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Original Article

Anaesthesia Section

Comparison of Fentanyl and Dexmedetomidine as Additives to Caudal Levobupivacaine in Paediatric Patients Undergoing Infraumbilical Surgeries: A Randomised Clinical Trial

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ABSTRACT

Introduction: In children, the most commonly used postoperative analgesic technique is epidural block via the caudal route. Levobupivacaine is an effective analgesic with a safer pharmacological profile. One of the primary drawbacks of a single-shot caudal block is its short duration of action. Fentanyl, although most commonly used opioid, it has many side-effects. Dexmedetomidine is an $\alpha 2$ agonist with the property of prolonging the analgesic effect of local anaesthetic. The effectiveness of fentanyl and dexmedetomidine as additives to caudal levobupivacaine has not been extensively studied; so, in the present investigation, the efficacy of aforementioned drugs was assessed in paediatric caudal analgesia using the Face, Legs, Activity, Cry, Consolability (FLACC) score.

Aim: To compare the analgesic efficacy and safety of fentanyl and dexmedetomidine as adjuvants to caudal levobupivacaine in paediatric patients undergoing infraumbilical surgeries, using the FLACC score for postoperative pain assessment.

Materials and Methods: This randomised, double-blind clinical trial was conducted at Shri BM Patil Medical College Hospital and Research Centre, BLDE DU, Bijapur, Karnataka, India, from December 2019 to August 2021 In this randomised clinical trial, caudal block was used to provide perioperative analgesia for children undergoing infraumbilical surgery. The children (n=46 per group) were randomly divided into two groups and given 0.75 mL/kg levobupivacaine 0.25% with dexmedetomidine 1 µg/kg and 0.75 mL/kg levobupivacaine 0.25% with fentanyl 1 µg/kg to group D (dexmedetomidine) and group F (fentanyl), respectively. Haemodynamic parameters, sedation score, side-effects, FLACC score, and length of analgesia were all noted. Statistical analysis was performed using the Mann-Whitney U test, with a p-value <0.05 considered significant.

Results: The two groups were comparable in terms of age, gender, weight, and duration of surgery. Both groups had stable comparable haemodynamic profiles, except at 20, 25, and 30 minutes post-block where MAP was higher in the fentanyl group. The mean Ramsay Sedation Score (RSS) was 2.1±0.3 (Group F) and 3.2±0.4 (Group D). The FLACC score was 3.79±0.47 (Group F) and 2.61±0.61 (Group D) at six hours. The mean duration of analgesia was 6.48±1.05 hours (Group F) and 8.76±1.06 hours (Group D). The mean discharge time was shorter in the dexmedetomidine group (3.13±1.22 days) compared to the fentanyl group (4.01±1.18 days).

Conclusion: With similar haemodynamics and arousable sedation, dexmedetomidine is a more potent adjuvant to levobupivacaine for caudal analgesia than fentanyl. Dexmedetomidine is linked to shorter recovery time and fewer adverse effects following surgery.

Keywords: Analgesics, Caudal epidural block, Postoperative pain, Sedatives

INTRODUCTION

Pain is an undesirable subjective feeling that children can only feel and not express because they rely on their caregivers for their well-being. Despite advances in analgesic techniques, postoperative pain in children remains undertreated of pain is due to the fear of needle stick injury, respiratory depression with opioids, and difficulty in the evaluation of pain in the children [1]. General anaesthesia combined with the epidural block via caudal approach is the most widely practised technique in infra umbilical paediatric surgeries, as it is a simple, reliable, and effective method with a high rate of success [2]. Not only does it offer analgesia following surgery, but it also lessens the need for anaesthetic agents and minimises discomfort throughout the procedure while also lowering the surgical stress response [3]. The primary drawback of a local anaesthetic-based one-time caudal block is the abbreviated period of analgesia. In order to increase the period of analgesia, efforts are continuously made to combine an adjuvant with local anaesthetics. Additive agents used to extend and enhance the duration and quality of local anaesthesia and analgesia include opioids, epinephrine, dexmedetomidine, clonidine, ketamine, and neostigmine [4]. Levobupivacaine, a pure (S) homologue of racemic bupivacaine, has similar potency and local anaesthetic properties. It is less harmful to the heart and central nervous system than bupivacaine and provides analgesia that is effective with less motor impairment [5]. Synthetic fentanyl is a highly lipophilic opioid agonist that readily traverses the lumbar dura mater when administered epidurally. It also passes through the lipid moiety of spinal cord tissue, preventing rostral migration of the drug and averting respiratory depression and cardiac events that are dependent on the central nervous system. However, fentanyl has adverse effects that include respiratory depression, pruritus, nausea, and vomiting [6]. Recent research has shown that caudal dexmedetomidine extends the duration of local anaesthetics and is known to have opioid-sparing, analgesic and sedative properties. When used in conjunction with a local anaesthetic, dexmedetomidine, a highly selective alpha-2 agonist, prolongs the duration of analgesia without significantly affecting respiration or haemodynamics [7]. The present study was conducted in view of the limited number of studies comparing the effects of fentanyl and dexmedetomidine as adjuvants to caudal levobupivacaine [8,9]. Hence, the present study aimed to compare the effectiveness of fentanyl and dexmedetomidine as additives to caudal levobupivacaine in paediatric patients undergoing infraumbilical surgeries. The primary objective was to use the FLACC scale to compare the two medication's analgesic

efficacy. Other goals included evaluating the duration of rescue analgesia, as well as their effects on haemodynamic parameters like Mean Arterial Pressure (MAP), mean Heart Rate (HR), sedation score, and adverse effects like hypotension, bradycardia, vomiting, nausea, and respiratory depression.

MATERIALS AND METHODS

This randomised, double-blind clinical trial was conducted at Shri BM Patil Medical College Hospital and Research Centre, BLDE DU, Bijapur, Karnataka, India, from December 2019 to August 2021 and was approved by the Institutional Ethical Committee (IEC No. 131) and registered in the Indian Clinical Trials Registry (CTRI No. CTRI/2021/07/034650). Written informed consent was obtained from the parents or guardians of all participants.

Inclusion criteria: Ninety-two children, aged 1 to 10 years, of either gender, with American Society of Anesthesiologists (ASA) physical status I and II, scheduled for elective infra-umbilical surgeries lasting less than 90 minutes were included in the study after obtaining parental consent.

Exclusion criteria: Children with a history of developmental delay, known allergy to the study medications, neurological diseases, cardiovascular diseases, sacral bone deformities, bleeding disorders, infection at the site of caudal block, and those whose parents did not consent to participate were excluded.

Sample size calculation: On the basis of the study conducted by Elfawal SM et al., the anticipated mean±SD of FLACC score in the fentanyl and dexmedetomidine group were 1.33±0.60 and 0.80±0.76 [8]. For each group, a minimum sample size of 46 is needed with a 95% power and a 5% significance level, so the study aimed to include 92 children.

The formula used to determine the sample size was:

$N = 2\{(Z\alpha+Z\beta) \times S/d\}^2$

Where:

- $Z\alpha$ (95% significance level) = 1.96
- $Z\beta$ (90% study power) = 1.28
- S (pooled standard deviation) = $\sqrt{\{(0.60^2+0.76^2)/2\}} = \sqrt{\{0.36+0.58\}/2} = \sqrt{0.47} = 0.69$
- d (clinically pertinent difference) = 1.33 - 0.80 = 0.53

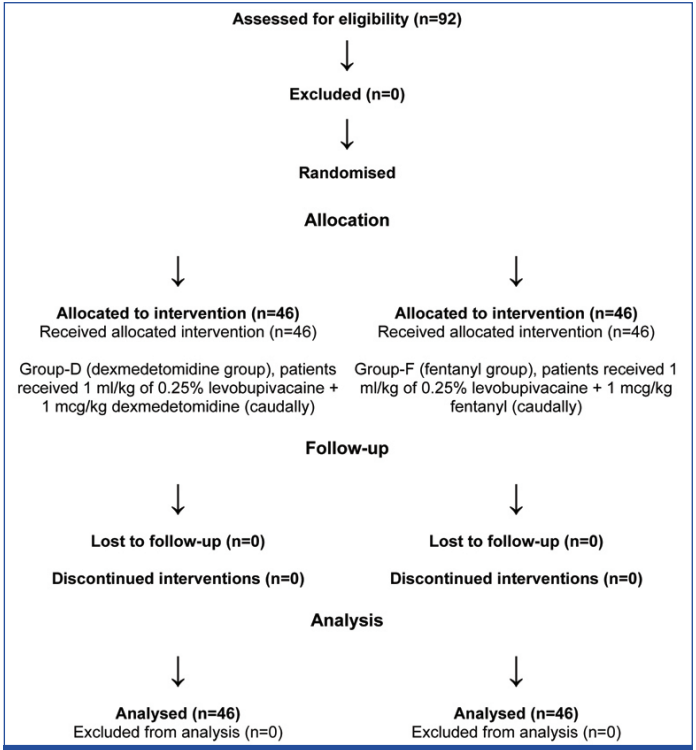
Numerical calculation: $N = 2\{(1.96+1.28) \times 0.69\}^2/(0.53)^2$ $N = 2\{(3.24) \times 0.69\}^2/(0.28)$ $N = 2(2.24)^2/0.28$ $N = 2(5.02)/0.28$ $N = 10.04/0.28$ $N = 35.9 \approx 36$ per group

Adding 10% for potential dropouts: 36+3.6 = 39.6 ≈ 40 per group. Therefore, a minimum sample size of 40 patients per group was calculated, though 46 patients per group to ensure adequate power were recruited.

Every research subject received routine testing and a comprehensive clinical assessment. For solids or semisolids, patients had to fast for six hours, and for clear liquids, it was two hours. After parents gave their informed written consent, patients were randomly allocated to either group F (Fentanyl) or group D (Dexmedetomidine). The random allocation sequence was computer-generated using a random number table by a statistician who was not involved in patient recruitment or clinical care. Participants were enrolled by the Principal Investigator (PI) and co-investigators after confirming eligibility criteria during the pre-anaesthetic evaluation.

The participant flow throughout the study is presented in [Table/Fig-1].

To ensure allocation concealment, the randomisation sequence was sealed in sequentially numbered, opaque envelopes prepared by the statistician. These envelopes were opened by a designated anaesthesiologist who was not involved in patient assessment or data collection, only after the participant had been enrolled and written informed consent obtained. The treating anaesthesiologist received the group allocation just before drug preparation.



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing participant enrollment, allocation, follow-up, and analysis in the study comparing fentanyl and dexmedetomidine as additives to caudal levobupivacaine.

Study Procedure

All patients received preoperative oral midazolam (0.5 mg/kg). Standard monitoring, including electrocardiography, pulse oximetry, and non invasive blood pressure, was attached to the patient as soon as they entered the operation room. Baseline vital data, including HR, MAP, and oxygen saturation by pulse oximetry (SPO^2), were obtained. An Intravenous (i.v.) solution was then delivered, utilising the 4-2-1 formula. Patients were premeditated with Injection glycopyrrolate (0.005 mg/kg) pre-oxygenation with 100% oxygen using a mask and Jackson Rees circuit was performed, propofol injection (2 mg/kg) was used for induction and injection Atracurium 0.5 mg/kg was used for intubation using appropriate size endotracheal tube. The child was then positioned with their hips flexed to a 90° angle in a lateral decubitus position.

The study did not involve the anaesthesiologist who prepared the drugs. The primary investigator was not aware of the medication used while carrying out the procedure. The caudal block medication was prepared according to the patient's body weight and assigned group. With a needle gauge of 23, the principal investigator administered a single-dose caudal block after completing all aseptic precautions. After identification of the sacral hiatus, the needle was inserted and a characteristic "pop" was felt upon piercing the sacrococcygeal ligament. Correct needle placement was confirmed by negative aspiration for blood or cerebrospinal fluid and free non resistant injection of the solution without subcutaneous swelling. The study medication was then injected slowly. 0.75 mL/kg of 0.25% levobupivacaine in addition to 1 µg/kg fentanyl was given to patients in group F and 0.75 mL/kg of 0.25% levobupivacaine along with 1 µg/kg dexmedetomidine caudally was given to patients in group D [8].

After the block, the patient was supinated and anaesthesia maintenance was achieved by controlled ventilation using 50% oxygen and 50% nitrous oxide and 1-2% sevoflurane with intermittent boluses of atracurium. The surgical procedure was allowed 15 minutes later. Following a skin incision, a 20% increase in baseline HR and MAP was deemed indicative of block failure, such patients were treated with injections of fentanyl at a dose of 1-2 µg/kg and were excluded from the study.

Intraoperatively, no other sedative, narcotic or analgesic was administered. HR and MAP were monitored every five minutes until the procedure was completed. Haemodynamic parameters (HR and MAP) were recorded at 5-minute intervals intraoperatively. Patient numbers decreased progressively as procedures of varying durations were completed and patients were transferred to Post-Anaesthesia Care Unit (PACU).

Throughout the study period, bradycardia was defined as a reduction in HR below 60 beats/min, and a decrease of MAP of more than 30% from baseline was considered hypotension. Injections of neostigmine (0.05 mg/kg) and glycopyrrolate (0.01 mg/kg) were used to perform extubation. Before each patient was moved to the PACU, the length of the procedure was documented.

Postoperatively HR and MAP were recorded. The FLACC score and modified RSS were recorded at 0, 2, 4, 6, 8, and 10 hour postoperatively to assess postoperative pain and sedation, respectively. As surgical procedures had variable durations (30 minutes to two hours), patients who completed surgery were transferred to PACU and were unavailable for subsequent intraoperative assessments. Therefore, sample sizes decreased progressively at each time interval, reflecting only patients with ongoing procedures.

When the FLACC score was ≥4, at this point, rescue analgesia was administered (paracetamol 15 mg/kg). From the caudal block until the FLACC score was 4 or higher, the length of analgesia was noted. Postoperative side-effects including vomiting, nausea, pruritus, and respiratory depression (described as reduced SPO^2 of less than 93% or needing oxygen supplementation/assisted ventilation) were recorded.

STATISTICAL ANALYSIS

While numerical data variables were displayed as mean, SD and diagrams (bar chart), categorical variables were given as frequency (%). An analysis of the Mann-Whitney U test was conducted with respect to variables such as age, weight, intraoperative mean HR, MAP variance between the groups, duration of analgesia and surgery, comparison of FLACC score and RSS. For statistical significance, P<0.05 was used. SPSS software v.23 (IBM Statistics, Chicago, USA) and Microsoft Office 2007 were used for data analysis.

RESULTS

A total of 92 participants were enrolled and assigned to one of the two experimental groups; No cases of caudal block failure were observed. The demographic characteristics like gender, weight, age and the length of the surgery of the two groups were comparable [Table/Fig-2]. After surgery, the FLACC pain scale was measured at 0, 2, 4, 6, 8, and 10 h. The FLACC score [Table/Fig-3] did not significantly differ between the two groups at 0 or 2 hours, but group F demonstrated significantly higher FLACC scores at 4, 6, and 8 hours than group D.

Parameters	Group D (n=46)	Group F (n=46)	p-value
Age (years)	6.28±3.07	5.48±3.15	0.22
Weight (kg)	21.06±8.92	17.56±9.04	0.06
Gender			
Male	41 (89%)	39 (84.78%)	-
Female	5 (86%)	7 (15.21%)	
Duration of surgery (minutes)	65.48±12.65	62.78±15.68	0.36

[Table/Fig-2]: Demographic profile and duration of surgery.

The average length of analgesia in group F reached 6.48±1.049 hours [Table/Fig-4], but in group D it was 8.76±1.058 hours (p-value <0.001). Compared to group D, the percentage of patients in group F who required rescue analgesia in the initial six hours after surgery was significantly higher (4 vs. 36). Group D's modified RSS [Table/Fig-5] at 0, 2, 4, and 6 hours postoperatively was significantly higher than group F's, with a p-value <0.001.

Time point	Group F (n)	Mean± SD	Group D (n)	Mean± SD	p-value
FLACC SCORE - 0 h	46	0.86±0.65	46	0.89±0.76	0.452
FLACC Score - 2 h	46	1.00±0.76	46	0.83±0.48	0.243
FLACC Score - 4 h	46	2.67±0.79	46	1.93±0.44	0.001*
FLACC Score - 6 h	38	3.79±0.47	46	2.61±0.61	0.001*
FLACC Score - 8 h	7	4.00±0.00	43	3.65±0.52	0.001*
FLACC Score - 10 h	0	0±0	14	4.00±0.00	NA

[Table/Fig-3]: Comparison of FLACC scores.
p-value <0.001 highly significant. Note: Sample sizes vary at each time point due to completion of surgical procedures and patient transfer to PACU

Parameters	Group F (n=46)	Group D (n=46)	p-value
Duration of Analgesia (H) Mean±SD	6.48±1.049	8.76±1.058	0.001
No. of patients requiring rescue analgesia (%)	36 (78.2%)	4 (8.6%)	0.001
Discharge time (Days)	4.01±1.18	3.13±1.22	0.001
Nausea and vomiting	4	1	-
Pruritus	3	0	-

[Table/Fig-4]: Comparison of duration of analgesia, number of patients requiring rescue analgesia and side-effects in group F and group D.

Modified Ramsay sedation score	Group F (Mean±SD)	Group D (Mean±SD)	p-value
0 h	2.82±0.62	3.64±0.57	0.001*
2 h	2.36±0.45	2.83±0.72	0.001*
4 h	1.62±0.49	2.42±0.54	0.001*
6 h	1.48±0.20	2.26±0.64	0.001*
8 h	1.32±0.24	1.38±0.34	0.33
Overall Mean Sedation Score	2.12±0.48	2.51±0.68	<0.001*

[Table/Fig-5]: Comparison of modified RSS in group F and group D.

The mean HR showed a progressive decline over time in both groups [Table/Fig-6]. The fentanyl group demonstrated significantly lower HR compared to the dexmedetomidine group at 20 minutes (p-value=0.041), 35 minutes (p-value=0.020), 45 minutes (p-value=0.031), and 50 minutes (p-value=0.014) postoperatively, suggesting differential cardiovascular effects of the two agents.

MAP showed significant differences between groups at multiple time points [Table/Fig-7]. The fentanyl group demonstrated significantly higher MAP values compared to the dexmedetomidine group at 10 minutes (p-value <0.001), 15 minutes (p-value=0.0001), 20 minutes (p-value <0.001), 25 minutes (p-value <0.001), and 30 minutes (p-value <0.001), indicating more pronounced vasodilatory effects with dexmedetomidine during the early intraoperative period.

Both patient groups did not exhibit any episodes of respiratory depression, bradycardia, or hypotension requiring medical intervention. As per [Table/Fig-4], pruritus was reported by three patients in the fentanyl group and not by group D. Additionally, nausea and vomiting were recorded by four participants in group F and one in group D.

DISCUSSION

It can be fairly tough and challenging to manage pain in young children. It is common to assume that youngsters do not experience or recall pain, which leads to inadequate treatment in such cases. Children do sense pain, as demonstrated by the activity of higher centres for conscious perception of pain revealed by positron emission tomography. Untreated pain may result in harmful physiological, psychological and long-term behavioural effects. The use of opioids and non opioid and behavioural treatment needs

Time point	Fentanyl (n)	Fentanyl (Mean±SD)	Dexmedetomidine (n)	Dexmedetomidine (Mean±SD)	Mann-Whitney U Test	p-value
Pre-op (h)	46	105.78±14.025	46	108.22±16.035	U=964.500	0.464
Intraop (h) 0 min	46	105.76±13.694	46	109.28±15.868	U=940.500	0.358
5 min	46	102.89±12.423	46	108.13±15.168	U=833.500	0.078
10 min	46	100.98±12.890	46	105.85±14.823	U=852.500	0.108
15 min	46	99.98±12.835	46	105.39±14.488	U=840.500	0.098
20 min	46	98.87±13.041	46	104.96±14.390	U=797.500	0.041*
25 min	46	99.65±13.468	46	104.52±14.468	U=846.500	0.098
30 min	46	98.61±13.483	46	104.13±14.850	U=813.500	0.056
35min	41	97.10±13.030	45	104.09±14.497	U=653.000	0.020*
40min	38	97.47±13.474	43	103.44±14.510	U=618.000	0.059
45min	29	96.48±13.165	31	103.97±14.593	U=304.500	0.031*
50 min	29	95.59±12.766	30	104.07±13.901	U=273.000	0.014*
55 min	18	97.22±11.705	20	102.05±13.442	U=143.500	0.290
60 min	18	98.44±11.429	20	101.80±12.780	U=151.500	0.409
65 min	3	94.67±12.220	2	112.00±11.314	U=1.000	0.400
70 min	3	93.67±8.505	2	112.00±14.142	U=0.500	0.200

[Table/Fig-6]: Comparison of Mean Heart Rate (HR) in group F and group D.
*Statistically significant

Time point	Fentanyl (n)	Fentanyl (Mean±SD)	Dexmedetomidine (n)	Dexmedetomidine (Mean±SD)	Mann-Whitney U test	p-value
Pre-op	46	66.96±7.027	46	66.96±7.027	958.500	0.427
intraop 0 min	46	63.11±7.772	46	65.96±6.498	1005.500	0.675
5 min	46	63.33±6.674	46	63.26±8.015	1011.000	0.711
10 min	46	66.46±6.978	46	63.28±7.606	581.000	0.0001*
15 min	46	67.93±7.844	46	61.07±6.038	550.500	0.0001*
20 min	46	68.26±7.088	46	61.52±6.589	532.500	0.0001*
25 min	46	68.07±7.31	46	62.52±6.303	633.000	0.001*
30 min	46	68.48±6.837	46	63.07±5.515	624.500	0.001*
35 min	40	68.7±7.707	46	63.8±5.205	699.000	0.075
40 min	40	69.13±7.14	45	66.58±5.699	754.500	0.334
45 min	30	68.17±7.382	43	68.21±6.632	436.500	0.680
50 min	30	69.4±7.375	31	69.32±7.273	439.500	0.876
55 min	18	69.83±8.528	30	70.1±6.809	142.500	0.728
60 min	18	72.11±9.068	17	68.59±7.961	114.000	0.194
65 min	3	68±8	17	70.59±4.109	2.500	0.564
70 min	3	69.33±7.572	2	64±11.314	2.500	0.767

[Table/Fig-7]: Comparison of Mean Arterial Pressure (MAP) in group F and group D.
*Statistically Significant

constant supervision. Complicated infrastructure is needed for patient-controlled analgesia and continuous i.v. infusion techniques [10]. Application of caudal block in paediatric infraumbilical surgeries provides a pain-free period both intraoperatively and postoperatively with minimal haemodynamic changes [11].

Numerous adverse reactions pertaining to the circulatory and neurological systems, including fatalities ascribed to the R (+) isomer of bupivacaine, have been documented following unintentional intravascular administration or while receiving i.v. regional anaesthesia [12]. The laevorotatory enantiomer, levobupivacaine, has a safe pharmacological profile as its local anaesthetic effect is attributed to the different affinity for sodium, potassium, and calcium ion channels of nerve conduction resulting in less cardiac and neurological toxicity [13].

In the present study, 0.25% levobupivacaine (2.5 mg/mL) was used in the dosage of 0.75 mL/kg for caudal block. Frawley GP et al., conducted a study on infants who compared caudal bupivacaine, and they concluded that levobupivacaine 0.25 % at 1 mg/kg produces effective caudal anaesthesia in paediatric patients [14]. Al-Zaben KR et al., found that using lower doses of (1 mcg/kg) dexmedetomidine as a caudal adjuvant result in prolonged duration of analgesia, shorter time for spontaneous waking, less postoperative drowsiness and a decreased frequency of adverse effects [15]. Thus, for the dexmedetomidine group in the current trial, a dose of 1 mcg/kg as an adjuvant was selected.

The duration of analgesia in group D was significantly longer than in group F. Group D had a mean analgesia duration of 8.76±1.058 hours, while group F experienced 6.48±1.049 hours of pain relief. This is an important finding, as a longer duration of analgesia reduces the need for rescue analgesics and enhances patient comfort, especially in the paediatric population where pain management is crucial for recovery. Elfawal SM et al., (2018), found that dexmedetomidine extended the duration of analgesia compared to fentanyl, with a mean duration of 490.4±13.6 minutes (approximately 8.2 hours) in the dexmedetomidine group vs. 330.4±14.7 minutes (approximately 5.5 hours) in the fentanyl group [8]. El-Feky EM and Abd El Aziz AA (2015), also demonstrated that dexmedetomidine produced significantly longer analgesia compared to fentanyl, supporting our findings [9]. This consistency with prior studies strengthens the argument that dexmedetomidine is a potent adjuvant in prolonging the effects of local anaesthetics like levobupivacaine in paediatric caudal blocks.

Given that the participants in this study range in age from one to ten, the intensity of pain was measured using the FLACC scale. The FLACC scale is a valid, dependable, and user-friendly measure for evaluating pain in infants, young children, and children who are sleeping without contact, ranging in age from two months to seven years [16]. The FLACC score at 4, 6, and 8 hours postoperatively was significantly higher in group F compared to group D, indicating that the children in the fentanyl group experienced more pain during the first eight hours after surgery. The higher FLACC score in group F suggests that fentanyl did not provide as prolonged or effective pain relief as dexmedetomidine. Elfawal SM et al., (2016) found similar results, where the dexmedetomidine group had lower FLACC scores than the fentanyl group [8]. This aligns with the current study's findings and suggests that dexmedetomidine is more effective at maintaining lower pain levels postoperatively. In a study by Singh A et al., (2017), it was similarly reported that dexmedetomidine produced a lower FLACC score compared to fentanyl, indicating superior analgesia [1]. These consistent results across studies suggest that dexmedetomidine, when used as an adjunct in caudal blocks, provides superior and longer-lasting pain relief than fentanyl.

Group F required more rescue analgesia within the first 6 hours (36 patients) compared to group D, which required rescue analgesia in only four patients. This difference is a critical finding, as the need for rescue analgesia directly reflects the effectiveness of the initial pain management strategy. Fewer patients in requiring additional analgesics suggest better initial pain control. El-Feky EM et al., (2015) noted a reduced need for rescue analgesics in the dexmedetomidine group [9]. In fact, the reduced requirement for additional analgesia in the dexmedetomidine group is a common finding in studies comparing fentanyl and dexmedetomidine.

Group F had a higher incidence of nausea (4 vs. 1), vomiting (4 vs. 1), and pruritus (3 vs. 0) when compared to group D. These side-effects are common with opioid use, particularly fentanyl, and can impact the overall comfort and recovery of paediatric patients postsurgery. Elfawal SM et al., reported that fentanyl use was associated with higher rates of postoperative nausea, vomiting, and pruritus, consistent with the results found in the present study [8]. El-Feky EM and Abd El Aziz AA (2015) also observed similar side-effects in their study, where the fentanyl group exhibited a significantly higher rate of vomiting and pruritus compared to the dexmedetomidine group [9]. This correlation suggests that while fentanyl is an effective analgesic, its opioid-related side-effects may outweigh its benefits in paediatric caudal blocks, particularly when compared to dexmedetomidine.

The sedation scores in group D were consistently higher at 0, 2, 4, and 6 hours postoperative compared to group F. This suggests that dexmedetomidine provides a sedative effect, which is beneficial in reducing the need for additional sedative drugs and improving patient comfort during recovery. Similar findings were observed by Singh A et al., (2017), who reported that dexmedetomidine induced more sedation at 0, 2, and 4 hours postoperative than fentanyl [1]. Saadawy I et al., also reported that dexmedetomidine induced better sleep quality and longer-lasting sedation compared to bupivacaine monotherapy [17]. El-Feky EM and Abd El Aziz AA (2015) found that dexmedetomidine resulted in higher sedation scores compared to fentanyl, which aligns with the current study's findings [9].

The longer duration of analgesia and higher sedation scores observed in the dexmedetomidine group can be attributed to the alpha-2 adrenergic agonist properties of dexmedetomidine. This results in a vasoconstrictor effect locally, prolonging the action of levobupivacaine by decreasing its absorption, and it also facilitates a blockade of A-delta and C-fibers at the spinal cord level [18-20]. The sedative effect of dexmedetomidine, which allows for natural sleep-like sedation, is beneficial in paediatric anaesthesia as it reduces anxiety and minimises the need for additional sedatives, contributing to a smoother recovery. El-Feky EM and Abd El Aziz AA and (2015) Saadawy I et al., highlighted the sedative effects of dexmedetomidine, attributing its efficacy to its action on the locus ceruleus in the brainstem, which causes sedation while maintaining a state of arousability [9,17]. This mechanism has been widely recognised as one of the reasons dexmedetomidine provides superior sedation and analgesia compared to opioids like fentanyl.

Limitation(s)

This study has several limitations. First, the sample size may limit generalisability. Second, the optimal dose of caudal adjuvants was not explored. Third, potential observer bias in FLACC scoring cannot be excluded.

CONCLUSION(S)

In comparison to fentanyl, the current study emphasises the clinical significance of using dexmedetomidine as an additive to levobupivacaine for single-dose caudal analgesia in paediatric surgery. At a dose of 1 mcg/kg, dexmedetomidine improves patient safety and comfort. It consistently results in extended postoperative analgesia with fewer side-effects and lower analgesic requirements, all the while keeping haemodynamics steady. These results offer a strong justification for thinking of dexmedetomidine as a useful instrument in paediatric caudal block. However, careful dose and patient selection are necessary to completely reap its benefits. As its uses are researched further, dexmedetomidine shows potential in enhancing patient outcomes and expanding anaesthetic practice.

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