Archives of Anesthesiology and Critical Care (Winter 2023); 9(1): 4-8.

Available online at http://aacc.tums.ac.ir

Research Article

# A Comparative Study of Ropivacaine with and without Fentanyl for Caudal Anesthesia in Pediatric Patients

***Rameesa Batul[1], Uzma Gulzar[1], Ouber Qayoom[2]****

[1]*Department of anesthesiology and critical care, SKIMS Soura, Srinagar, J&K, India.*

[2]*Department of Cardiology, GMC, Jammu, J&K, India.*

**ARTICLE INFO**

**Article history:**
Received 16 March 2022
Revised 06 April 2022
Accepted 20 April 2022

**Keywords:**
Caudal;
Pediatric;
Postoperative;
Fentanyl;
Ropivacaine

**ABSTRACT**

**Background:** One of the most prevalent regional methods in paediatric anaesthesia is the caudal epidural block. It is a safe, simple procedure that has proven to be quite beneficial in children following infra-umbilical surgery. Ropivacaine causes differential neuraxial blockade, which is associated with less motor block and lower cardiovascular damage. To extend the duration of action of local anaesthetics, several adjuvants are administered. Our goal was to see how fentanyl affected the duration of postoperative analgesia when used in conjunction with ropivacaine in a paediatric population of children aged 3 to 8 years following infraumbilical operations.

**Methods:** On 100 paediatric patients receiving elective infraumbilical operations, a prospective, comparative, and randomised investigation was done. Patients were randomised into two 50-person groups at random. Caudal anaesthesia was administered once the airway was secured. 0.2 percent ropivacaine 0.5ml/kg was given to Group R, while 0.2 percent ropivacaine 0.5ml/kg with fentanyl 0.5mcg/kg was given to Group RF. Face, legs, activity, cry, and consolability pain rating scales were used to measure postoperative pain for 24 hours. The length of the motor blockage and any negative effects were recorded. Hemodynamics, post-operative analgesia duration, and the number of rescue analgesics required were all recorded and statistically evaluated.

**Results:** The mean duration of analgesia in ropivacaine group was 440.60±101.29 minutes (7.25hrs) and in ropivacaine fentanyl group was 891±312.84 (14.76hrs). Statistically, the difference was highly significant.

**Conclusion:** In children having infraumbilical surgery, using fentanyl as an adjuvant to ropivacaine for caudal block enhanced analgesic effectiveness and extended post-operative analgesia.

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage by the International Association for the Study of Pain [1]. One of the most prevalent regional procedures in paediatric anaesthesia is the caudal epidural block. It is a safe, simple procedure that has proven to be quite beneficial in youngsters, particularly in infraumbilical procedures. It gives effective post-operative analgesia and quick anaesthetic recovery [2]. Caudal anaesthesia can help to minimise the quantity of inhaled and intravenous anaesthetics needed, as well as reduce the stress reaction to operation. Early ambulation and lower risk of chest infection, as well as reduced postoperative analgesic doses and early discharge are all advantages of caudal block [3].

The combination of local anesthetic with adjuvant is getting more popular for better post-operative pain control with less side effects and early discharge. Bupivacaine was a popular drug in regional anesthesia for years until toxic reactions were reported. Ropivacaine, the S-enantiomer of the amide local anesthetic, produces

The authors declare no conflicts of interest.

*Corresponding author.
E-mail address: anesthesia316@gmail.com

differential neural blockade, with less motor blockade, cardiovascular and neurological toxicity, making it suitable for day-care surgery in children. Caudal analgesia is more popular because of its simple technique, predictable level of blockade and high success rate, excellent postoperative analgesia with smooth recovery for various surgeries, for example, lower abdominal, urologic and lower limb operations. It reduces analgesic requirement and facilitates early discharge.

Ropivacaine was first used in clinical practise in 1996, and it has been shown to have a better safety profile than bupivacaine, with a lower risk of CNS and cardiotoxicity. Ropivacaine has recently gained popularity as a local anaesthetic for caudal blocks [4]. Adjuvants not only improve the effectiveness of a local anaesthetic by extending and increasing the sensory blockade, but they also reduce the dose of local anaesthetic drugs. Fentanyl is a synthetic, highly selective opioid agonist that operates primarily on the mu-opioid receptor but also on the delta and kappa receptors. Fentanyl is an extremely powerful opioid that is 100 to 300 times stronger than morphine. Because of its high lipophilicity, it can quickly penetrate CNS structures [5].

The purpose of this study was to see how fentanyl affected the duration of postoperative analgesia when used in conjunction with ropivacaine in a paediatric population of children aged 3 to 8 years following infraumbilical operations.

## Methods

After receiving clearance from the Institute's Ethical Committee, the current prospective, randomised study was carried out in the Department of Anesthesia, SKIMS, Soura. The study involved 100 paediatric patients of either gender, aged 3 to 8, who were receiving infraumbilical operations and belonged to the ASA-I and II groups. Parental rejection, a history of developmental delay or missed milestones, mental impairment, a kid with suspected coagulopathy or bleeding diathesis, a body weight of more than 30 kilograms, and local infection at the puncture site were all exclusion factors. After gaining parental or guardian approval, the children were separated into two groups, each with 50 children. A simple envelope approach was used for randomization.

Group R - received 0.2% ropivacaine 0.5ml/kg.

Group RF - received 0.2% ropivacaine 0.5ml/kg with fentanyl 0.5mcg/kg

Patients were fasted for 4 to 6 hours prior to surgery, depending on their age. Premedication was administered orally with syrup midazolam 0.5mg/kg 30-45 minutes prior to induction on the day of operation. Inj. glycopyrrolate 0.005- 0.01 mg/kg and inj. ondansetron 0.15 mg/kg were given through an intravenous line. Inductions were performed using either 2-3 mg/kg propofol or halothane/sevoflurane in 100% oxygen. Anesthesia was maintained with O2, N2O, and halothane/sevoflurane, and airway was secured using suitable diameters of endotracheal tube or laryngeal mask airway. ECG, blood pressure, SpO2, and heart rate were all monitored.

After securing the airway, the patient was put in the lateral decubitus position, and vitals and respiratory adequacy were assessed. The back was washed and wrapped with an antibacterial solution. Under aseptic circumstances, a sacral hiatus was discovered. The 22G hypodermic needle was advanced at a 45° angle cephalad until the sacrococcygeal ligament was pierced with a pop. After that, the needle's angle was flattened and it was advanced into the sacral hiatus. The conventional loss of resistance approach was used to locate the caudal epidural space. After negative aspiration for blood and cerebrospinal fluid, the medicines were delivered in caudal block according to the groups.

The patient was turned supine once the injection site was dressed. The operation was permitted to continue after 15 minutes of the process. The haemodynamic parameters SpO2, HR, SBP, DBP, MAP, and RR were measured during the preoperative period, then every 5 minutes intraoperatively for the first half hour, then every 10 minutes till the operation was completed. Hemodynamics, pain score, motor blockage, sedation score, and side effects were measured every 15 minutes until 2 hours, then every 2 hours until 12 hours, and finally at 24 hours. For pain assessment, the FLACC scale [6] (Table 1) was employed. The time from caudal drug insertion to the first recording of a FLACC scale 4 was used to determine the duration of analgesia.

**Table 1- FLACC Scale**

| Parameter | 0 | 1 | 2 |
|---|---|---|---|
| Face | No expression | Occasional grimace | Frequent to constant quivering chin. |
| Legs | Normal position or relaxed | Uneasy, restless, tense | Kicking or legs drawn up |
| Activity | Lying quiet | Squirming, shifting back and forth, tense | Arched, rigid or jerking |
| Cry | No cry | Moans or whimpers | Crying steadily |
| Consolability | Content, relaxed | Reassurance, hugging | Difficulty to console |

The degree of motor blockade was assessed by Bromage scale. Bromage 0 - Full flexion of knees and feet possible, able to lift extended legs. Bromage 1 - Unable to lift extended legs, but able to flex knees and

feet. Bromage 2 - Unable to flex knees but flexion of feet possible. Bromage 3 - Unable to move legs and feet at all. Sedation Score [7] had been assessed as 0-arousable, 1-arousable to voice, 2- arousable to pain and 3-unarousable.

Statistical Analysis: SPSS statistics were used to conduct the analysis (version 23). To compare the two groups, numerical data was reported as mean and standard deviation, and statistical analysis was performed using the independent t test. The Mann-Whitney U-test was performed to test for skewed data/scores. The Chi-square test was used to compare gender. A 0.05 p-value was regarded statistically significant, whereas a 0.001 p value was considered statistically very significant.

## Results

The research recruited 100 paediatric patients between the ages of three and eight years. All of the patients had a successful caudal block. The demographics of the two groups were identical (Table 2). The hemodynamic parameters of the two groups were not significantly different. After the procedure, there was no evidence of motor blockage. In Group R, two patients vomited, but in Group RF, six patients vomited. There were no additional negative effects in either group (Table 3). The FLACC pain score was compared between Group R and Group RF (Table 4).

The mean FLACC reached ≥ 4 in group R at 6 hours and at 12 hours in group RF. As shown in table 5 mean duration of analgesia in ropivacaine group is 440.60±101.29 minutes (7.35hrs) and in ropivacaine fentanyl group was 891±312.84 (14.86hrs) [p-value (<0.001)]. Mean no. of rescue analgesia that was needed in group R was 1.56±0.50 and in group RF was 0.84±0.37.

**Table 2- Demographic Data**

| Data | Group R | Group Rf | P value |
|---|---|---|---|
| Age (yrs.) | 5.04±1.42 | 4.64±1.49 | 0.339 |
| Weight (kgs) | 17.24±4.90 | 15.48±3.25 | 0.141 |
| Sex (%) | | | |
| Male | 88 | 84 | 0.684 |
| Female | 12 | 16 | |
| Duration of surgery(mins) | 45.2±9.94 | 45.2±11.8 | 0.911 |

**Table 3- Complications**

| Complication | Group R | Group Rf | P value |
|---|---|---|---|
| Bradycardia | 0 | 0 | |
| Hypotension | 0 | 0 | |
| Retching | 0 | 0 | |
| Vomiting | 2 | 6 | 0.297 |
| Respiratory Depression | 0 | 0 | |
| Urinary Retention | 0 | 0 | |

**Table 4- FLACC score (Mean ± SD) during postoperative period in two groups**

| Time | Group R | Group Rf | P value |
|---|---|---|---|
| 0 mins | 0.08±0.27 | 0.00±0.00 | 0.153 |
| 15 mins | 0.12±0.33 | 0.00±0.00 | 0.077 |
| 30 mins | 0.24±0.52 | 0.00±0.00 | 0.020 |
| 45 mins | 0.64±0.86 | 0.04±0.20 | 0.001 |
| 60 mins | 0.92±0.86 | 0.04±0.20 | <0.001 |
| 75 mins | 1.16±0.80 | 0.04±0.20 | <0.001 |
| 90 mins | 1.36±1.15 | 0.16±0.37 | <0.001 |
| 105 mins | 1.36±0.90 | 0.48±0.50 | <0.001 |
| 120 mins | 1.96±0.93 | 0.76±0.66 | <0.001 |
| 4 hrs | 1.84±1.06 | 0.28±0.61 | <0.001 |
| 6 hrs | 3.16±1.49 | 0.72±0.61 | <0.001 |
| 8 hrs | 2.48±1.73 | 0.76±0.59 | <0.001 |
| 10 hrs | 1.40±1.89 | 2.72±0.45 | <0.001 |
| 12 hrs | 2.28±0.84 | 3.28±1.30 | <0.001 |
| 24 hrs | 2.76±1.58 | 2.04±0.93 | 0.024 |

## Discussion

Because of its effectiveness and safety, paediatric regional anaesthesia is widely used across the world. The use of localised anaesthetic methods reduces postoperative pain and the need for systemic analgesics. The most popular regional anaesthetic approach for administering anaesthesia and analgesia in children having infra umbilical procedures is caudal epidural analgesia. The aim of the present study was to evaluate the efficacy of fentanyl in prolonging the analgesic duration when given along with ropivacaine in caudal block for paediatric postoperative analgesia.

In terms of age, weight, sex distribution, and operation length, the two groups were equivalent. All of the haemodynamic parameters in our investigation were comparable across all time periods. In 2014, Gupta et al. [8] evaluated ropivacaine alone and ropivacaine plus fentanyl in perineal and subumbilical operations, concluding that neither group had substantial haemodynamic instability during the research period. In 2015, Senugupta et al. [9] compared caudal epidural ropivacaine to fentanyl and bupivacaine for paediatric postoperative analgesia in children undergoing infraumbilical procedures and found no significant variations in haemodynamic parameters between the two groups. The findings of this study were consistent with those of Gupta et al. [8] and Senugupta et al [9].

Anand et al. [10] did a research in 2011 to investigate the effects of caudal dexmedetomidine mixed with ropivacaine for postoperative analgesia in children, and they measured the duration of analgesia using the FLACC Scale>4. The study found that 20 of the 30 children in the ropivacaine group had a pain level of 4 at the 6th hour. In a 2014 research, Gupta et al. [8]

compared fentanyl with ropivacaine and ropivacaine alone for caudal analgesia in paediatric patients, they found that pain score was > 4 at 16 hours in the ropivacaine group and > 4 at 36 hours in the ropivacaine fentanyl group. The mean FLACC in the current research was 4 in group R at 6 hours and 12 hours in group RF. Our results were in close agreement with the studies conducted by Anand et al. [10] and Gupta et al [8].

The duration of analgesia with caudal 0.1 percent ropivacaine, 0.2 percent ropivacaine, and 0.3 percent ropivacaine was roughly 3.3 hours, 4.5 hours, and 4.2 hours, according to Bosenberg et al. [11] in 2002. The use of 0.1 percent ropivacaine was shown to be less effective, whereas the use of 0.3 percent ropivacaine resulted in a larger incidence of motor block without a significant increase in analgesic duration. After elective inguinal surgery, 0.2 percent ropivacaine provided adequate postoperative analgesia. As a result, we employed 0.2 percent ropivacaine in this investigation. Gupta et al [8] did a study in 2014 to compare fentanyl with ropivacaine and ropivacaine alone for caudal analgesia and discovered that the ropivacaine fentanyl group had an analgesic duration of 16–20 hours longer than the ropivacaine alone group.

In 2016, Shukla et al. tested caudal fentanyl and clonidine as additives to ropivacaine in infraumbilical abdominal operations, finding that the addition of fentanyl to ropivacaine provided children with sustained postoperative analgesia. In 2016, Saini et al [13] conducted a study in children to compare the analgesic properties of clonidine and fentanyl as an analgesic adjunct in caudal epidural block with ropivacaine, and found that the mean duration of analgesia in the fentanyl ropivacaine group was 11.8 hours, which was similar to the findings in this study. In our study, we found that when fentanyl is used in conjunction with ropivacaine, the duration of analgesia is extended.

The result of present study was in close agreement with the above studies conducted by Bosenberg et al, [11] Gupta et al, [8] Shulka et al. [12] and Saini et al [13]. In contrast to forementioned studies, there were few studies where results are contrary to present study.

In 2006, Kawaraguchi et al. [14] did a study to see if adding fentanyl to ropivacaine extended the duration of analgesia following a single shot caudal block. They found that adding fentanyl to ropivacaine 0.2 percent gives no additional analgesic benefits over ropivacaine 0.2 percent alone. The difficulty in distinguishing between pain response and agitation on emergence, especially in younger children, might be the cause for this. Our study's pain score was calculated using a different scale. Among the patients who have been given analgesics, there may be one who is agitated rather than in pain. Furthermore, the study includes a variety of surgical procedures.

Rao et al. [15] in 2017 :conducted a study to compare ropivacaine 0.2% versus ropivacaine with fentanyl 1 mcg/kg versus ropivacaine 0.2% with neostigmine 2 mcg/kg as a single shot caudal block on post-operative analgesic effect in children and concluded that ropivacaine caused a prolongation of duration of analgesia, while a ropivacaine and fentanyl mixture did not cause any statistically significant increase in the duration of analgesia. The result is contrary to our study and the reason being that it was difficult to distinguish between sedation and analgesia in the study groups as a pain-free child is calm, comfortable or asleep. Other reason is that type of surgical procedures were varied. The intensity of post-operative pain may vary depending on the type of surgical procedure.

In our study as a result, the number of rescue analgesics required in the ropivacaine fentanyl group is lower than in the ropivacaine alone group. Patients in the ropivacaine fentanyl group required fewer doses of rescue analgesia than those in the bupivacaine fentanyl group, according to Senugupta et al. [9] in 2006. Our findings were consistent with those of Senugupta et alresearch. .'s [9] In a 2014 research, Gupta et al. [8] compared fentanyl with ropivacaine and ropivacaine alone, and found that neither group experienced severe motor blockage. There was no substantial motor obstruction in either group in this investigation. So present study is in accordance to the literature and had no motor blockade.

The mean sedation score (SS) in both groups during the postoperative phase was comparable at all intervals in this investigation. Kawaraguchi et al. [14] compared fentanyl to ropivacaine and ropivacaine alone and observed no significant difference in sedation score between the two groups, which is consistent with the current study.

Vomiting was found to be 4 percent in group R and 12 percent in group RF in this study. Bradycardia, hypotension, respiratory depression, retching, and urine retention occur in none of the patients in either group. In a 2006 study, Khatavkar et al. [16] compared clonidine with fentanyl as an adjuvant to ropivacaine for caudal block and found that no patients had urine retention, respiratory depression, or any other consequence. In a 2014 study, Gupta et al. [8] compared fentanyl to ropivacaine and ropivacaine alone for caudal analgesia in paediatric patients, finding that 1 patient in the ropivacaine group and 4 patients in the ropivacaine fentanyl group had vomiting. There were no cases of respiratory depression, bradycardia, or hypotension in any of the patients. The present study was in consistent with the studies done previously by Khatavkar et al. [16] and Gupta et al [8].

## Conclusion

Fentanyl is a safe and efficient adjuvant to ropivacaine when used in caudal anaesthesia in paediatric patients having infraumbilical surgery, according to the findings of this study. When fentanyl is added to ropivacaine, the duration of analgesia is extended and the requirement for rescue analgesia in the postoperative phase is reduced.

### References


[1] Pain terms: a list with definitions and notes on usage. Recommended by the IASP subcommittee on taxonomy. Pain. 1979; 6: 249.

[2] Ganeshnavar A, Joshi C, Masur S, Hulkund SY. Comparison of dexmedetomidine and clonidine as adjuvants to 0.25% bupivacaine in paediatric caudal block for infraumbilical surgeries. Intl.Jclin. Diag.Res.2015;3 (4).

[3] Palkhiwla BB, Gajjar HR., Shah R. Study of caudal anesthesia with ropivacaine under sedation for infraumbilical surgery in paediatrics patients: NHL .Journal of Medical Sciences.2014; 3(1):37-40.

[4] McClellan KJ, Faulds D. Ropivacaine: an update of its use in regional anaesthesia. Drugs. 2000; 60(5):1065-93.

[5] Henthorn TK, Liu Y, Mahapatro M, Ng KY. Active transport of fentanyl by the blood-brain barrier. J Pharmacol Exp Ther. 1999; 289 (2):1084-9.

[6] Chakravarthy K, Anupuram LN, Cherukuri SK, Nalagandla SR, Konda RRM. Evaluation of caudal epidural with bupivacaine 0.20% versus ropivacaine 0.2% for post operative pain relief in paediatric lower abdominal surgeries. IOSR Journal of Dental and Medical Sciences.2016;15(1):47-51.

[7] Ali G, Kala N, Rather MA, Taj A, Maqbool S, Bhat KA. Comparative evaluation of caudal ropivacaine and ropivacaine with clonidine for postoperative analgesia in children. IOSR Journal of Dental and Medical Sciences. 2015;14(9): 50-54.

[8] Gupta P, Sharma P, Jethava D, Jethava DD. A comparison of Ropivacaine alone and in combination with fentanyl for caudal analgesia in pediatric patients. J Med Dent Sci. 2014;13(11):1-4.

[9] Senugupta S, Mukherji S, Sheet J, Mandal A, Swaika S. Caudal-epidural bupivacaine versus ropivacaine with fentanyl for paediatric postoperative analgesia. Anesth Essays Res. 2015; 9:208-12.

[10] Anand VG, Kannan M, Thavamani A, Bridgit MJ. Effects of dexmedetomidine added to caudal ropivacaine in pediatric lower abdominal surgeries. Indian J Anesth. 2011; 55:340-6.

[11] Bosenberg A, Thomas J, Lopez T, Lybeck A, Huizar K, Larsson LE. The efficacy of caudal ropivacaine 1, 2 and 3 mg•ml−1 for postoperative analgesia in children. Paediatr Anaesth. 2002; 12: 53–58.

[12] Shukla U, Prabhakar T, Malhotra K. Postoperative analgesia in children when using clonidine or fentanyl with ropivacaine given caudally. J Anesthesiol Clin Pharmacol. 2011; 27:205–10.

[13] Saini S, Patodi V, Sethi SK, Jain N, Mathur P, Thada B. Comparison of caudal epidural clonidine with fentanyl as an adjuvant to ropivacaine 0.25% for postoperative analgesia in children undergoing various infraumbilical surgeries: A prospective randomized study. Ain-Shams J Anaesthesiol. 2016; 9:493-500.

[14] Kawaraguchi Y, Otomo T, Ota C, Uchida N, Taniguchi A, Inoue S. A prospective, double-blind, randomized trial of caudal block using ropivacaine 0.2% with or without fentanyl 1 μg kg−1 in children. Br J Anaesth. 2006;97(6): 858-61.

[15] Rao MP, Babu SP, Saroj P. A randomised, double-blind, prospective study of caudal ropivacaine versus ropivacaine with fentanyl versus ropivacaine with neostigmine for combined epidural and general anaesthesia in children. J Evolution Med Dent Sci. 2017; 6(44):3459-68.

[16] Khatavkar SS, Lonkar SS, Panchal PB, Thatte WS, Nagendra S, Tewari D. The efficacy of ropivacaine fentanyl versus ropivacaine-clonidine for pre-emptive caudal anesthesia in children. Anaesth Pain & Intensive Care. 2016; 20(1):54-8.