] of Ropivacaine show that 1ml/kg of 0.2% Ropivacaine by caudal block produces a maximal plasma concentration of 0.72+ 24 mg/L, which is much lower than the maximal tolerated plasma concentration of Ropivacaine in adult volunteers (2.2 + 0.8 mg/l). Habre et al.[10] reported that maximum plasma concentration of Ropivacainewas achieved at 2 hours following caudal block which is much later than for Bupivacaine (29 + 3.1) in children. Another reason of using 0.2% Ropivacaine is to avoid motor blockade in postoperative period. Low concentrations and large volumes are the key to obtaining differential block in children because of the small diameter of A-Delta and C-fibres and small distance between nodes of Ranvier. Results of present study show that a single shot caudal injection of Ropivacaine provides reliable and long lasting analgesia in paediatric patients following lower abdominal and perianal surgery. In this series, 1ml/kg of 0.2% Ropivacaine or 0.25% Bupivacaine was used for single shot caudal analgesia.

Limitations

Ultrasound hasn't been used to place caudal block which improves the safety and efficacy of the technique. Plasma concentrations of Ropivacaine and Bupivacaine has not been measured, however no signs of local anaesthetic toxicity were observed. 24 hr postoperative analgesic requirements were not quantitated, which are more predictive of efficacy of the drugs in comparision.

As the sample size is small, it cannot be concluded that the results of the present study are definitive and more trials are required before the results become conclusive

Conclusion

From the present study, it is concluded that both Bupivacaine and Ropivacaine are safe and similarly efficacious via caudal route for postoperative analgesia for urogenital procedures in Paediatric patients and Ropivacaine group had recovered the motor power early. Prolonged duration of analgesia was noted with Ropivacaine.No signs of local anaesthetic allergy and toxicity were observed. Thus the local anaesthetic Ropivacaine may prove to be a better alternative to Bupivacaine via caudal epidural route in Paediatric patients in urogenital surgeries.

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