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Original Research Article

Assessment of Infraorbital Levobupivacaine vs. Ropivacaine in Post Operative Analgesia Following Cleft Palate Surgery

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Abstract

Background: Ropivacaine and levobupivacaine have been used for the peripheral block in children for surgical pain. The present study is aimed to compare the effectiveness of 0.375% levobupivacaine and 0.375% ropivacaine in the infraorbital block for cleft palate surgery.

Methods: Eighty patients between the age group of 2–12 years planned for elective surgery for cleft palate were included in the study. The solution for Group L was a mixture of 0.375% levobupivacaine and the solution for Group R was a mixture of 0.375% ropivacaine. Infraorbital nerve blocks were conducted by landmark-guided technique. We used the Verbal Rating Scale (VRS) to assess the postoperative pain.

Results: There was a statistically significant difference in the time interval until the first request for pain medication was made by the participants in the two groups. There were differences in pain scores calculated at regular intervals after surgery comparing the two groups. There were differences in the need for rescue analgesics comparing the two groups.

Conclusion: The analgesic effects of levobupivacaine are statistically better than ropivacaine in the infraorbital block in children who underwent cleft palate surgery.

Keywords: Levobupivacaine, pain, regional anesthesia, ropivacaine

Introduction

Cleft palate repair is one of the commonly performed head-and-neck procedures done in children. As such, children with cleft palate tend to have a compromised airway due to associated congenital anomalies and hence, Postoperative respiratory complications, such as narrowed airway, increased secretions, pain, and bleeding, are expected in these surgeries. [1,2] bearing this in mind, regional anaesthesia becomes a viable option in this type of surgeries.

The superiority of bilateral infraorbital block employing levobupivacaine over intravenous fentanyl as well as over peri-incisional infiltration has been documented. Levobupivacaine was developed after ropivacaine as an agent was found to be associated with fewer adverse events. Both ropivacaine and levobupivacaine have been used for the peripheral block in children for surgical pain. However, no studies have established the comparative efficacy of

these drugs over each other in cleft palate surgeries. [3-5] Hence, the present study is aimed to compare the effectiveness of levobupivacaine and ropivacaine in the infraorbital block for cleft palate surgery among patients in Udaipur Rajasthan.

Methodology:

The study was performed at Pacific Institute of Medical Sciences, Udaipur after taking ethical approval from the institutional ethical committee. Forty patients in each group were included in the study. The children between the age group of 2–12-years planned for elective surgery for cleft palate were included after taking informed written consent from their respective parents or guardians. Patients who refused to give consent, known allergic to local anesthetics, on anticoagulants or bleeding disorder, and underlying other significant systemic diseases were excluded from the study.

The participants were randomly selected into Groups L or R using a computer-assisted block randomization technique.

The solution for Group L was a mixture of 7.5 ml of 0.5% levobupivacaine and 2.5 ml of saline (final concentration of the mixture was 0.375%). The solution for Group R was a mixture of 5 mL of 0.75% ropivacaine and 5 mL of saline (final concentration was 0.375%), of which 2–3 ml of these drugs are given in each group of patients by landmark technique.

The authors used 2 mg/kg propofol and 2 mcg/kg fentanyl for induction. A Ring-Adair-Elwyn south-facing endotracheal tube was used, and anaesthesia was maintained with 2%–4% sevoflurane. A bilateral infraorbital block is performed using 2–3 mL of 0.375% levobupivacaine (Group L) or ropivacaine (Group R). Ephedrine and phenylephrine were administered to maintain appropriate hemodynamic as necessary. At the end of the surgery, 2 mg/kg diclofenac sodium was routinely administered intravenously. The verbal rating scale (VRS), classified as 0 equals no pain and 5 equals the severest pain, was used to assess the pain. Parents/guardians were enquired regarding the pain if the child is not able to express. Nursing staff were educated before the study regarding the assessment of pain scores and neurologic evaluation.

The data analysis was performed using SPSS ver 21 software. Normally distributed continuous variables were presented as a mean ± standard deviation and analysed using unpaired Student's *t*-test. For categorical variables, Chi-square or Fisher's exact test was used to assess the difference between the groups. A value of $P < 0.05$ was considered statistically significant.

Observations:

A total of 80 patients were enrolled in this study. We found no significant differences in demographic data of the two groups (Table 1).

There was a significant difference in the time interval until the first request for pain medication was made by the participants in the two groups (10.6 [8.4, 12.8] vs. 8.5 [6.1, 10.8] h, $P = 0.002$). There were differences in pain scores calculated at regular intervals after the surgery comparing the two groups (2.7 ± 0.3 vs. 3.6 ± 0.3, $P = 0.01$) Table 2.

There were differences in the need for rescue analgesics comparing the two groups.

Table 1: Participant Data

Parameter	Group L	Group R
Number	40	40
Male	28	25
Female	12	15
Age	5.5 ± 3.1	5.2 ± 2.8

Weight	17.6 ± 3.3	17.8 ± 4.6

Table 2: Comparative Assessment

Parameters	Group L	Group R	P Value
Rescue Analgesia Duration (hrs)	10.6 (8.5-12.7)	8.5 (6.1-10.8)	0.02
Mean Pain Score at 1 hr Post op.	2.7 ± 0.22	3.6 ± 0.34	0.01

Discussion:

Regional Anaesthesia is preferred in cleft lip and palate surgeries to avoid postoperative pain and to avoid the side effects of opioids [6]. Appropriate local anaesthetics are chosen for peripheral nerve block based on their characteristics in operative and post operative scenarios. Levobupivacaine is considered more lipophilic compared to ropivacaine. Levobupivacaine is more potent than ropivacaine concerning postoperative analgesia and cardiac side effects. In comparison, levobupivacaine was found to produce more extended analgesia than ropivacaine.

This prospective, randomized, double-blind study was conducted to provide data of clinical use of 0.37% levobupivacaine and 0.37% ropivacaine for infraorbital nerve block using landmark technique for cleft palate surgeries. We found that 0.375% levobupivacaine provided longer postoperative analgesia when compared to 0.375% ropivacaine among the selected study subjects.

The efficacy of levobupivacaine over ropivacaine in terms of postoperative analgesia was proved in the study conducted by Fournier *et al*. [7] In their study, a total of 40 patients were enrolled and received equal volume and concentration of both drugs for sciatic nerve block. The median postoperative analgesia provided by levobupivacaine was longer (1605 min) s compared to that provided by ropivacaine (1035 min).

Cline *et al*. [8] compared 40 mL 0.5% levobupivacaine to 40 ml 0.5% ropivacaine in axillary brachial plexus block and found a significantly longer duration of analgesia with levobupivacaine compared to ropivacaine ($P = 0.013$).

The observed difference in the postoperative analgesia provided by levobupivacaine and ropivacaine was only 3 h in their study, while it was 8 h in our study. This shows that the duration of blockade may depend on regional techniques.

Cacciapuoti *et al*. [9] found that 1 mg/kg 0.5% levobupivacaine provides 3.5 h longer duration of analgesia compared to 1.45 mg/kg 0.5% ropivacaine in axillary plexus block. The study results are in accordance with the results of these studies. [10]

Limitations for our study were limited participants, and that we used the landmark-guided technique for the block. In the landmark-guided technique, the exact site of the block was unconfirmed, and it could have brought some difference. No postoperative complications were noted in both groups

Conclusion:

Among the selected study population, it was concluded that analgesic effects of levobupivacaine are statistically better than ropivacaine in the infraorbital block in children who underwent cleft palate surgery, however wider population-based studies are needed to generalise these findings.

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