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Original Research Article

Comparison of post-operative analgesia with caudal Ropivacaine and Levobupivacaine in pediatric patients undergoing infraumbilical surgery under general anaesthesia

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ABSTRACT

Background: Post-operative pain relief following pediatric abdominal surgery is of paramount consideration and caudal block is still a popular, easy as well as safe analgesic technique for effective analgesia in children. With the advent of newer local anaesthetics, there has been a renewed interest in pediatric caudal blocks after lower abdominal surgeries following general anaesthesia. The aim of our study was to compare the efficacy and duration of postoperative analgesia using caudal Ropivacaine and Levobupivacaine in pediatric patients undergoing infraumbilical surgery under general anaesthesia.

Materials and Methods: The study was conducted on sixty, ASA grade 1, pediatric patients of age 2 to 6 years, of either sex, posted for elective infraumbilical surgery under general anaesthesia. They were randomly divided in two groups of 30 patients each. Group 1: - (n = 30) received caudal block with injection Ropivacaine, 0.25%, 1ml/kg. Group 2: - (n = 30) received caudal block with injection Levobupivacaine, 0.25%, 1ml/kg.

Study Design: Comparative, randomized, single blinded, observational study.

Results: The demographic data was comparable in both the groups. Postoperatively, the quality of analgesia was assessed by the MOP (Modified Objective Pain Scale) score. Duration of postoperative analgesia was assessed by noting the time of giving rescue analgesia in the post-operative period. We also noted side effects, if any in both the groups.

The quality of analgesia was found to be similar with both the drug groups (p value >0.05). The duration of analgesia was longer and statistically significant (p value = 0.0006) in the Ropivacaine group (8.43 ± 0.77 hours) as compared to the Levobupivacaine group (7.03 ± 2.03 hours). Statistically significant difference (P value = 0.026) was seen in the requirement rescue analgesia between Ropivacaine (3.33%) and Levobupivacaine (26.67%) groups. There were no major side effects in either of the groups, apart from a single patient out of 30 patients of Levobupivacaine group who had vomiting, compared with none in the Ropivacaine group.

Conclusions: We conclude that caudal block with 0.25% Ropivacaine has a longer duration of action as compared to 0.25% Levobupivacaine in children undergoing infraumbilical surgery under general anaesthesia. Both Ropivacaine and Levobupivacaine, have similar quality of postoperative analgesia and side effect profile.

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1. Introduction

Pain is an unpleasant, emotional and subjective sensory experience associated with actual or potential tissue damage.[1,2] Pain in children is most misinterpreted, undiagnosed and untreated medical problem.[1] The effects of post-operative pain in childhood can have negative psychological effects in their adulthood.[3]

Pain can be treated by various means, like systemic analgesics, peripheral nerve blocks, epidural analgesia and topical analgesia.[1]

Caudal epidural block is a central neuraxial technique useful in a variety of infra-umbilical surgeries in pediatric patients for both intra-operative and post-operative analgesia.[4,5] Quality and level of analgesia depend on dose, volume and concentration of injected local anesthetic agent.[4] It is a simple and safe technique in pediatric patients for pain relief.[2,3,6] Besides pain relief, it also reduces peri-operative stress and requirements of intravenous narcotics.[2,3] There is plenty of literature regarding use of caudal epidural Bupivacaine for post-operative pain relief, but there is paucity of studies comparing Levo-Bupivacaine and Ropivacaine for pediatric caudal blocks.[7–9]

Bupivacaine was introduced in 1963, is racemic mixture of R and S enantiomer, R- enantiomer of which is cardiotoxic. The drug also has neurotoxicity and residual motor block effects.[3,10,11] Ropivacaine and levi-bupivacaine have lesser side effects than Bupivacaine, are well tolerated via caudal route, provide excellent analgesic effect with a wide margin of safety and minimal post-operative motor block.[1,2,6,11,12]

Hence, we aimed to compare equal volumes of caudal 0.25% Levobupivacaine and 0.25% Ropivacaine [1 ml/kg each], for post-operative analgesia in pediatric patients undergoing infra- umbilical surgery. We did this study to evaluate the quality and duration of post-operative analgesia and occurrence of side effects, if any.

2. Materials and Methods

After the approval of hospital ethics committee, institutional research board, registration with CTRI and written informed consent, 60 pediatric patients were enrolled into the study. Sample size calculation was done using the standard Z-alpha and Z-beta formula, with a power of study of 95% and 1% level of significance, which was found to be 8 in each study group. As per the parent/reference study of Astuto M et al (which enrolled 60 patients) and to reduce margin of error, the sample size was taken to be 30 patients in each study group (Total = 60 children). The pediatric patients of ASA grade 1, between 2 to 6 years of age, undergoing infra umbilical surgery under general anaesthesia of either sex were included. Randomisation was achieved by computer generated random number table. Subjects were randomly divided into one of the two groups with 30 patients each: - Group 1 (n = 30) received caudal injection of Ropivacaine 0.25%, 1ml/kg. Group 2 (n = 30) received caudal injection of Levobupivacaine 0.25%, 1ml/kg). A detailed pre - anesthetic check-up was done in all children. Demographic characteristics (age, gender, height weight), detailed clinical history, complete general physical and systemic examination, pre-operative ECG, chest X-ray (PA View), complete hemogram (hemoglobin, total leucocyte count, differential leucocyte count, hematocrit, red blood cell count, platelet count), coagulation profile (bleeding time, clotting time, PT/INR, aPTT) and examination of back was done before the procedure. After explanation of risks and benefits of caudal block to guardian/parents of the child, written informed consent was taken. Patient and parents were counselled to understand MOPS (Modified Objective Pain Score) to be done postoperatively and first MOP score was recorded in the preoperative period.

2.1. Method of giving general anaesthesia

Patient was brought to operation theatre and standard monitors were attached. Baseline readings were recorded, patient was pre oxygenated with 100% oxygen. Pre-induction, injection fentanyl citrate 1-2 microgram/kg and injection midazolam 0.05-0.1 mg/kg I. V. was given. Anaesthesia was induced with propofol, 1-2 mg / kg I. V. and muscle relaxant (injection vecuronium bromide 0.1 mg / kg) was given. Airway was secured with an appropriate size uncuffed endotracheal tube (E.T.T.), tube position and bilateral air entry was confirmed. The patient was ventilated on control mode of ventilation through the anaesthesia workstation, using $O_2 + N_2O$ + Isoflurane (1 MAC). Surgery was allowed to proceed. After completion of operation, caudal block using one of the study drugs was given.

2.2. Method of giving caudal block

Timing: The caudal block in both the groups were given post-operatively, before reversal of general anaesthesia and extubation.

Position: Patients were positioned laterally with left side down with hip joint fully flexed. A dry gauze swab was placed in natal cleft to protect the anus and genitalia from disinfectants. Skin preparation and sterile draping of the entire region was performed to achieve asepsis.

Method: A triangle was marked on skin over the sacrum, using the posterior superior iliac spines (PSIS) as the base, with apex pointing inferiorly (caudally). Normally, this apex sits over or immediately adjacent to the sacral hiatus. The hiatus was marked, and the tip of index finger was placed on the tip of coccyx in the natal cleft while the thumb of the same hand palpated the two sacral cornua. The sacral cornua was identified by gently moving the palpating index

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finger from side to side. The palpating thumb was allowed to sink into the hollow between the two cornua, as if between two knuckles of a closed fist. A 20/22 G hypodermic needle or caudal cannula was inserted either in the midline or para medially into caudal canal. A feeling of a slight snap may be appreciated when advancing needle pierces the sacrococcygeal ligament.

Once the needle reached the ventral wall of sacral canal, it was slowly withdrawn and turned 90°to face cranially, directing it more cranially for further insertion into the canal. Loss of resistance technique was used to establish entry into the epidural space. Then caudal block was given, using either 0.25% ropivacaine or 0.25% levobupivacaine, 1 ml/kg.

2.3. Method of reversal of GA

General anesthesia was then reversed using neostigmine (0.05 mg/kg) and (0.01 mg/kg) glycopyrrolate and then extubated once extubation criteria well adequately met. Patient was shifted to post anesthetic care unit (PACU) for 2 hours after operation. Patient was monitored for postoperative pain relief in PACU and in ward and time of rescue analgesia was noted.

Criterion for giving Rescue Analgesia – MOPS more than six.

Measurement and parameters (duration in hours and quality by MOPS)

1. Duration of analgesia
   a. Starting time (time 0) at 15 min after reversal
   b. Finishing time (time to rescue analgesia; MOPS >6)

Quality of postoperative analgesia - Starting point, at 15 min after reversal (when first MOPS reading was taken).

2.4. Statistical analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected, then non-parametric test was used.

Statistical tests were applied as follows-

1. Quantitative variables were compared using Mann-Whitney Test (as the data sets were not normally distributed) between the two groups.
2. Qualitative variables were compared using Fisher Exact test.

2.4.1. Value of <0 05 was considered statistically significant

The data was entered in MS EXCEL spread sheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

3. Results

Sixty patients divided into group 1 and group 2 were studied over a period of 1 year. There was no significant difference in, age, sex and ASA physical status distribution between the two groups. The Mean age of the patients in group 1 was 4.93 ± 1.46 and in group 2 was 4.93 ± 1.51 years, and percentage ratio of male compared to female was 96.67: 3.33 in group 1 and 100: 0 in group 2, which was statistically insignificant. (Tables 1 and 2)

Significant difference was seen in duration of action of drug (in hours) in group 1 and 2 (Table 3). Mean duration of action in group 1 was 8.43 ± 0.77 hours and in group 2 was 7.03 ± 2.03 hours, (p value = 0.0006). The group 1 drug, Ropivacaine provided longer duration of action than Levobupivacaine.

Quality of analgesia was compared using MOP score. The quality of analgesia generated in two groups was statistically similar in both groups at 15 min, 30 min, 2^{nd} hour, 5^{th} hour, 6^{th} hour, 7^{th} hour and 8^{th} hour after the surgery. Mean MOP score was significantly different at 1^{st}, 3^{rd} and 4^{th} hours post operatively (Table 4). During these hours, patients of Levobupivacaine group reported mild pain. Actual mean value of MOP scores was well less than 0.6. But overall, the quality of pain relief in both the group was satisfactory.

Significant difference was seen in requirement of rescue analgesia (intravascular paracetamol) between group 1 and 2, with P value = 0.026 (Table 5).

No significant difference was seen in adverse effects between the group 1 and 2 (Table 6), with P value = 1. Only a single patient reported an incident of vomiting in group 2.

4. Discussion

The present study was done to compare the quality and duration of postoperative analgesia of two local anaesthetics, Ropivacaine and Levobupivacaine given caudally. The similarity of the characteristics such as distribution of age, gender and ASA physical status of patients ensures that any difference in outcome is due to the intervention and not due to demographic bias.

Similarly, other comparative studies done by Veeravalli S et al,[3] Soujanya U et al,[13] Locatelli B, et al,[11] and Astuto M, et al,[14] also had no significant difference in the demographic variables among the groups.

4.1. Modified objective pain score (MOPS)

In our study, the quality of postoperative analgesia measured by MOP score was comparable preoperatively (p value > 0.05), The difference in MOP score was statistically insignificant at following postoperative intervals – 15 min, 30min, 2^{nd} hour, 5^{th} hour, 6^{th} hour, 7^{th} hour and 8^{th} hour, between the two groups. Mean MOP score between two groups was statistically significant at 1^{st} hour, 3^{rd} hour,

Table 1: Comparison of age (years) between group 1 and 2

Age (years)	Group 1(n=30)	Group 2(n=30)	P value	Testperformed
2-3	2 (6.67%)	3 (10%)		
3-4	6 (20%)	5 (16.67%)	1.00 (NS)	Fisher Exact test
4-5	2 (6.67%)	1 (3.33%)		
5-6	20 (66.67%)	21 (70%)		
Mean ± Stdev	4.93 ± 1.46	4.93 ± 1.51		
Median (IQR)	6 (3.25-6)	6 (3.25-6)	0.973 (NS)	Mann Whitney test;
Range	2 - 6	2 - 6		

NS = Not significant

Table 2: Comparison of gender between group 1 and 2

Gender	Group 1(n=30)	Group 2 (n=30)	P value	Testperformed
Female	1 (3.33%)	0 (0%)		
Male	29 (96.67%)	30 (100%)	1.00 (NS)	Fisher Exact test
Total	30 (100%)	30 (100%)		

NS = Not significant

Table 3: Comparison of duration of action (in hours) between group 1 and 2

Duration of action (in hours)	Group 1(n=30)	Group 2(n=30)	P value	Testperformed
Mean ± Stdev	8.43 ± 0.77	7.03 ± 2.03		
Median (IQR)	8 (8 - 9)	8 (7 - 8)	0.0006 (S)	Mann Whitney test
Range	7 - 10	2 - 9		

S = Significant

Table 4: Comparison of MOP score between group 1 and 2

Time	MOPS score	Group 1(n=30)	Group 2(n=30)	P value
Pre-operative	Mean ± Stdev	0.63 ± 0.72	0.67 ± 0.66	0.763 (NS)
At 15 minutes	Mean ± Stdev	0.43 ± 0.5	0.53 ± 0.73	0.824 (NS)
At 30 minutes	Mean ± Stdev	0.07 ± 0.25	0.3 ± 0.65	0.114 (NS)
At 1 hour	Mean ± Stdev	0 ± 0	0.43 ± 1.36	0.02 (S)
At 2 hours	Mean ± Stdev	0.07 ± 0.25	0.63 ± 1.63	0.184 (NS)
At 3 hours	Mean ± Stdev	0 ± 0	0.33 ± 0.88	0.04 (S)
At 4 hours	Mean ± Stdev	0 ± 0	0.47 ± 1.53	0.04 (S)
At 5 hours	Mean ± Stdev	0.07 ± 0.25	0.27 ± 0.98	0.6 (NS)
At 6 hours	Mean ± Stdev	0.23 ± 0.5	0.27 ± 1.14	0.172 (NS)
At 7 hours	Mean ± Stdev	0.43 ± 1.19	0.73 ± 1.93	0.64 (NS)
At 8 hours	Mean ± Stdev	0.5 ± 1.11	0.33 ± 1.03	0.334 (NS)

S = Significant
NS = Not significant
St dev = Standard deviation

Table 5: Comparison of rescue analgesia required between group 1 and 2

IV PCM (paracetamol) required	Group 1(n=30)	Group 2(n=30)	P value	Testperformed
Not required	29 (96.67%)	22 (73.33%)		
Required	1 (3.33%)	8 (26.67%)	0.026 (S)	Fisher Exact test
Total	30 (100%)	30 (100%)		

S = Significant

Table 6: Comparison of adverse effects between groups 1 and 2

Adverse effect	Group 1(n=30)	Group 2 (n=30)	P value
Nil	30 (100%)	29 (96.67%)	
Vomiting	0 (0%)	1 (3.33%)	1.00 (NS)
Total	30 (100%)	30 (100%)	

NS = Not significant

and 4^{th} hour, with p value < 0.05, i. e. during early hours of caudal anaesthesia. Residual effect of GA might have had an influence on quality of analgesia in early hours after reversal.

Ivani G, et al,[15] conducted study comparing Ropivacaine 0.2% with Levobupivacaine 0.25% in 60 pediatric patients (1 to 7 years) undergoing minor sub - umbilical surgery. In group R (n = 30) 1 ml / kg of 0.2% Ropivacaine was given and in group L (n = 30), 1 ml / kg of 0.2% Levobupivacaine was given. Postoperative CHIPPS score were almost identical in both groups. The quality of analgesia produced by two drugs was similar to our study.

Soujanya U et al,[13] conducted a study to compare postoperative analgesia by using equal volume of 0.25% Levobupivacaine, Ropivacaine and Bupivacaine 1ml/kg for caudal anaesthesia among children of age 2-10 years. The authors reported, mean FLACC Score at recovery from anaesthesia and at 30 minutes was insignificant with P value > 0.05. Mean FLACC Score was significant with p value < 0.05 at 60 minutes, at 120 minute and at 240 minutes. The result was similar to our study in early hours, with p value (< 0.05) significant at 1^{st} hour 3^{rd} hour and 4^{th} hour.

Astuto M, et al,[14] compared postoperative analgesic effect between Ropivacaine and Levobupivacaine, divided 60 patients, age 2- 6 years and ASA grade 1 - 2, into two groups. Group 1 received 1 ml/kg of 0.25% Levobupivacaine and group 2 received 1ml/kg of 0.25% Ropivacaine The pain assessment score (according to the Children Hospital Eastern Ontario Pain Scale) was comparable in two groups for first two hours. The result was similar to our study in the early hours, with p value > 0.05 at 15 min, 30 min, 2^{nd} hours. But caudal anaesthesia was given preoperatively by them.

Veeravalli S et al,[3] in their study compared postoperative analgesic efficacy of caudal Levobupivacaine with Ropivacaine in pediatric patients. They divide 80 patients of 1- 10 years in two groups. Group A receiving 1ml/ kg of 0.25% caudal Levobupivacaine and group B receiving 1ml/ kg of 0.25% caudal Ropivacaine. Postoperative pain was assessed using CHIPPS Score in patients (< 6 years) and by numerical scale (> 6 years), with standard deviation between groups revealed no variation statistically (p value > 0.05), implying similar postoperative pain score between the groups.

Contrary to this, the quality of postoperative analgesia was significant at 1^{st} hour, 3^{rd} hour, 4^{th} hour respectively between the two groups. The age of patient taken for consideration was different from our study.

Locatelli B, et al,[11] in randomized, controlled trial compared Levobupivacaine 0.25%, Ropivacaine 0.25% and Bupivacaine 0.25% by caudal route in children (6 months to 10 years) undergoing infra - umbilical surgery. Authors found no significant difference in analgesic efficacy between these three groups, using CHIPPS score. Comparing this, the difference in quality of postoperative analgesia was significant at 1^{st} hour, 3^{rd} hour, 4^{th} hour respectively between two groups in our study. Different volume of drug (mostly 0.5ml/kg) was used by them, compared to our study.

4.2. Duration of action

Duration of analgesic action in our study, in Group 1 was 8.45 ± 0.77 hours and 7.03 ± 2.03 hours in group 2. Significant statistical difference was found in both the groups (p value 0.0006) during early hour of block.

Veeravalli S et al,[3] in similar study, compared 0.25% of caudal Levobupivacaine with Ropivacaine in pediatric patients and inferred that mean duration of analgesia with Levobupivacaine was 404.8 ± 67.66 min and Ropivacaine was 413.5 ± 44.47 min, which is similar to our result.

Astuto M, et al,[14] compared equal volume of 0.25% of Levobupivacaine with 0.25% of Ropivacaine 1ml/kg for caudal anaesthesia in children and found mean duration of action of 302 ± 29 min for Levobupivacaine group and 230 ± 38 min for Ropivacaine group (p value 0.32). Which was significantly less than our study with mean duration of action of Ropivacaine 8.43 ± 0.77 and Levobupivacaine 7.03 ± 2.03 when given postoperatively. But like us, they also found Ropivacaine to be longer acting than Levobupivacaine.

Locatelli B. et al,[11] studied the clinical efficacy of single dose administration of caudal Levobupivacaine 0.25%, Ropivacaine 0.25% and Bupivacaine 0.25%, in children undergoing sub - umbilical surgery. They noted that duration of action was 2.45 ± 0.6 hours in Bupivacaine, 1.7 ± 0.4 hours in the Levobupivacaine and 1.6 ± 0.6 hours in Ropivacaine (p value = 0.3). Which is significantly less than our study.

Soujanya U et al,[13] studied postoperative analgesia between 0.25% Levobupivacaine, Ropivacaine and Bupivacaine, and reported that mean duration of analgesia in Levobupivacaine group was more (273.5 ± 48.89 min) than Ropivacaine (255 ± 41.89 min). However, in our study Ropivacaine group had longer duration than Levobupivacaine group.

4.3. Requirement of rescue analgesia

In our study the difference in requirement of intravascular paracetamol as rescue analgesia in the two groups was statistically significant. Patients receiving Ropivacaine required it much less than those receiving Levobupivacaine (p value = 0.026).

Astuto M, et al,[14] recorded no significant difference for mean time to requirement of additional analgesia, with rectal acetaminophen, which was 302 ± 29 min for the Levobupivacaine group, 230 ± 38 min for the Ropivacaine group (p value = 0.32). This differs from our study, but they gave caudal block preoperatively while we gave after the

operation.

Locatelli B, et al,[11] in randomized, controlled trial compared Levobupivacaine 0.25%, Ropivacaine 0.25% and Bupivacaine 0.25% by caudal route in children (6 months to 10 years) undergoing infra - umbilical surgery. The mean time from caudal injection to the first administration of analgesic medication was 1.7 (0.4) hours in the Levobupivacaine group and 1.6 (0.6) hours in the Ropivacaine group, which differs from our study.

4.4. Adverse effects

In our study, only one out of 30 patients of group Levobupivacaine showed vomiting compared to nil in group Ropivacaine [P value = 1 which was statistically insignificant].

Locatelli B, et al,[11] in his study also reported nausea or vomiting post-surgery with both Levobupivacaine and Ropivacaine in equal proportion. The difference was statistically insignificant, which is similar to our study.

Soujanya U et al,[13] compared equal volume of 1ml/ kg of 0.25% Levobupivacaine, 0.25% Ropivacaine and 0.25% Bupivacaine. Postoperative complications like nausea and vomiting were not reported in either of the groups, just like in our study.

5. Conclusion

We conclude that caudal block with 0.25% Ropivacaine has a longer duration of action as compared to 0.25% Levobupivacaine in children undergoing infraumbilical surgery under general anaesthesia. Both Ropivacaine and Levobupivacaine, have similar quality of postoperative analgesia and side effect profile.

6. Source of Funding

None.

7. Conflict of Interest

None.

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