

Comparative Study Caudal Anesthesia between 0.375% Ropivacaine and 0.375% Bupivacaine in Pediatric Patients Undergoing Circumcision

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Abstract

Background: Effective post-operative pain control is an essential component of the care of the surgical patient. Certain patient population are at risk of in-adequate pain control and requires special attention, including pediatric patients, geriatric patients and patients with difficulty in communication. **Objectives:** To compare quality and duration of analgesia, motor and sensory block after caudal block with either Bupivacaine or Ropivacaine in pediatric cases aged 2–6 years. **Materials and Methods:** An observational study with consecutive sampling technique getting either of two interventions are recruited till the sample size is attained. 74 pediatric patients planned for circumcision with ASA1 allocated in two different groups, to receive either 0.375% ropivacaine or 0.375% bupivacaine. Onset of action and return of motor movements assessed based on Bromage scale. Mean duration of onset of anesthesia, duration of motor blockade and post-operative analgesia among two groups are compared using t-test. Proportions of children with adverse effect among two groups are compared using Chi-square test. **Results:** Both the groups were comparable regarding age, weight, onset of action and post-operative analgesia but significant difference was noted in return of motor movements in both groups. **Conclusion:** Not much significant difference observed in the post-operative analgesia among the study groups. As regard to the motor function recovery is much faster with ropivacaine than with bupivacaine.

Keywords: Caudal Anesthesia' Ropivacaine' Bupivacaine' Circumcision.

How to cite this article:

Koshy Thomas, Rajiv Alex MR, Joe Joseph. Comparative Study Caudal Anesthesia between 0.375% Ropivacaine and 0.375% Bupivacaine in Pediatric Patients Undergoing Circumcision. Indian J Anesth Analg. 2019;6(6 Part -I):1964-1968.

Introduction

The International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential “tissue damage, or described in terms of such damage”¹. Caudal epidural technique has attracted attention of many research workers for the simplicity in its technique, rapidity with which it is accomplished and the extensive safety record in patients. Caudal epidural blocks are the most

widely used regional anesthetic technique for any procedures on the lower part of the abdomen and lower limbs, especially in neonates, infants, and certain high risk children.² The popularity of these procedures seems to be due to the presence of clearly defined anatomical landmarks, safety, ease of performance and availability of data on dose and pharmacokinetics of local anesthetics in infants and older children.³ Caudal epidural anesthesia is a common regional technique in pediatric patient. The caudal space is the sacral portion of the

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Received on 06.06.2019, **Accepted on** 26.08.2019

epidural space. Caudal anesthesia involves needle and/or catheter penetration of the sacrococcygeal ligament covering the sacral hiatus that is created by the unfused S4 and S5 laminae. The hiatus may be felt as a groove or notch above the coccyx and between two bony prominences, the sacral cornua.⁴ Caudal epidural blockade is the useful alternative to general anesthesia or total intravenous anesthesia as it provides effective post-operative analgesia. This regional technique avoids polypharmacy and other complications related to general anesthesia. It is the most popular, reliable, safe and easy method to administer and is therefore, commonly performed procedure for subumbilical surgeries in children. Caudally administered ropivacaine provides effective post-operative analgesia, like bupivacaine in pediatric patient.⁵ Less motor blockade of ropivacaine makes it a more suitable agent for day care surgery. As there are lacuna in literature, so the rationale behind the study is to compare between two local anesthetic drugs namely ropivacaine and bupivacaine both belongs to the amide group of local anesthetics in pediatric patients undergoing circumcision.

Materials and Methods

Study design: Observational Analytical study;

Study setting: The study was done under the department of anesthesiology, Pushpagiri Institute of Medical Sciences, Thiruvalla after obtaining approval from Institutional Review Board and Scientific Review Committee;

Study population: Patients undergoing circumcision under caudal anesthesia for elective surgeries at Pushpagiri Institute of Medical Science and Research Centre, Thiruvalla;

Sample size: Assuming a significance level of 5% to the power of 80%, Post-operative analgesia duration with mean time of 5 (SD 3.2) h in the ropivacaine group compared with 5 (SD 2.8) h in the bupivacaine group in the parent study and expected mean difference of 2 hours in the current study (equivalent study), a sample size of 37 pediatric patients undergoing circumcision for each group;

Sampling Technique: Consecutive sampling technique.

Inclusion criteria

- American Society of anesthesiologists (ASA) physical status I;

- Age between 2 and 6 years;
- Weight upto 15 kgs.

Exclusion criteria

- ASA grade more than 2;
- Weight more than 15 kg;
- Local infection at the caudal region;
- Congenital anomaly of the lower back and emergencies.

Methodology

Clearance has been obtained from Institutional Review Board and scientific Review Committee. During the pre-operative visit, all the patients were evaluated and assessed. The study protocol was explained to the parents and written informed consent was taken from them. Cases satisfying the inclusion criteria were selected and allotted into Groups 1 and 2. All the patients were pre-medicated with syp. Pedicloryl (Triclorofos) 75 mg/kg 1 hour before the surgery, Nil per oral status as per guidelines was ensured.

On arrival to operation theatre, standard monitoring was instituted, including ECG, non-invasive blood pressure and pulse oximetry. Baseline vitals of the patients were recorded. An intravenous line was established, and Isolyte p solution was infused to provide fluid during surgery.

Patient was randomly allotted to one of two Groups of 37 patients each:

- Group 1 Received 1 ml/kg of 0.375% bupivacaine;
- Group 2 Received 1 ml/kg of 0.375% ropivacaine.

Intravenous access secured before the procedure and child is sedated with intravenous ketamine, midazolam and atropine. Patients were placed in prone position, wedge kept under the pelvis and a caudal injection was performed using aseptic technique, with 22-gauge needle. Immediately after the caudal injection, the patients were turned to supine position for performance of surgical procedure. Skin incision was allowed after 10 minutes of caudal block. The Heart rate mean arterial pressure and oxygen saturation were recorded just before and after skin incision and then every 5 minutes interval till the end of surgery. If a child responds to the incision, with an increase in blood pressure (> 10 mm of Hg) or heart rate (> 10 beats/min), it is considered as failure of caudal block. These patients were excluded from the study. Patients were transferred to

post-operative wards, and they were monitored. They were assessed for quality of pain relief. Rectal paracetamol 15–20 mg/kg was administered when patients scored or more on pain scale and the duration of pain relief was recorded. Motor power and level of sensory block were evaluated every 30-minute interval until they regained complete motor power.

Statistical Analysis

Data was entered in Microsoft excel for statistical analysis. Quantitative variables were summarized using mean with standard deviation. Qualitative variables were summarized using proportions with 95% confidence interval. Test of significance using independent *t*-test for quantitative variables and mean Whitney *U* test for qualitative variables has been done. A *p* value of < 0.05 was considered statistically significant.

Results

Table 1: Age wise Distribution of Cases

| Group | Mean | SD | N | t | p value |
|-------------|------|--------|----|-----|---------|
| Bupivacaine | 2.81 | .81096 | 37 | 583 | 0.244 |
| Ropivacaine | 3.03 | .79884 | 37 | | |

Shown as per **Table 1**, age distribution of two Groups are given. As there were no statistical difference between ($p > 0.05$) two Groups, the two Groups were comparable, or age matched.

Table 2: Weight wise distribution of cases

| Group | Mean | SD | N | t | p value |
|-------------|-------|---------|----|--------|---------|
| Bupivacaine | 12.54 | 1.09531 | 37 | 519.00 | 0.063 |
| Ropivacaine | 13.03 | 0.98563 | 37 | | |

Shown as per **Table 2**, weight distribution of two Groups is given. As there were no statistical difference between ($p > 0.05$) two Groups, the two Groups were comparable, or weight matched.

Table 3: Onset of Action (A), Duration of Blockade (B), Post-op Analgesia (C)

Onset of Action 3 (A)

| Group | Mean | SD | N | t | p value |
|-------------|------|---------|----|--------|---------|
| Bupivacaine | 5.95 | 1.5340 | 37 | 527.00 | 0.074 |
| Ropivacaine | 6.43 | 1.04191 | 37 | | |

Duration of Blockade 3 (B)

| Group | Mean | SD | N | t | p value |
|-------------|-------|---------|----|-------|---------|
| Bupivacaine | 90.76 | 3.35175 | 37 | 0.000 | 0.000 |
| Ropivacaine | 67.54 | 3.37140 | 37 | | |

Post-op Analgesia (C)

| Group | Mean | SD | N | t | p value |
|-------------|--------|---------|----|--------|---------|
| Bupivacaine | 119.16 | 4.21975 | 37 | 647.00 | .683 |
| Ropivacaine | 119.65 | 3.35175 | 37 | | |

Shown as per **Table 3**, (A, B, C) analyzed using independent *t*-test. No significance difference in onset of action between two Groups ($p > 0.05$) which is statistically insignificant, and both were comparable. Duration of blockade are given and there is statistically significant difference ($p < 0.05$) observed between two groups with early return of motor movements observed in ropivacaine group. Post-operative analgesia of two groups are given and there was no statistical difference ($p > 0.05$) between two Groups, the two Groups were comparable or post-operative analgesia were comparable in both groups.

Table 4: Variations in Heart Rate

| | Heart Rate | N | Mean Rank | Std Deviation | t value | p value |
|--------|-------------|----|-----------|---------------|---------|---------|
| 5 min | Bupivacaine | 37 | 138.41 | 4.862 | | |
| | Ropivacaine | 37 | 138.92 | 2.510 | 629.500 | 0.548 |
| | Total | 74 | | | | |
| 10 min | Bupivacaine | 37 | 137.89 | 4.313 | 641.000 | |
| | Ropivacaine | 37 | 139.03 | 2.744 | | 0.635 |
| | Total | 74 | | | | |
| 15 min | Bupivacaine | 37 | 137.92 | 4.037 | | |
| | Ropivacaine | 37 | 139.32 | 2.161 | 609.500 | 0.410 |
| | Total | 74 | | | | |
| 20 min | Bupivacaine | 37 | 138.16 | 4.304 | | |
| | Ropivacaine | 37 | 139.35 | 2.214 | 587.500 | 0.290 |
| | Total | 74 | | | | |
| 25 min | Bupivacaine | 37 | 137.97 | 5.284 | | |
| | Ropivacaine | 37 | 139.22 | 2.250 | 659.000 | 0.780 |
| | Total | 74 | | | | |
| 30 min | Bupivacaine | 37 | 137.68 | 5.740 | | |
| | Ropivacaine | 37 | 138.97 | 3.005 | 668.500 | 0.862 |
| | Total | 74 | | | | |
| 35 min | Bupivacaine | 37 | 137.43 | 5.086 | | |
| | Ropivacaine | 37 | 138.70 | 2.788 | 664.000 | 0.823 |
| | Total | 74 | | | | |
| 40 min | Bupivacaine | 37 | 137.00 | 4.813 | | |
| | Ropivacaine | 37 | 138.62 | 2.453 | 578.000 | 0.245 |
| | Total | 74 | | | | |

Shown as per (**Table 4**), comparison of baseline heart rate in the two Groups indicates that there is no significant difference between the two Groups. The mean heart rate is lower in Group 1 (Bupivacaine) as compared to Group 2 (Ropivacaine) at five minutes, ten minutes, fifteen minutes, twenty minutes, twenty five minutes, thirty minutes, thirty five minutes and forty minutes. Statistical analysis proved that there is no significant difference in mean heart rate of two Groups at various time period (p value > 0.05).

Table 5: Variations in Mean Arterial Pressure

| | MAP | N | Mean Rank | Std Deviation | t value | p value |
|--------|-------------|----|-----------|---------------|---------|---------|
| 5 min | Bupivacaine | 37 | 79.73 | 3.150 | 621.500 | 0.486 |
| | Ropivacaine | 37 | 79.92 | 2.253 | | |
| | Total | 74 | | | | |
| 10 min | Bupivacaine | 37 | 80.22 | 3.318 | 641.500 | 0.639 |
| | Ropivacaine | 37 | 79.84 | 2.339 | | |
| | Total | 74 | | | | |
| 15 min | Bupivacaine | 37 | 80.51 | 3.461 | 402.000 | 0.002 |
| | Ropivacaine | 37 | 78.54 | 2.193 | | |
| | Total | 74 | | | | |
| 20 min | Bupivacaine | 37 | 80.11 | 3.213 | 391.500 | 0.001 |
| | Ropivacaine | 37 | 78.30 | 2.026 | | |
| | Total | 74 | | | | |
| 25 min | Bupivacaine | 37 | 79.73 | 3.687 | 594.500 | 0.325 |
| | Ropivacaine | 37 | 79.43 | 2.205 | | |
| | Total | 74 | | | | |
| 30 min | Bupivacaine | 37 | 79.08 | 3.443 | 600.000 | 0.356 |
| | Ropivacaine | 37 | 79.81 | 2.145 | | |
| | Total | 74 | | | | |
| 35 min | Bupivacaine | 37 | 79.11 | 2.979 | 529.500 | 0.090 |
| | Ropivacaine | 37 | 78.46 | 2.231 | | |
| | Total | 74 | | | | |
| 40 min | Bupivacaine | 37 | 78.70 | 2.933 | 614.000 | 0.439 |
| | Ropivacaine | 37 | 78.73 | 2.130 | | |
| | Total | 74 | | | | |

Shown in **Table 5**, comparison of mean arterial pressure in the two Groups indicates that there is no significant difference. Statistical analysis proved that there is no significant difference in mean heart rate of two Groups at various time period (p value > 0.05).

Table 6: Comparison of oxygen saturation at different intervals of time based on groups

| | SpO ₂ | N | Mean Rank | Std deviation | t value | p Value |
|--------|------------------|----|-----------|---------------|---------|---------|
| 5 min | Bupivacaine | 37 | 99.84 | 0.442 | 646.000 | 0.439 |
| | Ropivacaine | 37 | 99.92 | 0.277 | | |
| | Total | 74 | | | | |
| 10 min | Bupivacaine | 37 | 99.89 | 0.315 | 664.000 | 0.696 |
| | Ropivacaine | 37 | 99.84 | 0.442 | | |
| | Total | 74 | | | | |
| 15 min | Bupivacaine | 37 | 99.57 | 0.689 | 590.000 | 0.240 |
| | Ropivacaine | 37 | 99.38 | 0.758 | | |
| | Total | 74 | | | | |
| 20 min | Bupivacaine | 37 | 99.54 | 0.730 | 640.500 | 0.554 |
| | Ropivacaine | 37 | 99.65 | 0.633 | | |
| | Total | 74 | | | | |
| 25 min | Bupivacaine | 37 | 99.59 | 0.686 | 684.500 | 1.00 |
| | Ropivacaine | 37 | 99.59 | 0.686 | | |
| | Total | 74 | | | | |
| 30 min | Bupivacaine | 37 | 99.51 | 0.731 | 646.000 | 0.614 |
| | Ropivacaine | 37 | 99.59 | 0.686 | | |
| | Total | 74 | | | | |
| 35 min | Bupivacaine | 37 | 99.76 | 0.548 | 681.000 | 0.956 |
| | Ropivacaine | 37 | 99.73 | 0.608 | | |
| | Total | 74 | | | | |
| 40 min | Bupivacaine | 37 | 99.76 | 0.548 | 681.000 | 0.956 |
| | Ropivacaine | 37 | 99.73 | 0.608 | | |
| | Total | 74 | | | | |

Shown as per **Table 6**, Comparison of SpO₂ in the two Groups indicates that there is no significant difference. Statistical analysis proved that there is no significant difference in oxygen saturation of two Groups at various time period (p value > 0.05).

Discussion

Caudal block is the useful alternative to general anesthesia or total intravenous anesthesia as it provides effective post-operative analgesia. It is the most popular, reliable, safe and easy method to administer and is therefore, the commonly performed procedure for subumbilical surgeries in children. In-adequate treatment of pain can result in short-term and long-term morbidity. Post-operative pain management is an integral part of practice of pediatric anesthesia. In this study, caudal anesthesia was given using either 0.375% bupivacaine 1 ml/kg or 0.375% ropivacaine 1 ml/kg with maximum dose upto 2-3 mg/kg was used. There was no significant difference observed between the two groups in age, weight, onset of action, post-operative analgesia, heart rate, mean arterial pressure and oxygen saturation. Patient remained hemodynamically stable throughout the operation in both groups. The quality and duration of post-operative pain relief did not differ significantly between the two Groups. Post-operative pain score was comparable in two Groups, there was no significant difference at any time interval ($p > 0.05$).

Wilton and Da Conceiao reported significantly shorter duration of motor block with 0.375% ropivacaine as compared to 0.375% bupivacaine.^{6,8} Ivani *et al.* reported that 2 mg/kg of 0.2% ropivacaine is sufficient to obtain sensory block for lower abdominal or genital surgery in children. In our study, 0.375% ropivacaine has provided excellent analgesia during surgery and post-operative period.⁷ Hannallah *et al.* reported a significant difference in the duration of analgesia between bupivacaine and ropivacaine.⁹ Habre *et al.* reported that maximum plasma concentration of ropivacaine was achieved at 2 hours following caudal block which is much later than for bupivacaine in (29 ± 3.1) children.¹⁰ But other workers did not support their view and average duration was 5 hrs for both the drugs.¹¹ Khalil *et al.* also reported significant motor block initially which almost recovered to normal power with three hours in ropivacaine group. Motor recovery was significantly slow in bupivacaine group in their study.¹² Suresh *et al.* suggest that caudal anesthesia with ropivacaine in pediatric patients is effective and produces

less motor block in the post-operative period. Ropivacaine has greater sensory and fewer motor effects than bupivacaine. No significant difference between the groups in time to first post-operative analgesia.¹³

Conclusion

Caudal epidural blockade with either 0.375% bupivacaine or 0.375% ropivacaine, are effective in providing post-operative analgesia after circumcision in children. Ropivacaine provides effective post-operative analgesia like bupivacaine in pediatric patients. The efficacy of ropivacaine is like that of bupivacaine for caudal blocks and, although it may be slightly less potent than bupivacaine when administered epidurally, equi-effective doses have been established. Less motor blockade of ropivacaine makes it a more suitable agent for day care surgery.

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