Original Article

Comparative Study between Bupivacaine with Dexmedetemidine and Bupivacaine with Fentanyl for Caudal Epidural Analgesia Perioperatively in Paediatric Infraumbilical Surgery

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Abstract

Background: Caudal epidural analgesia is a widely used technique to provide intraoperative and postoperative pain relief in paediatric patients undergoing infra-umbilical surgeries. However, a single-dose caudal block with local anaesthetic alone offers only a limited duration of analgesia. To address this, various adjuvants have been combined with local anesthetics to extend analgesic Effects. Although opioids are commonly used as adjuvants, their use is associated with significant adverse Effects, notably respiratory depression.

Objective: To compare the efficacy and safety of dexmedetomidine versus fentanyl as adjuvants to bupivacaine in caudal epidural analgesia for paediatric infra-umbilical surgeries.

Methods: A total of 45 children (aged 2–7 years, ASA I–II) undergoing elective infra-umbilical surgeries were randomly assigned to two groups of 25 each. Following anaesthesia induction, Group F received 0.25% bupivacaine (0.75 ml/kg) with fentanyl (2 µg/kg) while Group D received 0.25% bupivacaine (0.75 ml/kg) with dexmedetomidine (2 µg/kg) via caudal block. Hemodynamic parameters were monitored regularly. Postoperative pain and sedation were assessed using the FLACC and Ramsay scales, respectively. Time to first rescue analgesia, total 24-hour analgesic use and perioperative complications over six hours were documented.

Results: Both paediatric groups (Group F and Group D, n=45) were comparable in demographics, ASA class, surgery type, and anaesthesia duration ($p>0.05$). Surgical indications were similarly distributed ($p=0.762$). Heart rate and blood pressures were initially similar but significantly lower in Group D after 10–20 minutes ($p<0.05$). Group D required fewer intraoperative sedative doses and had higher Ramsay Sedation scores early in the PACU ($p<0.05$). FLACC scores were mostly similar, except at the 4th PACU hour where Group D had better pain control ($p=0.016$). Time to first rescue analgesia was longer in Group D ($p=0.001$), though total 24-hour analgesic use was similar ($p=0.458$). Adverse events were comparable in both groups ($p>0.05$).

Conclusion: Dexmedetomidine, when used as an adjuvant to bupivacaine in infraumbilical surgeries, provides longer sedation and extended postoperative analgesia compared to fentanyl. It enhances the effect of local anesthetics without increasing side effects.

Keywords: Bupivacaine with Dexmedetemidine, Bupivacaine with Fentanyl, Caudal Epidural Analgesia, Paediatric Infraumbilical Surgery, Intraoperative and postoperative.

Introduction

Pain is often misunderstood, underdiagnosed and inadequately treated in children. Poorly managed pain can lead to long-term physical, emotional, and behavioural issues. Due to challenges in assessing pain in young children, undertreatment remains common.[1] The Society of Paediatric Anaesthesia, during its 15th annual meeting in 2001, recognized pain relief as a basic human right, regardless of age or medical condition. Although pain was previously underestimated in children, the recognition of established pain pathways has emphasized the growing importance of effective postoperative analgesia in paediatric care.[2]

Infra-umbilical surgeries such as circumcision, herniotomy, orchidopexy, urethroplasty, and cystolithotomy is common in paediatric patients.[3] Caudal epidural block is the most used regional anaesthesia technique for these procedures, offering benefits like early extubation, reduced risk of respiratory complications, lower postoperative analgesic requirements, faster ambulation, and earlier discharge. While continuous caudal infusion via catheter is an option, it is less commonly used due to contamination risks.[4] Single-shot caudal blocks are favoured for their simplicity and reliable immediate postoperative pain relief. However, the primary limitation of using local anaesthetics alone is their short duration of action, often requiring early postoperative analgesia. To enhance both the duration and quality of analgesia, various adjuvants—such as opioids (fentanyl, nalbuphine), epinephrine, clonidine, dexmedetomidine, steroids, ketamine, and neostigmine—have been used.[5,6] Although these additives improve analgesic efficacy, many are associated with potential side effects.

Fentanyl is commonly used as an adjuvant to local anesthetics in caudal blocks. It works by acting on the substantia gelatinosa in the dorsal horn of the spinal cord, inhibiting nociceptive signal transmission both pre- and postsynaptically. However, its use is associated with potential side effects such as respiratory depression, constipation, urinary retention, itching, nausea and vomiting.[7,8]

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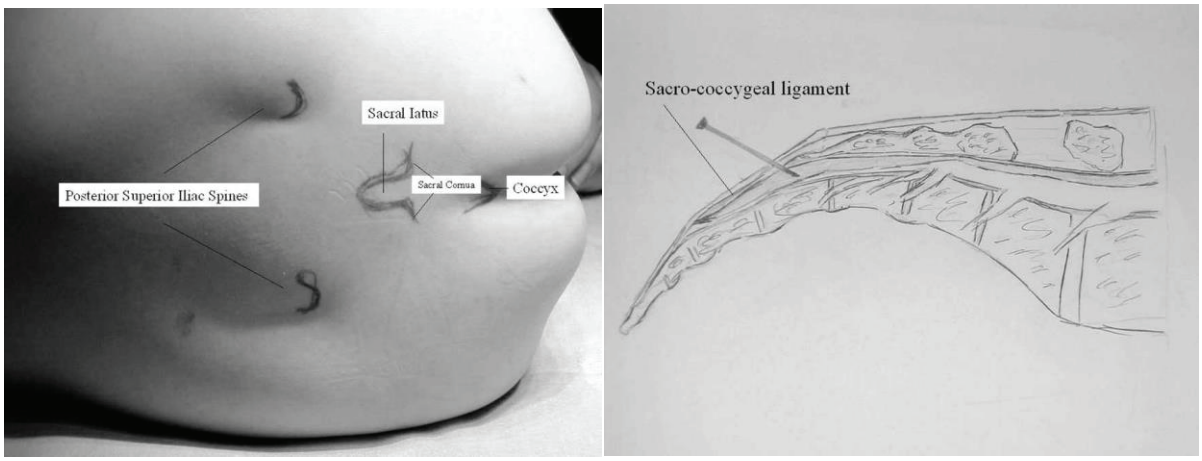

Figure-I: Anatomic landmarks and needle placement for the caudal block

Dexmedetomidine is a potent and highly selective α2-adrenergic agonist known for its sedative, sympatholytic, and analgesic properties. It has been recognized as a safe and effective adjuvant in various anesthetic and analgesic techniques. Approved by the FDA in late 1999, its analgesic effect is achieved through α2 receptor stimulation in the nervous system, which reduces calcium influx at nerve terminals and inhibits neurotransmitter release. Compared to clonidine, dexmedetomidine has approximately eight times greater affinity for α2 receptors and significantly lower affinity for α1 receptors. It also shows a higher selectivity for the α2A subtype, which is primarily responsible for its analgesic effects.[9,10,11]

Currently, there is no clear consensus on the optimal adjuvant for caudal anaesthesia. Additionally, the application of caudal anaesthesia in pediatric thoracic surgeries remains underexplored. This study aimed to compare the efficacy of dexmedetomidine and fentanyl as adjuvants to bupivacaine in caudal anaesthesia for pediatric patients undergoing Infra-umbilical surgeries.

To compare fentanyl and dexamethasone as adjuvants to caudal bupivacaine in paediatric infraumbilical surgeries, focusing on intraoperative hemodynamic stability and time to first rescue analgesia. To assess total analgesic requirements in the first 24 hours, postoperative sedation, pain scores and perioperative side effects.

Materials and Methods

This study was performed in the Department of Anaesthesiology, Combined Military Hospital (CMH), Savar, Dhaka. The study included paediatric patients aged 2 to 7 years, classified as ASA grade I or II, scheduled for infraumbilical surgeries such as inguinal hernia repair, circumcision, or urogenital procedures lasting 60 minutes or less. Patients were excluded if they had allergies to study drugs, ASA grade III or higher, coagulopathy, infection or anatomical abnormalities at the caudal block site, contraindications to caudal block, developmental delays, cardiopulmonary congenital anomalies, neurological disorders, or if parental consent was not given.

This was a prospective, double blind, randomized comparative study. The study was conducted over a period of six months, spanning from November 2024 to April 2025. The sample size was calculated using Power Analysis and Sample Size (PASS) 15.0 software (NCSS, Kaysville, UT). Based on mean values from a previous study 12, one-sided analysis of variance was used with $\alpha = 0.05$, $\beta = 0.1$, and MSE = 1/1, setting $\mu1 = 2.5$, $\mu2 = 2.5$, and $\mu3 = 1.25$. The resulting λ value produced a non-central χ^2 distribution of 12.66, determining a requirement of 16 patients per group. To accommodate possible dropouts, 25 patients were included in each group.

All patients underwent a preanaesthetic evaluation a day before surgery, including assessment for systemic diseases and review of necessary investigations like routine labs and ECG based on surgical requirements. Preoperative fasting guidelines were followed: light meals or formula up to 6 hours, breast milk up to 4 hours, and clear fluids up to 2 hours before induction.

Study Procedures: Patients were randomly assigned into two groups (25 patients each).
- Group F received 0.25% bupivacaine (0.75 ml/kg) combined with fentanyl (2 µg/kg) caudally.
- Group D received 0.25% bupivacaine (0.75 ml/kg) combined with dexmedetomidine (2 µg/kg) caudally.

In the operating room, premedication included IV atropine (0.02 mg/kg) and IV midazolam (0.05 mg/kg) via secured venous access. Baseline vital signs were recorded. Anaesthesia was induced with IV ketamine (2 mg/kg) and maintained with a 50% O_2 and 50% N_2O mixture via face mask. Patients were placed in the lateral position for caudal block under sterile conditions. Using standard landmarks, a 22G short, bevelled needle was inserted into the caudal epidural space. After confirming negative aspiration for blood or cerebrospinal fluid, the study drug was administered as per group allocation. The drug preparation was done by an anaesthesiologist not involved in the study, and the caudal block was performed by a blinded anaesthesiologist.

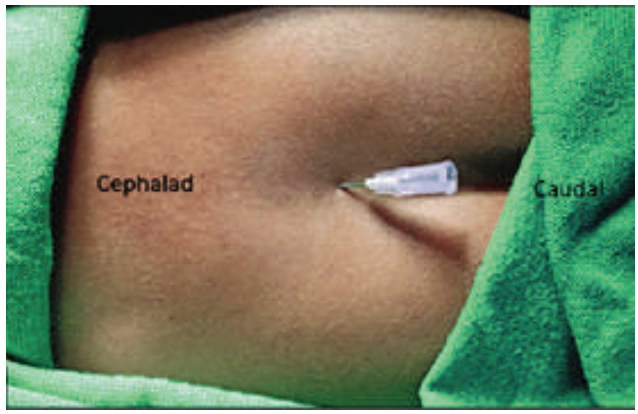

Figure-2: Needle insertion by anaesthesiologist during caudal anaesthesia

Failed blocks—identified by limb movements or a >30% rise in heart rate/mean arterial pressure from baseline during incision—led to patient exclusion. Once the caudal block was deemed effective, surgery proceeded. During surgery, if patients exhibited upper limb movement or inadequate sedation (Ramsay Sedation Score ≤4), additional IV midazolam (0.02 mg/kg) was administered, and the number of doses recorded.

Intraoperative monitoring included pulse rate, SBP, DBP, and SpO_2 recorded every 5 minutes for the first 20 minutes, then every 10 minutes until surgery completion. Total surgery time was noted. Postoperatively, patients were observed in the recovery area. Pain was assessed hourly using the FLACC scale until the score exceeded 4, at which point rescue analgesia (oral paracetamol 15 mg/kg) was given, and the time to first rescue analgesia was recorded. Total analgesic consumption over 24 hours was also documented.

Adverse events were managed as follows:
1. Respiratory depression (SpO_2 <95%) – supplemental oxygen and discontinuation of N_2O.
2. Bradycardia (20% fall in heart rate) – IV atropine (0.01–0.02 mg/kg).
3. Hypotension (20% drop in MAP) – IV fluids.
4. Postoperative nausea/vomiting – IV ondansetron (0.15 mg/kg).

Parameter	Finding	Points
Face	• No expression or smile • Occasional grimace or disinterested • Quivering chin or clenched jaw	➢ **0** ➢ **12**
Leg	• Normal position or relaxed • Restless tense • Kicking or legs drawn up	➢ **0** ➢ **1** ➢ **2**
Activity	• Lying quietly, normal position • Shifting back and forth, tense • Arched, rigid or jerking	➢ **0** ➢ **1** ➢ **2**
Cry	• No cry (awake or asleep) • Moans or whispers occasionally • Crying steadily or screams	➢ **0** ➢ **1** ➢ **2**
Consolability	• Content relaxed • Reassured by occasional touching or hugging • Difficult to console or comfort	➢ **0** ➢ **1** ➢ **2**

Chart-1: Face, leg, activity, cry, consolability pain score

Degree of sedation (Ramsay sedation score) was also observed at regular intervals up to 2 hours postoperatively..

1	Anxiety and completely awake
2	Completely awake
3	Awake but drowsy
4	Asleep but responsive to verbal commands
5	Asleep but responsive to tactile stimulus
6	Asleep and not responsive to any stimulus

Chart-2: Ramsay Sedation Score

All collected data were compiled into a master chart and analysed using the Statistical Package for Social Sciences (SPSS) v26.0 for Windows. Qualitative variables were expressed as percentages, and quantitative variables as mean ± standard deviation. Categorical variables were compared using the Chi-square test, and continuous variables using the unpaired t-test. ANOVA was applied where appropriate. Results were presented in tables, graphs, or pie charts and a p-value of <0.05 was considered statistically significant.

The study was approved by the Institutional Review Board of CMH. Informed consent was obtained after explaining the study in simple local language, assuring confidentiality and the right to withdraw anytime without affecting care.

Results

Two patients from Group F and three from Group D were excluded due to failed caudal blocks. The final analysis included 45 patients, comprising 30 boys (66.7%) and 15 girls (33.3%). There was no significant association between gender and study groups.

Table-I: Demographic characteristics of paediatric patients (n=45)

Characteristics		Group F (n=23)	Group D (n=22)	P value
Age (years)		4.6±1.5	4.3±1.3	0.689*
Sex	**Male**	16 (69.5%)	14 (63.6%)	0.538**
	Female	7 (30.5%)	8 (36.4%)	0.563**
Weight (kg)		16.7±4.5	15.4±3.8	0.458*
ASA classification	**Class I**	17 (73.9%)	18 (81.8%)	0.530**
	Class II	6 (20.1%)	4 (18.2%)	0.548**
Duration of surgery (minutes)		35.2±9.7	40.5±10.8	0.071*
Duration of Anesthesia (minutes)		44.2±10.4	50.6±12.1	0.068*
Indication of surgery	Circumcision	4 (17.4%)	5 (22.7%)	0.713**
	Herniotomy	8 (34.8%)	7 (31.8%)	0.742**
	Orchidopexy	3 (13.1%)	2 (9.2%)	0.614**
	Urethroplasty	6 (26.1%)	5 (22.7%)	0.752**
	Hypospadias	2 (8.6%)	3 (13.6%)	0.772**

*Values were expressed as mean±SD and values within parenthesis indicates corresponding percentage (%), p value was determined by **Student t-test and *Chi-square test ($\chi 2$)*

The two groups (Group F and Group D) of paediatric patients (n=45) were comparable in age, sex, weight, ASA classification, surgery duration, and anaesthesia duration, with no statistically significant differences (p>0.05). The indications for surgery (circumcision, herniotomy, orchidopexy, urethroplasty, hypospadias) were similarly distributed between Group F and Group D, with no significant difference (p=0.762) (Table-I).

Table-II: Comparison of heart rate during different time intervals between two groups (n=45)

Time interval	Group F (n=23)	Group D (n=22)	P value
Baseline	94.3±6.8	95±6.7	0.889
After CA	103.4±6.4	102.6±6.6	0.730
5minutes after CA	100.3±6.5	97.2±10.2	0.240
10minutes after CA	98.3±6.7	94.1±9.8	0.245
15minutes after CA	93.8±10.6	90.6±9.2	0.074
20minutes after CA	92.2±9.4	86.5±11.1	**0.008ss**
30minutes after CA	96.7±6.8	89.4±9.8	**0.004ss**
40minutes after CA	94.3±6.5	86.1±7.7	**0.005ss**
50minutes after CA	92.7±6.2	85.7±6.6	**0.001ss**
Ends of surgery	89.7±6.4	81.7±6.7	**0.001ss**

*CA= caudal anesthesia. Values were expressed as mean±SD. p value was determined by *Student t-test. ss=statistically significant.*

Heart rates remained comparable between Group F and Group D up to 15 minutes following caudal anaesthesia. After 20 minutes, Group D exhibited significantly lower heart rates compared to Group F (p<0.05) (Table-II).

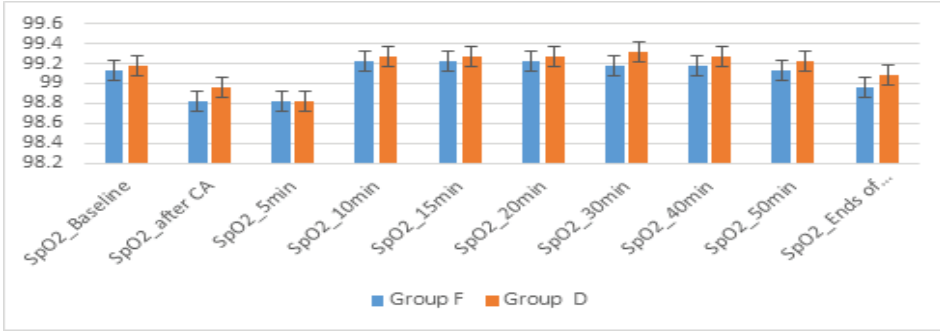

Figure-3: Comparison of oxygen saturation during different time intervals between two groups (n=45)

Table-III: Comparison of FLACC core during different time intervals between two groups (n=45)

Time interval	Group F (n=23)	Group D (n=22)	P value
On arrival at PACU	2.5±0.9	2.2±0.6	0.142
2nd hrs. at PACU	2.7±1.0	2.3±0.7	0.127
4th hrs. at PACU	4.0±1.8	2.7±1.5	**0.016ss**
6th hrs. at PACU	4.1±1.3	3.7±1.3	0.350
12th hrs. at PACU	3.3±0.9	3.2±1.0	0.340
16th hrs. at PACU	2.6±0.9	2.2±0.6	0.347
24th hrs. at PACU	2.5±0.8	2.3±0.7	0.077

*PACU= postanesthetic care unit. Values were expressed as mean±SD. p value was determined by *Student t-test. ss=statistically significant.*

FLACC scores between Group F and Group D were comparable at most time points. However, at the 4th hour in the PACU, Group D had significantly lower FLACC scores compared to Group F (p=0.016), indicating better pain control at that interval. No other time points showed statistically significant differences (Table-III).

Table-IV: comparison of first rescue analgesia and total analgesic requirements between two groups (n=45).

Numbers	Group F (n=23)	Group D (n=22)	P value
Time for first rescue analgesia (minutes)	226.9±26.4	284.1±31.1	**0.001ss**
Total analgesic requirements in 24hours (milligram)	253.3±37.5	239.3±28.7	**0.458**

*Values were expressed as mean±SD. p value was determined by *Student t-test. ss=statistically significant.*

Group D had a significantly longer time to first rescue analgesia compared to Group F (p=0.001). However, total analgesic requirements over 24 hours were similar between the two groups (p=0.458) (Table-IV).

Table-V: comparison of adverse events during peri-operative period between two groups (n=45)

Adverse events	Group F (n=23)	Group D (n=22)	P value
Hypotension	2 (8.7%)	3 (13.6%)	
Hypertension	5 (21.7%)	2 (9.1%)	
Bradycardia	2 (8.7%)	4 (18.2%)	**0.192**
PONV	4 (13.1%)	2(9.1%)	
Itching	4 (17.4%)	0	

Values were expressed as parenthesis indicates corresponding percentage (%), p value was determined by Chi-square test (χ2). Adverse events during the perioperative period, including hypotension, hypertension, bradycardia, PONV and itching, were comparable between Group F and Group D, with no statistically significant differences (p>0.05) (Table-V).

Discussion

Postoperative pain is common and often poorly managed in paediatric patients. Caudal block, a safe and reliable technique in children for infraumbilical surgeries, offers good intra- and postoperative analgesia but with short-lived effects from bupivacaine alone.[12] To extend analgesia, adjuvants like fentanyl and dexmedetomidine are added. In our study, we used 0.75 ml/kg of 0.25% bupivacaine with 2 µg/kg of either fentanyl or dexmedetomidine.

In this study, 50 patients were initially enrolled (25 in each group). However, two patients from Group F and three from Group D were excluded due to failed caudal blocks. Thus, data from 23 patients in Group F and 22 in Group D, totalling 45 patients, were analysed.

In this study, the two groups (Group F and Group D, n=45) were similar in age, sex, weight, ASA classification, surgery duration, and anaesthesia time, with no statistically significant differences (p>0.05). Surgical indications (circumcision, herniotomy, orchidopexy, urethroplasty, hypospadias) were also evenly distributed between the groups (p=0.762). Similarly, El Shamaa HA and Kapadia R found no significant differences in demographics or surgical indications when evaluating the analgesic efficacy of caudal anaesthesia with 0.25% bupivacaine in paediatric infraumbilical surgeries.[13,14]

Evaluation of the hemodynamic parameters revealed that heart rates were comparable between Group F and Group D up to 15 minutes following caudal anaesthesia. However, from 20 minutes onward, Group D demonstrated significantly lower heart rates (p<0.05). Systolic and diastolic blood pressures were initially similar but became significantly lower in Group D from 10 minutes after the block (p<0.05).

These findings are in line with previous studies. Khan MK reported reduced heart rates in the dexmedetomidine group after 30 minutes in a similar comparison of caudal bupivacaine with dexmedetomidine versus fentanyl.[15] Kanojia UK et al also observed

consistently lower intraoperative and postoperative heart rates and blood pressures in the dexmedetomidine group.[16] Godbole et al supported these results, noting lower heart rate and blood pressure values with dexmedetomidine compared to fentanyl.[17] Similarly, Ahmed R found significantly higher perioperative heart rate and blood pressure in the fentanyl group than in the dexmedetomidine group during epidural analgesia for hepatobiliary pancreatic surgery ($p<0.05$).[18] These previous observations align closely with the current study's outcomes.

In this study, Group D required significantly fewer repeated sedative doses during the intraoperative period compared to Group F ($p<0.05$). Ramsay Sedation Scores (RSS) were significantly higher in Group D at early postoperative time points-on arrival, and at 10 and 20 minutes post-PACU admission ($p<0.05$), with no significant differences observed at 30, 60, and 120 minutes. FLACC scores were similar between the groups at most intervals, except at the 4th hour in the PACU where Group D demonstrated significantly lower scores than Group F ($p<0.05$), suggesting superior analgesic efficacy.

These findings are consistent with previous studies. Jarin shin et al reported higher sedation scores in the dexmedetomidine group compared to fentanyl, particularly at 30 minutes postoperatively, while sedation scores at 60 minutes, 1 hour, and 24 hours showed no significant difference between the groups.[19] Similarly, Elf Awal et al. observed significantly lower FLACC scores and higher sedation scores in the dexmedetomidine group compared to both the fentanyl and control groups[20], aligning closely with the results of our study. Another study reported a statistical comparison of postoperative mean RASS scores and CHEOPS scores at various time intervals across three groups, revealing that the mean differences were both comparable and statistically significant ($p<0.05$).[15] In contrast, Godbole et al. found that the mean sedation scores were significantly higher in the dexmedetomidine group compared to the fentanyl group during the first 21 hours postoperatively ($p<0.05$ at all-time points). However, the mean pain scores over the first 24 hours did not differ significantly between the two groups ($p>0.05$).[17] These findings differ from our study, possibly due to variations in drug dosage and patient population, as they used fentanyl (1 µg/kg) and dexmedetomidine (1 µg/kg) in combination with 0.75 mL/kg of 0.25% bupivacaine for paediatric lower abdominal and urogenital surgeries.

The FLACC pain scores were comparable between Group F and Group D at most time points, except at the 4th postoperative hour, where Group D demonstrated significantly better analgesia ($p=0.016$). This aligns with findings from another study, which reported significantly lower pain scores in the dexmedetomidine group during the early postoperative period (1st, 2nd, and 4th hours), though the differences were not significant in later hours.[19] Similarly, the median pain score score in the dexmedetomidine group was lower than in the fentanyl group at 6 hours postoperatively, but no significant differences were observed between the groups from 6 to 48 hours after surgery.[21]

Group D experienced a significantly longer duration before the first rescue analgesic was required compared to Group F ($p=0.001$), although the total analgesic consumption over 24 hours was comparable between the groups ($p=0.458$). These findings are consistent with previous studies, which reported enhanced analgesic and sedative effects when dexmedetomidine was combined with bupivacaine compared to bupivacaine alone.[22,23] Similarly, one study also demonstrated improved outcomes with the combination of fentanyl and bupivacaine over bupivacaine alone.[24]

In this study, the incidence of adverse effects such as hypotension, hypertension, bradycardia, postoperative nausea and vomiting (PONV) and itching was comparable between Group F and Group D, with no statistically significant differences ($p>0.05$). However, postoperative vomiting, itching, and respiratory depression were significantly more frequent in the fentanyl group compared to others 20. Similarly, another study reported no cases of respiratory depression, bradycardia, or hypotension and found no significant differences between groups regarding oversedation, nausea and vomiting, urinary retention, or pruritus.[21]

These findings suggest that dexmedetomidine is a safe and effective caudal adjuvant for children undergoing infraumbilical surgery when administered as a single preoperative dose. Compared to fentanyl, dexmedetomidine offers superior early postoperative analgesia without increasing the risk of hemodynamic instability or oversedation.

Conclusion

Dexmedetomidine, when used as an adjuvant to bupivacaine in infraumbilical surgeries, provides longer sedation and extended postoperative analgesia compared to fentanyl. It enhances the effects of local anesthetics without increasing the incidence of side effects relative to fentanyl.

Limitations

The onset time of analgesia following caudal block administration was not anticipated or recorded. Additionally, comprehensive pain assessment poses challenges due to the subjective nature of pain and its variability among individuals, particularly in paediatric patients and those with cognitive impairments. To reduce assessment bias, the FLACC scale was employed in this study, as it is a validated and reliable tool for evaluating pain even in children with differing levels of cognitive ability.

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