International Journal of Research in Medical Sciences
Alam F et al. Int J Res Med Sci. 2026 Jun;14(6):2364-2367
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20261472

Original Research Article

Comparative study between bupivacaine plus fentanyl and bupivacaine plus dexmedetomidine for epidural caudal analgesia in pediatric patients: a double blind randomized controlled trial

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Received: 025 April 2026
Revised: 07 May 2026
Accepted: 08 May 2026

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ABSTRACT

Background: For postoperative pain following juvenile infraumbilical procedures, caudal epidural analgesia is frequently utilized. Analgesia is improved when bupivacaine is combined with adjuvants. In this study, the adjuvants fentanyl and dexmedetomidine are compared.
Methods: In this prospective, randomized, double-blind trial, sixty ASA I–II children (ages 1–8) were split into two groups: Bupivacaine and dexmedetomidine were administered to group BD, and bupivacaine and fentanyl were administered caudally to group BF. Every two hours for the duration of the day, pain was measured using the FLACC score. Rescue analgesia was given when FLACC≥4. Hemodynamic parameters and adverse consequences were observed.
Results: The groups' demographic characteristics were similar. After four hours, group BD's FLACC ratings were considerably lower than group BF's and group BD required rescue analgesia at a considerably lower rate than Group BF
Conclusions: Dexmedetomidine provides greater and longer-lasting postoperative analgesia with fewer rescue analgesic doses and less side effects than fentanyl in pediatric patients.

Keywords: Caudal analgesia, Dexmedetomidine, Fentanyl, Bupivacaine, Pediatric anesthesia, FLACC score

INTRODUCTION

For anesthesiologists, effectively managing postoperative pain in pediatric patients continues to be a major issue since insufficient analgesia can result in physiological stress, delayed recovery, and long-term behavioral repercussions.[1] Because of its ease of use, safety, and dependability, caudal epidural analgesia is one of the most often used regional anesthetic procedures for children undergoing infraumbilical surgeries.[2]

Although bupivacaine, a long-acting amide local anesthetic, is frequently used for caudal blocks, its comparatively short duration of action requires the addition of adjuvants to enhance quality and prolong analgesia.[3] In order to increase the analgesic effectiveness of caudal blocks, opioids like fentanyl have historically been added to local anesthetics. Fentanyl provides strong analgesia without substantial motor inhibition by acting mainly through μ-opioid receptor agonism in the spinal cord's dorsal horn.[4] However, opioid-related side effects, including as respiratory depression, nausea, vomiting, and pruritus, continue to be a concern, especially in the pediatric population.[5]

Dexmedetomidine and other α2-adrenergic agonists have drawn interest as useful adjuvants in regional anesthesia in recent years. By preventing the release of nociceptive neurotransmitters and hyperpolarizing interneurons in the spinal cord, dexmedetomidine causes analgesia.[6] It is a

desirable substitute for opioids due to its less respiratory depression.[7] Additionally, dexmedetomidine provides sedative and sympatholytic effects, which may contribute to improved perioperative hemodynamic stability.[8] Dexmedetomidine has been demonstrated to considerably increase the duration of analgesia and decrease the need for postoperative analgesics, whilst fentanyl provides quick onset and efficient pain relief.[9] However, dexmedetomidine should be carefully evaluated due to concerns about bradycardia and hypotension, particularly in youngsters.[10]

METHODS

Study type

This study was a prospective, randomized, double-blind controlled trial.

Study place and period

The study was conducted in the Department of Anaesthesiology from April 2021 to October 2021.

Inclusion criteria

Sixty ASA physical status I–II pediatric patients aged 1–8 years undergoing elective infraumbilical surgeries were included.

Exclusion criteria

Exclusion criteria included patients with neurological disorders, coagulopathy, infection at injection site, spinal deformities, known drug allergy, or parental refusal.

Procedure

Patients were randomly allocated into two groups (n=30 each) using a computer-generated randomization table with sealed envelope technique.

Group BD received caudal bupivacaine (0.25%) with dexmedetomidine (1 µg/kg) and group BF received caudal bupivacaine (0.25%) with fentanyl (1 µg/kg).

Total volume administered was 1 ml/kg.

All patients received standard general anesthesia. After induction, patients were placed in the lateral position and caudal epidural block was performed under strict aseptic precautions. After confirming negative aspiration for blood and cerebrospinal fluid, the study drug was administered slowly.

Postoperative pain was assessed using the FLACC score at 2-hour intervals for 24 hours. Rescue analgesia (intravenous paracetamol 15 mg/kg) was administered when FLACC score ≥4.

Hemodynamic parameters (heart rate, blood pressure, oxygen saturation) were recorded perioperatively. Adverse effects such as bradycardia, hypotension, respiratory depression, nausea, and vomiting were monitored.

Ethical approval

The study was approved by the Institutional Ethics Committee, and the trial was registered with the Clinical Trials Registry of India (CTRI).

Statistical analysis

Statistical analysis was performed using statistical package for the social sciences (SPSS) version 26. Continuous variables were expressed as mean±standard deviation and compared using appropriate tests. Categorical variables were analyzed using the chi-square test. A $p<0.05$ was considered statistically significant.

RESULTS

Demographic profile

Age, weight, gender distribution, and length of surgery were similar for both groups. The groups did not differ statistically significantly ($p>0.05$) (Table 1).

Postoperative FLACC score (primary outcome)

The FLACC scores were comparable in the initial postoperative period (0–2 hours) (Table 2).

Rescue analgesic requirement (secondary outcome)

When compared to group BD, group BF's overall need for rescue analgesia (intravenous paracetamol) was much greater. group BF needed 2.3±0.8 dosages in a 24-hour period, while group BD needed 1.2±0.6 ($p<0.001$) (Table 3).

Table 1: Demographic and baseline characteristics.

Parameter	Group BF (n=30)	Group BD (n=30)	P value
Age group (in years)	4.2±1.8	4.5±1.6	0.52
Weight (in kg)	14.8±3.2	15.1±3.5	0.68
Gender	18/12	17/13	0.79
Time taken for surgery (in min)	52±10	55±12	0.41

Table 2: Comparison of FLACC scores.

Time (hours)	Group BF	Group BD	P value
0	0	0	-
2	1.2±0.6	1.0±0.5	0.18
4	2.8±0.9	1.6±0.7	<0.001
6	3.5±1.0	2.0±0.8	<0.001
8	4.2±1.1	2.5±0.9	<0.001
12	3.8±1.0	2.3±0.7	<0.001
24	2.5±0.8	1.8±0.6	0.002

Table 3: Rescue analgesia requirement.

Parameter	Group BF	Group BD	P value
No. of paracetamol doses (24 hours)	2.3±0.8	1.2±0.6	<0.001

Hemodynamic parameters

At every time point, the two groups' hemodynamic characteristics, such as heart rate and mean arterial pressure, were similar (Table 4).

Table 4: Hemodynamic parameters (mean values).

Parameter	Group BF	Group BD	P value
Heart rate (bpm)	102±8	96±7	0.06
MAP (mmHg)	68±6	66±5	0.21

Adverse effects

The incidence of adverse effects was low in both groups. Mild nausea and vomiting were observed in 3 patients (10%) in group BF, whereas no such cases were noted in group BD. No cases of respiratory depression were observed in either group.

DISCUSSION

In comparison to fentanyl as an adjuvant, the current study shows that adding dexmedetomidine in pediatric patients results in better and longer-lasting postoperative analgesia. This is demonstrated by the dexmedetomidine group's considerably lower FLACC scores starting at 4 hours and their decreased need for rescue analgesia.

Using dexmedetomidine as a caudal adjuvant improved the duration and quality of analgesia. In children undergoing infraumbilical operations, stated that adding dexmedetomidine to bupivacaine greatly prolongs postoperative analgesia and postpones the need for rescue analgesics.[11] In a similar vein, Singh et al found that dexmedetomidine offers superior sedation and analgesic efficacy than opioid-based adjuvants without escalating side effects.[12]

Dexmedetomidine suppresses the release of substance P and decreases nociceptive transmission at the dorsal horn level, which is how it improves analgesia.[13] On the other hand, μ-opioid receptor activation is the primary mechanism of action for opioids like fentanyl, which, while effective, has a shorter duration of action and a higher prevalence of side effects.[14]

In the current investigation, the FLACC ratings were similar for the first four hours following surgery but considerably decreased in the dexmedetomidine group, suggesting a persistent analgesic effect.[15]

The much lower need for rescue analgesia in the dexmedetomidine group is another noteworthy result of our investigation. This is clinically significant because it minimizes the need for further analgesics, which lowers drug exposure and enhances patient comfort. When compared to other adjuvants, dexmedetomidine significantly reduced postoperative analgesic usage, according to Mohamed et al.[16]

A crucial factor to take into account while employing α2 agonists is hemodynamic stability. The dexmedetomidine group in this study did not require intervention because these changes were not clinically significant. This is in line with the findings of Patel et al, who discovered that dexmedetomidine generates stable hemodynamics when given in pediatric caudal blocks at the appropriate doses.[17]

In terms of side effects, the dexmedetomidine group demonstrated a higher safety profile, while the fentanyl group experienced opioid-related problems like nausea and vomiting more frequently.[18]

Limitations

This study had certain limitations. The sample size was relatively small and conducted at a single center, which may limit generalizability. Long-term outcomes and neurobehavioral effects were not assessed. Additionally, only one dose of adjuvants was evaluated; dose-response relationships were not explored. Further multicentric studies with larger sample sizes are recommended.

CONCLUSION

Dexmedetomidine is a superior adjuvant that provides prolonged postoperative pain relief, reduced need for rescue analgesia, and a favorable safety profile compared to fentanyl. It can be considered a better alternative to opioids for enhancing the efficacy of caudal blocks in children.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Alam F, Ankesh. Comparative study between bupivacaine plus fentanyl and bupivacaine plus dexmedetomidine for epidural caudal analgesia in pediatric patients: a double blind randomized controlled trial. Int J Res Med Sci 2026;14:2364-7.