e-ISSN: 0975-1556, p-ISSN:2820-2643
Available online on www.ijpcr.com
International Journal of Pharmaceutical and Clinical Research 2024; 16(10); 378-382
Original Research Article

A Randomized, Comparative Study of Levobupivacaine and Ropivacaine using Fentanyl as an Adjuvant in Caudal Block for Postoperative Analgesia in Pediatric Patients

Ayush Pachauri[1], Pramod Chand[2], Subhash Dahiya[3], Gaurav[4*], Gauri Arora[5], Varun Br[1]

[1]Junior Resident, Department of Anaesthesiology, L.L.R.M. Medical College, Meerut, Uttar Pradesh, India
[2]MD Anaesthesia, Associate Professor, Department of Anaesthesiology, L.L.R.M. Medical College, Meerut, Uttar Pradesh, India
[3]MD Anaesthesia, Professor, Department of Anaesthesiology, L.L.R.M. Medical College, Meerut, Uttar Pradesh, India
[4]MD Anaesthesia, Assistant Professor, Department of Anaesthesiology, L.L.R.M. Medical College, Meerut, Uttar Pradesh, India
[5]Senior Resident, Department of Anaesthesiology, L.L.R.M. Medical College, Meerut, Uttar Pradesh, India

Received: 25-07-2024 / Revised: 23-08-2024 / Accepted: 25-09-2024
Corresponding Author: Dr Gaurav
Conflict of interest: Nil

Abstract:

Background: Caudal epidural blocks are a widely used regional anesthesia technique in pediatric surgery, offering effective pain control with minimal side effects.

Aim and Objectives: To compare the efficacy and safety of Ropivacaine and Levobupivacaine, each combined with fentanyl, for postoperative analgesia in pediatric patients undergoing infraumbilical surgeries.

Materials and Methods: This prospective, randomized study included 50 pediatric patients aged 3-12 years with American Society of Anesthesiologists (ASA) physical status I and II. Patients were randomized into two groups: Group A received Ropivacaine 0.25% (0.5 ml/kg) with fentanyl (0.1 µg/kg), and Group B received Levobupivacaine 0.25% (0.5 ml/kg) with fentanyl (0.1 µg/kg). Hemodynamic parameters, postoperative analgesia duration, and complications were monitored postoperatively. Data were analyzed using SPSS version 20.0, with $p < 0.05$ considered statistically significant.

Results: The mean Duration of postoperative analgesia was 4.96 ± 0.79 hours for Group A and 4.88 ± 0.79 hours for Group B, with no statistically significant difference between the groups ($p = 0.720$). Hemodynamic parameters, including heart rate, systolic and diastolic blood pressure, mean arterial pressure, and oxygen saturation, remained stable in both groups with no significant differences. One patient in Group A experienced seizures, which was the only complication reported.

Conclusion: Both Ropivacaine and Levobupivacaine, when combined with fentanyl, provided comparable durations of postoperative analgesia in pediatric patients undergoing infraumbilical surgeries. The hemodynamic stability and low incidence of complications in both groups suggest that both anesthetics are safe and effective for pediatric caudal blocks. However, larger multi-center studies with varying drug concentrations are recommended to validate these findings further.

Keywords: Caudal block, Ropivacaine, Levobupivacaine, Fentanyl, Postoperative analgesia, Pediatric anesthesia.

Introduction

Postoperative pain management is a crucial aspect of pediatric care, as it ensures the patient's comfort and facilitates their recovery and rehabilitation. [1] Caudal block, a regional anesthesia technique, has been widely used to provide effective postoperative analgesia in pediatric patients undergoing various surgical procedures. [2]

Levobupivacaine and ropivacaine are local anesthetics that have been extensively studied in the context of regional anesthesia. [3] These agents have demonstrated favorable safety profiles and are commonly used in pediatric anesthesia. [4] The addition of adjuvants, such as fentanyl, has been shown to enhance the analgesic efficacy of caudal

blocks, leading to prolonged Duration of pain relief and improved patient satisfaction. [5]

This study aims to compare the efficacy and safety of levobupivacaine and ropivacaine, both combined with fentanyl, in providing postoperative analgesia in pediatric patients undergoing caudal block. The findings will contribute to the ongoing efforts to optimize postoperative pain management in the pediatric population, ultimately improving patient outcomes and reducing the risk of adverse events.

Materials and Methods

This prospective, randomized, comparative study was conducted on 50 pediatric patients aged 3-12 years, of both genders, with American Society of Anesthesiologists (ASA) physical status I and II, admitted to SVBP Hospital, affiliated with LLRM Medical College, Meerut. All patients were scheduled for infra-umbilical elective surgeries under general anesthesia. Ethical committee approval was obtained before the study initiation, and written informed consent was collected from the parents or legal guardians of the patients. The study was registered with the National Clinical Trial Registry of India on February 21, 2024 (CTRI/2024/02/062946).

Patients were randomly assigned into two groups using a computer-generated table to ensure unbiased distribution. The allocation was done via the sealed envelope method, and each envelope was opened by an anesthesiologist who was not involved in the study. Group A received Ropivacaine 0.25% (0.5 ml/kg) with fentanyl (0.1 µg/kg), while Group B received Levobupivacaine 0.25% (0.5 ml/kg) with fentanyl (0.1 µg/kg). The drug administration was performed according to the Armitage regime for caudal block, ensuring consistency in dosing. A blinded investigator administered the caudal block, while postoperative analgesia was evaluated by an independent anesthesiologist who was not aware of the group allocations.

The inclusion criteria for this study required patients to be classified as American Society of Anesthesiologists (ASA) grade I or II, aged between 3 and 12 years, and of either gender, undergoing elective infraumbilical surgeries. The exclusion criteria included refusal of the patient or guardian to participate, infection at the injection site, coagulopathy, a history of epilepsy, cardiac abnormalities, or peripheral neuropathy.

Preoperative Assessment

All patients underwent a detailed pre-anesthetic check-up (PAC) to assess weight and rule out cardiovascular, respiratory, or neurological conditions. Airway assessments were also performed during PAC clinic visits. Standard preoperative investigations were carried out according to institutional guidelines, including hemoglobin, total leukocyte count (TLC), platelet count, and prothrombin time.

Intraoperative Procedures

On the day of surgery, the patient was connected to monitors, including electrocardiography (ECG), pulse oximetry, and non-invasive blood pressure (systolic, diastolic, and mean arterial pressure). A 20-22 gauge intravenous cannula was inserted for IV access, and an Isolyte-P solution was administered. General anesthesia was induced, followed by insertion of an appropriately sized endotracheal tube. The caudal block was performed immediately following the surgery but before the reversal of anesthesia. Neostigmine 0.05 mg/kg IV and Glycopyrrolate 0.01 mg/kg IV were used to reverse anesthesia. Post-surgery, the patient was extubated and transferred to the postoperative ward.

Caudal Block Technique

The caudal block was performed by identifying the sacral hiatus and inserting a beveled needle at a 45-degree angle to the skin. Upon contacting the sacral bone, the needle was redirected parallel to the skin until a "pop" or "give" sensation was felt, indicating penetration of the sacrococcygeal ligament. The "whoosh test" was used to confirm placement in the epidural space. The correct dose of medication was administered based on group allocation.

Postoperative Monitoring

An independent anesthesiologist monitored patients in the postoperative ward. Postoperative pain was assessed using the FLACC scale, which evaluates five parameters: face, legs, activity, cry, and controllability. The FLACC scale ranges from 0 to 10, with higher scores indicating more severe pain. Pain assessments were conducted every hour until the FLACC score exceeded 4, at which point rescue analgesia was provided.

Statistical Analysis

Data were analyzed using SPSS version 20.0 for Windows. Continuous variables were presented as mean ± standard deviation, and categorical variables were presented as frequencies (percentages). The two groups were compared using the Student's t-test for continuous variables and the chi-square test for categorical data. For non-parametric variables, the Mann-Whitney test was used. A p-value <0.05 was considered statistically significant.

Results

The study included 50 pediatric patients, equally divided into two groups: Group A (Ropivacaine 0.25% with fentanyl) and Group B (Levobupiva-

caine 0.25% with fentanyl), with 25 patients in each group. The male-to-female ratio was comparable, with Group A comprising 20 males and 5 females and Group B comprising 19 males and 6 females. The mean age of patients in Group A was 7.08 years (SD = ±1.5) compared to 6.64 years (SD = ±1.7) in Group B. There was no statistically significant difference in age between the groups (p = 0.565). Most patients were within the 3-7 years age range, with 64% in Group A and 68% in Group B. The mean weight of patients in Group A was 22.72 kg (SD = ±6.59), while Group B's mean weight was 22.52 kg (SD = ±8.77). There was no significant difference in weight between the two groups (p = 0.928), indicating comparable patient characteristics.

Hemodynamic Parameters

The baseline heart rate in Group A was 107.36 ± 10.83 beats/min, compared to 102.4 ± 14.5 beats/min in Group B. There were no statistically significant differences in heart rate at any time points measured between the two groups (p > 0.05). Both groups exhibited stable heart rate trends postoperatively. The systolic blood pressure (SBP) was recorded at baseline and various postoperative intervals. At baseline, Group A had a mean SBP of 109.2 ± 7.88 mmHg, while Group B had 113.44 ± 9.19 mmHg. There were no significant differences in SBP between the groups at any recorded time. At baseline, Group A had a mean diastolic blood pressure (DBP) of 70.8 ± 7.49 mmHg, compared to 69.6 ± 4.18 mmHg in Group B. There were no significant differences in DBP between the two groups at any measured time points, except at the 6th hour, where Group B showed a slightly higher DBP (p = 0.043). Oxygen saturation remained stable in both groups. There were no significant differences in oxygen saturation levels between the two groups at any time, indicating similar respiratory function and recovery profiles.

Postoperative Analgesia (FLACC Score)

Postoperative pain was assessed using the FLACC scale. The mean Duration of postoperative analgesia in Group A was 4.96 ± 0.79 hours, while Group B had a mean duration of 4.88 ± 0.79 hours. The difference between the two groups was not statistically significant (p = 0.720).

Table 1: Comparison of Postoperative Analgesia Duration (hours) Between Group A and Group B

Group	Mean Duration (hours)	Standard Deviation (SD)	p-value
Group A	4.96 ± 0.79	0.79	0.720
Group B	4.88 ± 0.79	0.79	

Complications: Complications were minimal, with only one instance of seizures reported in Group A during the 6th postoperative hour. No vascular injuries, nerve injuries, hematomas, or respiratory difficulties were observed in either group.

Table 2: Comparison of Complications Between Group A and Group B

Complication	Group A (n=25)	Group B (n=25)
Vascular injury	0	0
Nerve injury	0	0
Seizures	1	0
Hematoma	0	0
Difficulty in breathing	0	0

Discussion

Regional anesthesia provides effective pain relief without the common side effects associated with general anesthesia, such as nausea, vomiting, excessive sedation, or respiratory depression. [1,2] Caudal blocks are beneficial in pediatric anesthesia, especially in sedated children, as they allow for early ambulation, maintain hemodynamic stability during the procedure, and promote spontaneous breathing. [3,4] This is particularly advantageous for high-risk pediatric groups, including preterm infants and children with cardiopulmonary comorbidities. Due to these benefits, Wiegele et al. [6] noted that caudal blocks remain an important aspect of modern pediatric anesthesia.

Postoperative analgesia duration and hemodynamic parameters were carefully monitored, including heart rate, systolic and diastolic blood pressure, mean arterial pressure and oxygen saturation. Both groups exhibited stable hemodynamics; these parameters had no significant differences throughout the study. This supports previous findings, such as those of Acharya et al. [7], Sharma et al. [8], and Yildiz et al. [9], who observed no significant hemodynamic variability in pediatric patients receiving caudal blocks.

Regarding postoperative analgesia, the mean Duration was 4.96 ± 0.79 hours for Group A and 4.88 ± 0.79 hours for Group B, which was statistically non-significant. This aligns with the results of Sharma et al. [8] and Biswas et al. [10], who also found no significant difference in the postoperative

analgesic efficacy between Ropivacaine and Levobupivacaine. Both studies concluded that Ropivacaine and Levobupivacaine offer comparable postoperative pain control, supporting our findings that both agents provide effective and similar durations of analgesia in children undergoing infraumbilical surgeries.

Furthermore, previous studies have shown that the addition of fentanyl as an adjuvant in caudal blocks prolongs the Duration of analgesia. In our study, the inclusion of fentanyl in both groups likely contributed to the extended analgesic Duration. This is consistent with the findings of Acharya et al.7 and Desai et al. [11], who reported that adding Fentanyl to Bupivacaine or Levobupivacaine significantly extended the Duration of analgesia, further enhancing postoperative pain control.

Regarding complications, only one case of seizures was reported in Group A, which received Ropivacaine with Fentanyl. This rare complication aligns with previous studies, such as the one by Suresh et al. [12], which found an overall low incidence of complications associated with caudal blocks in pediatric patients. The study by Beyaz et al. [13] also highlighted the safety of caudal epidural blocks in pediatric patients with few perioperative complications. Although rare, seizures have been documented in the literature, making it important to monitor patients closely postoperatively.

Additionally, studies like those by Ivani et al. [14] and Aouad et al. [15] have further established that caudal administration of anesthetics combined with adjuvants, such as Fentanyl or Clonidine, can enhance postoperative pain relief while maintaining hemodynamic stability. This aligns with our study's findings, where both groups maintained hemodynamic stability throughout the study duration, and complications were minimal.

Limitations

This study had several limitations that should be acknowledged. Firstly, it was a single-center study with a relatively small sample size, which may limit the generalizability of the findings. A larger, multi-center study would be necessary to provide more conclusive and widely applicable results. Secondly, the concentrations of local anesthetics used in the study were relatively low, and higher concentrations might have resulted in a longer duration of postoperative analgesia. Further studies could explore the effects of different anesthetic concentrations. Additionally, the study focused solely on pediatric patients, which limits its applicability to other age groups. Including adult populations in future research could provide a broader understanding of the efficacy of caudal blocks across different demographics. Finally, the study was conducted in a limited-resource setting, which may have impacted the scope of the data collected. Future research in more advanced medical settings could yield a more detailed evaluation of caudal blocks and their effects on postoperative outcomes.

Conclusion

The findings of this study support the effectiveness and safety of both Ropivacaine and Levobupivacaine, combined with fentanyl, for providing postoperative analgesia in pediatric patients undergoing infraumbilical surgeries. Both local anesthetics showed comparable analgesic durations, stable hemodynamic profiles, and a low incidence of complications. Further research, including studies with larger sample sizes and varying drug concentrations, must enhance understanding and optimize pain management in pediatric anesthesia.

References

1. Ertürk E, Tütüncü AÇ, Eroğlu A, Gökben M. Clinical comparison of 12 mg ropivacaine and 8 mg bupivacaine, both with 20 µg fentanyl, in spinal anaesthesia for major orthopaedic surgery in geriatric patients. Eur Neurol. 2010; 19 (2):142-7. doi: 10.1159/000249581.
2. Dewhirst E, Fedel G, Raman VT, Rice J, Barry N, Jatana KR, et al. Pain management following myringotomy and tube placement: Intranasal dexmedetomidine versus intranasal fentanyl. Int J Pediatr Otorhinolaryngol. 2014;78 (7):1090-4. doi: 10.1016/j.ijporl.2014.04.014.
3. Ivani G, Negri PD. New insights into paediatric regional anaesthesia: new drugs. Curr Opin Anaesthesiol. 2001;14(3):353-7. doi:10.1097 / 00001503-200106000-00012.
4. Negri PD, Ivani G, Tirri T, Piano ACD. New local anesthetics for pediatric anesthesia. Curr Opin Anaesthesiol. 2005;18(3):289-92. doi: 1 0.1097/01.aco.0000169237.29303.00.
5. Jöhr M. Regional anaesthesia in neonates, infants and children. Eur J Anaesthesiol. 2015 ;32(5):289-97. doi:10.1097/eja.000000000000 0239.
6. Wiegele M, Marhofer P, Lonnqvist PA. Caudal epidural blocks in paediatric patients: a review and practical considerations. Br J Anaesth. 2019;122(4):509-17. doi:10.1016/j.bja.2018.1 2.040.
7. Acharya R, Jena SK, Samal S, Mishra SN. Postoperative analgesia in pediatrics patients through caudal block with bupivacaine and two different doses of fentanyl - a comparative study. J Evol Med Dent Sci. 2013;2(39):7596-603. doi: 10.14260/jemds/1306.
8. Sharma J, Gupta R, Kumari A, Mahajan L, Singh J. A comparative study of 0.25% levobupivacaine, 0.25% ropivacaine, and 0.25% bupivacaine in paediatric single shot caudal block. Anesthesiol Res Pract. 2018;2018: 1486261. doi: 10.1155/2018/1486261.

9. Yildiz TS, Ozdamar D, Bagus F, Solak M, Toker K. Levobupivacaine-tramadol combination for caudal block in children: a randomized, double-blinded, prospective study. Paediatr Anaesth. 2010;20(6):524-9. doi:10.1111/j.1460-9592.2010.03296.x.
10. Biswas S, Mukherjee G, Sarkar UK, Ghose T, Das R. Randomized, double-blind controlled trial to compare the postoperative analgesic efficacy of a single dose administration of caudal levo-bupivacaine (0.25%) vs ropivacaine (0.25%) in infraumbilical surgeries in children. J Evol Med Dent Sci. 2013;2(31):5691-6. doi: 10.14260/jemds/1081.
11. Desai DJ, Swadia VN, Gupta KK. Comparative study of two different doses of fentanyl with 0.25% bupivacaine through caudal route for paediatric anaesthesia and postoperative analgesia. J Anaesthesiol Clin Pharmacol. 2008;24(1):31-4.
12. Suresh S, Long J, Birmingham PK, De Oliveira GS Jr. Are caudal blocks for pain control safe in children? An analysis of 18,650 caudal blocks from the Pediatric Regional Anesthesia Network (PRAN) database. Anesth Analg. 2015;120(1):151-6. doi: 10.1213/ANE.0000000000000446.
13. Beyaz SG, Tokgöz O, Tüfek A. Caudal epidural block in children and infants: retrospective analysis of 2088 cases. Ann Saudi Med. 2011;31(5):494-7. doi: 10.4103/0256-4947.84627.
14. Ivani G, De Negri P, Lonnqvist PA, L'Erario M, Mossetti V, Difilippo A, et al. Caudal anesthesia for minor pediatric surgery: a prospective randomized comparison of ropivacaine 0.2% vs levobupivacaine 0.2%. Paediatr Anaesth. 2005;15(6):491-4. doi: 10.1111/j.1460-9592.2004.01536.x.
15. Aouad MT, Kanazi GE, Siddik-Sayyid SM, Gerges FJ, Rizk LB, Baraka AS. Preoperative caudal block prevents emergence agitation in children following sevoflurane anesthesia. Acta Anaesthesiol Scand. 2005;49(3):300-4. doi: 10.1111/j.1399-6576.2005.00642.x.