Section: Anaesthesia

Original Research Article

COMPARATIVE STUDY OF ULTRASOUND GUIDED CAUDAL BLOCK IN PAEDIATRIC AGE GROUP WITH ROPIVACAINE AND BUPIVACAINE

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Abstract

Background: Pain management is a crucial aspect of care provided by paediatric anaesthesiologists. Caudal epidural blockade is one of the most frequently utilized regional anaesthesia techniques for intraoperative and postoperative pain relief in paediatric infraumbilical surgeries. It decreases stress response to surgery. When used alongside general anaesthesia, it helps to decrease the need of opioids and inhalational agents. Ultrasonography guided caudal block promotes safety measures of the technique and lowers the complication rates. **Objectives:** The aim of this study is to compare Ropivacaine (0.125%) (1ml/kg) with Bupivacaine (0.125%) (1ml/kg) in caudal block for infraumbilical surgeries in children aged between 1-12 yrs with respect to postoperative analgesia. **Materials & Methods:** A Prospective Randomized Double blinded study was conducted on 44 children. 22 each in group R(Ropivacaine) and 22 in group B (Bupivacaine) of 1 12 years with ASA 1 and 2 who are admitted for elective infraumbilical surgeries at Navodaya medical college, Raichur over a period of 18 months from July 2022 to December 2023 after approval from our college ethics committee. **Results:** There were 44 children 22 in group R and 22 in group B. Mean duration of anaesthesia for group R is 78.41± 8.51 and group B is 31.82± 5.68.When compared with respect to preoperative, intraoperative, post-operative vitals and rescue analgesia the differences in means between Group-R and Group-B are small, the 95% confidence intervals include zero, and the p-values are all above 0.05.This indicates that there is no statistically significant difference between Group-R and Group-B at any measured time point. **Conclusion:** Caudal Ropivacaine 0.125%, 1ml/kg provided good quality, reliable and long duration of analgesia similar to Bupivacaine 0.125 % 1ml/kg and ensured sufficient analgesic effect postoperatively in children undergoing infraumbilical surgeries.

INTRODUCTION

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”.[1] Postoperative pain in children is a common and distressing complication of surgery. It can cause agony, prolonged recovery, reduced physical function, and even permanent pain. Effective postoperative pain management is important for improving patient outcomes.[2] Postoperative pain in children is a significant concern for both parents and healthcare providers. In paediatrics, postoperative pain should be evaluated and managed according to the child's age, type of operation, and pain severity. Prevention of postoperative pain is also important and can be achieved through the administration of analgesics before to surgery and early postoperative care.[3] Caudal epidural block is one of the most widely administered techniques of regional anaesthesia in paediatric patients. It is an efficient way to offer intra operative and post-operative analgesia for sub-umbilical surgical interventions. It decreases the stress hormone response to surgery.[4] Local anaesthetics are widely administered via the caudal route, either alone or with additives, although the motor block caused may cause distress in children in the postoperative period5. Ultrasound guided block is performed after visualization of the sacral cornu and hiatus and then injecting the drug in sacral canal under direct vision. Hence, ultrasonography-guided caudal blocks have become popular among paediatric

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anaesthesiologists for promoting safety of the technique and lowering the complication rates.[6] Bupivacaine is a long-acting amide local anaesthetic that has provided reliable anaesthesia and analgesia with differential motor-sensory blockade for few decades. Toxicity due to accidental intravascular or intrathecal injections of bupivacaine results in severe neurological, cardiovascular depression even leading to death shown by studies on the mechanism of the cardiotoxic effects of local anaesthetics and search for drugs with less cardiotoxicity.[7] 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. Studies have shown that ropivacaine is less cardio and neurotoxic than bupivacaine8. The sensory block provided by ropivacaine is similar to that produced by an equivalent dose of bupivacaine in extradural and peripheral nerve block whereas the motor block produced by ropivacaine is slower in onset, less intense and shorter in duration than bupivacaine9. These features combined with decreased cardiovascular and neurological toxicity make ropivacaine very useful in paediatric practice especially for day case surgery which is increasing in frequency.

Aims and Objectives: To compare Ropivacaine (0.125%) (1ml/kg) with Bupivacaine (0.125%) (1ml/kg) in caudal block for infraumbilical surgeries in children aged between 1-12 yrs with respect to postoperative analgesia.

MATERIALS AND METHODS

This is a Prospective randomised double-blind study conducted in Department of Anaesthesiology, Navodaya Medical College Hospital and Research Centre, Raichur from July 2022 to December 2023 for a period of 18 months. The study was conducted in 44 children (22 each in group R and group B) of 01 to 12 years of the age scheduled to undergo infraumbilical surgeries like herniotomy, circumcision, orchidopexy surgery and minor lower extremity procedures at Navodaya Medical College Hospital and Research Centre (NMCH&RC) Raichur. Patients in age group of 1 to 12 years of either sex, belonging to ASA-Grade I and II coming to hospital for infraumbilical surgeries were included in the study. Patients with significant coagulopathies and other contraindications for regional anaesthesia, with pre-existing significant systemic diseases, allergic to local anaesthetics, having infection of the skin at the injection site, belonging to ASA Grade 3 and Grade 4 and immunocompromised patients were excluded from the study. Computer generated random numbers were used to select the study participants. After obtaining institutional ethical committee approval written and informed consent from the patient's parent were obtained.

Sample size was estimated (10) using the formula n = (Z1 - α + Z1 - β)2 (VS + Ve) / (μS - μe - δ)2, where μs is the mean of first group = 8.18; μe- mean of second group = 7.61, sd1- SD of first group= 4.86; sd2- SD of first group= 4.12, Z1-α = 95% confidence level (one sided) = 1.64; Z1 - β = 80% power = 0.84, D = Absolute difference (μs-μe); δ = Max. Clinical difference acceptable from μs (D) =3; n=22. The children are randomly divided into 2 groups each containing of 22 members. Group R- For USG guided Caudal block using 1ml/kg of 0.125% Ropivacaine and group B- For USG guided Caudal block using 1ml/kg of 0.125 % Bupivacaine. Heart rate, blood pressure, saturation after administration of caudal block at 0,5,15,30,45,60,120 and 180 minutes and the values were recorded. All the patients have undergone pre anaesthetic Evaluation which includes a detailed history taking, general, systemic examination including airway and spine and necessary investigations like complete blood count, urine examination, bleeding and clotting time, special investigations are done only for specific diseases only like Chest X-ray, HIV, HBsAg and electrocardiogram. Solid food was restricted for 6 hours, milk for 4-5 hours and clear fluids for 2-3 hours prior to surgery. IV Premedication glycopyrrolate (0.004mg/kg), midazolam (0.03mg/kg) was given in preoperative room with adequate monitoring. Monitoring included precordial stethoscope, pulse oximetry, NIBP, respiratory rate and ECG and temperature probe was attached. Only after patient is adequately sedated, patient was taken to the operation theatre. Monitors were connected. IV fluids were started according to the 4-2-1 rule. Child was administered general anaesthesia using sevoflurane concentration to 4-6% and orotracheal intubation was done using atracurium 0.5 mg/kg. Ultrasound probe was covered in a sterile cover. Initial scanning was done in the transverse plane which allowed for visualization of the midline and identification of the sacrococcygeal ligament between the 2 sacral comua. The probe was then be rotated 90 degrees to acquire a longitudinal view. The needle was advanced at a 20-degree angle with needle tip and length. A pop was appreciated as the needle passes through the sacrococcygeal ligament. Once the needle was confirmed to be in the caudal space on the screen, carefully aspiration was done to confirm absence of CSF or blood. The use of a saline bolus (0.1-0.2 mL/kg) was performed to confirm correct positioning. Safety of the caudal block drug administration is done with incremental injection with repeat aspiration. Anaesthetic agents were discontinued at the end of skin closure. Once adequate spontaneous efforts were seen patient was extubated after giving reversal agent. 100% oxygen through a face mask was administered for 3-5 minutes. Once the vitals were stable and the child was awake, the child was shifted and placed in semi-prone position in the recovery room. On arrival to the recovery room, the child was monitored for another 6 hours with SpO2, respiratory rate, NIBP and heart

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rate every 15 minutes for first 2 hrs and every half hour in next 4 hrs. After that the child was shifted to the ward and monitored thereafter.

Post-operative analgesia is assessed by Paediatric Pain Scale (FLACC Score for children aged 01-03 years and Wong-Baker FACES Pain Rating scale for children aged 04-12). The assessment was be done for a period of 24 hours after caudal block. Suppose the pain score showed more than or equal to 4, then supplementary analgesia with Inj. Paracetamol (15 mg/kg) was given. These assessments will be made at 1,2,3,4,5,6,7,8,12 and 24 hours after caudal block. The following parameters i.e intra operative hemodynamic parameters, post-operative hemodynamic parameters, pain assessment by FLACC score (depicted in Table 1) or Wong Baker FACES Pain Rating scale (depicted in Figure1), total number of paracetamol (rescue analgesia) required, outcome and complications in both groups were recorded at each point and compared.

Table 1: FLACC Score

	0	1	2
FACE	No particular expression or smile	Occasional grimace/frown; withdrawn or disinterested (appears sad or worried)	Consistent grimace or frown/constant quivering chin, clenched jaw (distressed-looking face; expression of fright or panic)
LEGS	Normal position or relaxed	Uneasy, restless, tense (occasional tremors)	Kicking, or legs drawn up (marked increase in spasticity, constant tremors, or jerking)
ACTIVITY	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense (mildly agitated) e.g., head back and forth, aggression' shallow, splinting respirations	Arched, rigid or jerking (severe agitation) e.g., head banging; shivering (not rigors), breath holding, gasping or sharp intake of breath, severe splinting).
CRY	No cry (awake or asleep)	Moans or whimpers, occasional complaint occasion verbal outburst or grunt	Crying steadily, screams pr sobs, frequent complaints (repeated outbursts, constant grunting)
CONSOLABILITY	Content, relaxed	Reassured by occasional touching, hugging or talking; distractable	Difficult to console or comfort (pushing away care giver, resisting care or comfort measures)

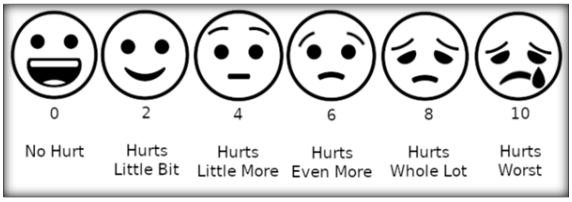

Figure 1: Wong- Baker Pain scale

The collected data was entered in Microsoft excel. Descriptive statistics such as mean, SD and percentage was used to present the data. Comparison between groups was performed by using t-test for normally distributed data whereas Mann Whitney test was used for non-normally distributed data. Chi-square test was used for categorical variables. A p-values more than 0.05 were considered as insignificant. Data analysis was performed by using statistical software SPSS v27.0.

RESULTS

Both the groups were comparable with respect to demographic profiles like age, weight, height, BMI, gender. Mean age of the children in group R was 6.27 ± 3.01 years as compared to 7.27 ± 2.64 years in group B. Mean weight in group R is 19.41± 8.70 as compared to 23.95± 8.22 in group B. Mean height in group R is 113.54±22.49 as compared to group 119.82±18.24 in group B. Mean BMI in group R is 14.68±2.55 as compared to group 16.33±1.92 in group B. The gender distribution between group R and group B is similar. Across all socio demographic parameters means between group R and group B are not statistically significant. The confidence intervals include zero and the p values are all above 0.05 indicating that any observed differences are likely due to random variation rather than a true effect. The average age in Group-B is slightly higher than in Group-R. However, the mean difference of 1.0 year is not statistically significant (p = 0.25). Group-B has a higher average weight than Group-R. The mean difference of 4.54 kg approaches statistical significance but does not quite reach it (p = 0.08). Group-B is taller on average than Group-R. However, the mean difference of 6.27 cm is not statistically significant (p = 0.32). The average BMI is higher in Group-B than in Group-R. The mean difference of 1.65 is statistically significant (p = 0.02), indicating a real difference in BMI between the groups. The gender distribution between Group-R and Group-B is similar. The chi-square test indicates no statistically significant difference in gender distribution between the two groups (p = 0.55). [Table 2]

All patients in both groups were discharged, indicating no differences in discharge rates between the groups. No deaths occurred in either group, which suggests that the intervention did not lead to fatal outcomes. No complications were reported in either group, indicating that both interventions were safe in terms of post-operative complications. Overall, these results suggest that both groups had similar outcomes and experienced no adverse events. [Table 5]

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Table 2: Distribution according to age, weight, height, BMI, gender between Group R and Group B

	Group-R	Group-B	Mean difference	p value	CI
Age	6.27 ± 3.01	7.27 ± 2.64	1.0	0.25	-2.72 – 0.722
Weight	19.41 ± 8.70	23.95 ± 8.22	4.54	0.08	- 9.69 – 0.61
Height	113.54 ± 22.49	119.82 ± 18.24	6.27	0.32	- 18.73 – 6.18
BMI	14.68 ± 2.55	16.33 ± 1.92	1.65	0.02	0 .27 – 3.03
Gender (M/F)	20 / 2	21 / 1		**0.55**	

Table 3: Distribution according to diagnosis and surgical procedures between group R and group B

		Group-R		Group-B	
		Number	Percentage	Number	Percentage
DIAGNOSIS	Acute Appendicitis	3	13.6	7	31.8
	Congenital Hydrocele	3	13.6	0	0.0
	Left Congenital Hydrocele	1	4.5	1	4.5
	Left Congenital Inguinal Hernia	1	4.5	0	0.0
	Left Side Undescended testis	1	4.5	0	0.0
	Paraphimosis	0	0.0	1	4.5
	Perforation Appendicitis	0	0.0	1	4.5
	Phimosis	6	27.3	8	36.4
	Rec Appendicitis	1	4.5	0	0.0
	Right Inguinal Hernia	0	0.0	1	4.5
	Right Congenital Hydrocele	4	18.2	1	4.5
	Right Retractile Testes	1	4.5	1	4.5
	Umbilical Hernia	1	4.5	1	4.5
SURGERY	Bilateral Herniotomy	1	4.5	0	0.0
	Circumcision	6	27.3	9	40.9
	Herniotomy	9	40.9	4	18.2
	Open Appendicectomy	4	18.2	8	36.4
	Orchidopexy	2	9.1	1	4.5

Table 4: Distribution of duration of surgery and Anaesthesia, pre-operative, intraoperative and post-operative vital parameters score between two groups

Parameter	Group-R (Mean ± SD)	Group-B (Mean ± SD)	Mean Difference	95% CI	Z-value	p-value
Duration (mins)						
Surgery	32.05 ± 5.91	31.82 ± 5.68	0.23	-3.29 to 3.75	-0.061	0.95
Anaesthesia	78.41 ± 8.51	77.50 ± 9.35	0.91	-4.53 to 6.35	0.34	0.74
Pre-operative Vitals						
PR	99.54 ± 12.26	96.73 ± 12.88	2.82	-4.83 to 10.47	0.93	0.35
SBP	94.36 ± 6.09	94.82 ± 5.91	0.45	-4.11 to 3.19	1.16	0.25
DBP	61.18 ± 8.12	62.45 ± 6.38	2.27	-6.71 to 2.17	1.03	0.31
RR	23.55 ± 3.23	22.54 ± 2.44	1.00	-0.74 to 2.74	1.16	0.25
Saturation	100.82 ± 6.55	99.36 ± 0.73	1.45	-1.38 to 4.29	0.53	0.59

Table 5: Comparing FLACC Score, Wong-Baker Facies Pain rating, post-operative events and total number of doses of rescue analgesia score between Group R and Group B

FLACC Scores Over Time					
Time (min/hr)	**Group-R (Mean ± SD)**	**Group-B (Mean ± SD)**	**Mean Difference**	**95% CI**	**p-value**
90	1.6 ± 0.9	2.0 ± 0.0	0.4	-2.12 to 1.32	0.5
120	1.6 ± 0.9	1.0 ± 1.4	0.6	-1.59 to 2.79	0.5
150	2.0 ± 0.0	2.0 ± 0.0	1.6	-0.12 to 3.32	1.0
180	1.6 ± 0.9	0.0 ± 0.0	0.2	4.39 to 4.79	0.1
5 hr	5.6 ± 2.6	6.0 ± 2.8	0.2	-0.90 to 3.5	0.8
24 hr	3.6 ± 4.1	1.0 ± 1.4	0.6	-1.59 to 2.79	0.5
Wong-Baker Faces Pain Scale Over Time					
90	1.4 ± 0.9	1.5 ± 0.9	0.1	-0.70 to 0.52	0.8
150	1.4 ± 0.9	1.8 ± 0.6	0.4	-0.91 to 0.13	0.1
6 hr	1.9 ± 2.5	1.5 ± 2.2	0.4	-1.20 to 1.96	0.5
24 hr	3.4 ± 3.7	2.8 ± 3.6	0.6	-1.81 to 3.03	0.4
Postoperative Events					
Paracetamol Dose (mg)	283.86 ± 133.97	352.04 ± 120.74	68.18	-145.78 to 9.42	0.05
First Analgesic Time (hrs)	5.43 ± 1.00	5.36 ± 0.99	0.068	-0.54 to 0.67	0.81
Duration of Hospitalization (days)	2.18 ± 0.39	2.04 ± 0.21	0.14	-0.06 to 0.33	0.16
Number of Rescue Analgesia Doses	2.14 ± 0.56	2.0 ± 0.54	0.14	-0.19 to 0.47	0.40

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DISCUSSION

Pain is regarded one of the most essential elements influencing the quality of recovery. Postoperative discomfort causes delays in early ambulation, lengthens hospitalization, increases resource consumption, and reduces patient satisfaction. Caudal epidural analgesia is effective way of providing pain relief in children. It not only provides intra operative and post-operative pain relief but also has other benefits like reducing the stress hormone levels produced during anaesthesia. Caudal block is safe and effective method for managing pain in paediatric patients. Our study showed that a Caudal Ropivacaine 0.125% 1ml/kg provided good quality, reliable and long duration of analgesia similar to bupivacaine 0.125% 1ml/kg and ensured sufficient analgesic effect postoperatively in children of age 01-12 undergoing infraumbilical surgeries.

In our study, the mean duration of surgery in group R is 32.05±5.91 min and 31.82± 5.68 min in group is B. The mean duration of anaesthesia in group R is 78.41±8.51 min and 77.50± 9.35 min in group B. There is no significant difference in the duration of surgery between Group-R and Group-B. The mean difference is very small (0.23 minutes) ($p>0.05$). This suggests that any observed difference in surgery duration is not statistically significant and likely due to random variation. Similarly, there is no significant difference in the duration of anaesthesia between Group-R and Group-B. The mean difference is small (0.91 minutes) ($p>0.05$). The post-operative analgesia was evaluated using FLACC scale for children aged 01-03 years and Wong Baker pain scale for children aged 4-12 years which was similar in both the groups. The mean duration of analgesia in group R is 5.43±1.0 hrs and 5.36±0.99 hrs in group B. There is no significant difference between the groups in the time needed to administer the first analgesic in wards. The high p-value suggests that any observed difference is not statistically significant ($p=0.81$). The difference was statistically insignificant using Mann-Whitney test.

Similar results were seen in a study conducted by Surhan Ozer Ciner et al,[11] included 80 children of ASA1&2 in the study and compared the postoperative analgesic efficacy of ropivacaine 0.175%(1ml/kg) &bupivacaine 0.175%(1ml/kg) injected caudally into infants aged 3-12 months for lower abdominal surgery. They found no significant differences among the groups in demographic data, MAP, objective pain scale during four hours postoperatively. The duration of analgesia was 527.5± 150.62 minutes in group R and 692.77± 139.01 minutes in group B. Rescue analgesics administered showed no statistically significant difference between the two groups. No statistically significant difference was observed between two groups when side effects were compared. They indicated that a concentration of 0.175% ropivacaine and 0.175 % bupivacaine administered to the infants via caudal route provided effective and similar postoperative pain relief in infants who underwent lower abdominal surgery. This study results are well relevant with current study.

A randomized control trial,[12] on comparison of caudal ropivacaine 0.2% (group A) with bupivacaine 0.2% (group B) in 60 children aged 2-8 years of ASA1&2. Demographic data & duration of surgery were compared and found statistically insignificant. Variation in vital parameters in perioperative period was comparable in both groups and there was no significant effect on hemodynamics during perioperative period. Average duration of analgesia was 390.2 ± 35.16 min and 377.0 ± 34.41 min in Group A and B respectively. They concluded 0.2% ropivacaine provides a reliable postoperative analgesia similar to 0.2% bupivacaine in terms of quality and duration, but with shorter duration of motor blockade. Hence, ropivacaine may be a more suitable agent for day care surgery.

Tarika P. Doctor et al (13) did comparison of ropivacaine (0.2 or 0.25) or bupivacaine (0.25%) with fentanyl for caudal epidural in paediatric surgery for intra and post-operative analgesia. Demographic data and vitals were compared. No statistically significant difference noted between the two groups. The duration of analgesia was slightly more with the ropivacaine fentanyl (6.1 hr) as compared to 5.6 hr in bupivacaine group but difference was statistically insignificant.

Samia Khalil et al Khalil S, Campos C, Farag AM, Vijeh, Ritchey M, Chuang A. Caudal block in children, Ropivacaine compared with bupivacaine. Anaesthesiology 1999; 91:1279-84. (14) conducted a study on 81 children. The quality and duration of postoperative pain relief did not differ between the two groups. The median time from caudal placement to the first administration of pain medication (either morphine or acetaminophen- codeine) was 680 min for both treatment groups. caudal ropivacaine provided reliable postoperative 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 cardiotoxic, it may be safer.

CONCLUSION

From our study we conclude that Caudal Ropivacaine 0.125% 1ml/kg provided good quality, reliable and long duration of analgesia similar to Bupivacaine 0.125 % 1 ml/kg and ensured sufficient analgesic effect postoperatively in children aged between 1-12 years undergoing infraumbilical surgeries in our study. Time required for rescue analgesia was similar for both Ropivacaine and Bupivacaine. Total rescue analgesia dose required is also similar for both Ropivacaine and Bupivacaine.

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