Comparative Study between Different Additives to Levobupivacaine in Caudal Block for Postoperative Pain Management in Pediatrics Undergoing Hypospadias Repair: Randomized Controlled Study

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ABSTRACT

Background: For both children and their caregivers, postoperative pain is an irritating experience. Several approaches have been used to treat postoperative pain in pediatric patients improving sleep quality, and extending sedation time.

Objectives: This work aimed to compare the postoperative analgesic effect and any complications of addition of one of these drugs nalbuphine versus fentanyl versus dexamethasone to levobupivacaine in caudal block (CB) in pediatric patients undergoing hypospadias repair.

Patient and Methods: 90 ASA status I and II patients aged 2 to 9 years underwent hypospadias repair were prospectively involved in this study. Patients were randomized into three equal groups (Group N, Group F and Group D).

Result: There was no statistically significant difference between three groups as regards systolic blood pressure (SBP) except after 60 and 70 minutes after caudal block as there was a significant difference as SBP decreased in the group (N) more than in both groups (F and D). Also there was a significant deference between the three groups in SBP at 1, 1.5, 2 and 4 hours postoperatively. FLACC pain score between three groups showed a significant difference between three groups at 2, 6 and 8 hours postoperatively otherwise no significant difference

Conclusion: Adding a nalbuphine to levobupivacaine in caudal block had longer duration for postoperative analgesia and showed more sedation time than that of fentanyl and dexamethasone with more stability in hemodynamics.

Keywords: Bupivacaine, Caudal analgesia, Children, Fentanyl, Nalbuphine, Dexamethasone.

INTRODUCTION

In recent years, the understanding of postoperative pain management and its implementation in children has dramatically improved. Many different approaches for providing postoperative pain relief in pediatric patients have emerged in recent years, with some of them having side effects that preclude their use in children ⁽¹⁾.

The caudal block is one of the most important regional blocks in pediatrics. It is most widely used for operations below the umbilicus, such as urogenital, rectal, inguinal, and lower extremity surgery. It is considered one of the most common strategies for providing intraoperative and postoperative analgesia in pediatric patients of single-shot caudal epidural blockade ⁽²⁾. In pediatrics, caudal block (CB) is typically used in conjunction with general anesthesia to allow for a quicker and more relaxed recovery from anesthesia and better pain control during various procedures, especially those involving the lower half of the body. However, CB with only local anesthetics offers superior short-term analgesia. As a result, different additives are being investigated to check whether they can provide longer-lasting pain relief. The use of caudal analgesia decreased the amount of inhaled and intravenous anesthetics given and the stress response to surgery promoted rapid, smooth

recovery, and provided rapid solid postoperative analgesia. To minimize intra- and postoperative analgesic requirements after a single shot caudal blockade, various additives, such as opioids and non-opioid drugs, were used ⁽³⁾. As a result, multiple medications have been applied to local anesthetics to increase the pain-free duration ⁽⁴⁾.

Levobupivacaine is The S-isomer of racemic bupivacaine. It is a new long-acting amide local anesthetic. It is less toxic to the central nervous system than bupivacaine, and it is less likely to cause myocardial depression and fatal arrhythmias. Several researchers have reported that levobupivacaine have potential benefits for clinical use. The short duration of analgesia following a single injection is one of the main disadvantages of caudal analgesia. Multiple additives of local anesthetics, such as morphine, fentanyl, ketamine, clonidine, and dexmedetomidine have been used to minimize postoperative analgesic requirements after a single shot caudal epidural blockade ⁽⁵⁾.

Fentanyl is a strong opioid mu receptorstimulating with a short half-life ⁽⁶⁾. It was the first opioid in the fentanyl family, which later included sufentanil, alfentanil, and remifentanil for human patients ⁽⁷⁾. It has limited cardiovascular effects, does not cause a spike in plasma histamine, is relatively



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short-acting, and is simple to synthesize and prepare for the market ⁽⁸⁾.

Nalbuphine is a phenanthrene-derived synthetic opioid agonist-antagonist analgesic with a structure close to that of naloxone and oxymorphone. It acts as an agonist for kappa opioid receptors (KORs) and mu-opioid receptors (MORs), providing analgesia and sedation while also guarding against receptor blockade-induced respiratory failure. Nalbuphine has a ceiling effect, which means that once the maximum plasma concentration is reached, incremental doses do not increase the risk of respiratory failure or potentiate the analgesic effects ⁽⁹⁾. The use of opioid additives in children undergoing day-case surgery has been restricted due to unacceptable side effects such as nausea, vomiting, pruritus, and the risk of respiratory depression ⁽¹⁰⁾. The primary aim of CB is to relieve postoperative pain, and it is widely understood that the procedure is carried out on anesthetized children⁽¹¹⁾.

This work aimed to compare the postoperative analgesic effect and any complications of addition of one of these drugs, nalbuphine versus fentanyl versus dexamethasone, to levobupivacaine in caudal block (CB) in pediatric patients undergoing hypospidius repair.

PATIENT AND METHODS

90 ASA status I and II patients aged 2 to 9 years who underwent elective hypospadias surgery were prospectively enrolled in this study. Patients with congenital abnormalities of the lower spine or meninges, elevated intracranial pressure, ASA grading 3 or above, history of developmental delay or mental retardation, skin infection at the injection site, bleeding diathesis, documented allergy to any medication used in this research, bilateral or chronic inguinal hernia, and cardiopulmonary disease, were excluded.

The standard monitors were inserted into an accessible peripheral vein upon arrival to the operating theatre, including noninvasive blood pressure, five lead electrocardiography and pulse oximetry, temperature monitor, and 22-24-gauge cannula. Patients were put in a supine position, and general anesthesia was induced with sevoflurane in oxygen/air (FiO2 50%). In older children, an i.v. cannula was implanted, and propofol 2 mg/kg was used in the induction phase. Cis-atracurium 0.1 mg/kg was administered intravenously (IV), and intubation and managed mechanical ventilation were performed. Isoflurane (1.0-2.0 percent) was used to sustain anesthesia with normal monitoring.

Patients were put in a lateral decubitus position with their hips flexed to 90 degrees, and a single dose caudal block was performed using a 23-gauge needle and the standard loss of resistance technique under strict aseptic conditions. After needle insertion and negative aspiration of blood or cerebrospinal fluid, the proper location of the needle was confirmed by a pop felt during penetration of the sacro-coccygeal ligament, which was accompanied by a whoosh test using 1-3 ml of air.

Patients were divided into three equal groups (each with 30 patients); in group (N) we gave 0.75 ml/kg levobupivacaine of 0.25 percent diluted in regular saline + nalbuphine 0.2 mg kg. Group (F) received 0.75 ml/kg levobupivacaine of 0.25 percent with fentanyl 1 μ g/kg. Group (D) received levobupivacaine 0.75 ml/kg of 0.25 percent diluted in regular saline + dexamethasone 0.1 mg/kg.

Procedures:

- 1. Demographic Information: Age, weight, gender, duration of operation and time of anesthesia.
- 2. Before induction haemodynamics: Heart rate and mean blood pressure were registered, as well as every 10 minutes before the operation was completed. When the wound dressing was applied, the anesthesia was shut off, and the endotracheal tube was removed. Monitoring of hemodynamic status (MAP and HR), as well as analgesia and the occurrence of any side effects, for the first 12 hours following caudal block. For Bradycardia treated with atropine 0.01 mg/kg intravenous, which was described as a 20% decrease in HR compared to preoperative values. The use of ephedrine 1-2 mg intravenous was used to treat hypotension, which was described as a 20% decrease in SAP compared to preoperative values. Analgesia would be deemed inadequate if HR or SAP increases by more than 20% more than 60 minutes after skin incision, and the child will receive rescue opioid (Fentanyl lug/kg) throughout the procedure.
- 3. Analgesia was measured using the pediatric observational Face/ Leg/ Activity/ crying / Consolability (FLACC) pain scale (Table 1), which has a 0–10 score range. Each child was evaluated upon arrival in the ward, every 1/2 hour for the first two hours, and then every two hours for the next twelve hours. Supplementary analgesics in the form of 15 mg/kg rectal paracetamol were given if the FLACC pain scale score was 4 or higher at any time or if the patient showed clear signs of pain.

Table (1): FLACC behavioral	pain assessment scale (12)
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	Score							
Parameters	0	1	2					
Face	No particular expression or smile	Occasional grimace or frown; withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin					
Leg	Normal position or relaxed Uneasy, restless, tense		Kicking or legs drawn up					
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking					
Crying	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs; frequent complaints					
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to; distractible	Difficult to console or comfort					

Score: 0 = no pain, score: 1-3 = mild pain, score: 4-7 = moderate pain and score: <math>8-10 = severe pain, FLACC: face, legs, activity, crying, and consolability.

4. Sedation assessment using the Richmond Agitation Sedation Scale (RASS) ⁽¹³⁾. It is a medical scale that is used to assess a person's level of agitation or sedation. It was created by the efforts of various clinicians, including doctors, nurses, and pharmacists.

5. Follow up the adverse effects such as postoperative nausea and vomiting, respiratory distress, urinary retention, pruritus, hypotension, and bradycardia.

6. The cumulative volume of paracetamol dose as well as the time to first rescue analgesia is evaluated.

Ethical approval and written informed consent: An approval of the study was obtained from Sohag University Academic and Ethical Committee. Written informed consents were taken from parents for participation in the study.

Statistical analysis

To avoid any decline in patients during the study, the sample size was determined using nighty patients, with 30 in each category. The statistical data analysis was performed using IBM-SPSS, version 20 IBM-Chicago, USA. The mean, standard deviation (SD), number, and percentage are all used to express the results. For quantitative results, the mean and standard deviation were used as descriptive values. The qualitative data between the two groups was compared using the Chi square test, and the means were compared using the student t test. The degree of significance (P-value) for both of these measures can be determined as follows: If P > 0.05 it has no statistical significance, but if $P \le 0.05$ it is significant.

RESULTS

This prospective randomized controlled-study was carried out in Sohag University Hospital in the period from 2018 to 2020. 90 patients prepared for hypospadias repair were included in the study. To compare data of the three groups, all data are represented as mean \pm standard deviation (SD). Mean and standard deviation were used as descriptive value for quantitative data. Chi square test was used to compare the qualitative data between the three groups and student T test was used to compare the means between the three groups.

	Groups	Mean +SD	p value
Age (year)	Ν	3.433±1.104	
	F	3.567 ± 1.43	0.685 (NS)
	D	3.432±1.23	
Weight	Ν	13.80±3.21	
(Kg)	F	13.87±3.56	0.940 (NS)
-	D	13.77±3.63	
ASA	Ν	1.3±4.6	
classification	F	1.5 ± 3.2	NS
	D	1.6±3.7	
Duration of	N	56.4±8.6	
operation	F	55.7±3.6	NS
_	D	55.7±2.4	
Anesthesia	Ν	77.6±5.7	
ime	F	75.7±6.7	N S
	D	76.8±4.3	

Table (2): Demographic data of the three groups

There was no statistically significant difference between the three groups as regards age, weight, duration of operation or anesthesia time (Table 2).

Table (3): The relation of intraoperative SBP in the three groups

Time Group		Mean± SD	T test	P value	
Pre	N	98.67 ± 7.74			
	F	99.55 ± 8.66	1.316	0.193	
	D	101.60 ± 9.46			
5min	Ν	107.37 ± 13.67			
	F	112.34 ± 14.76	1.297	0.200	
	D	112.63 ± 18.40			
10min	Ν	105.833 ± 15.65			
	F	105.541 ± 16.76	0.135	0.893	
	D	106.400 ± 15.75			
20min	N	101.37 ± 13.21			
	F	104.33 ± 11.2	0.539	0.592	
	D	103.37 ± 23.4			
30min	N	99.41 ± 13.54			
	F	99.55 ± 14.23	0.847	0.401	
	D	102.78 ± 13.76			
40min	N	100.167 ± 16.6			
	F	100.11 ± 17.5	0.066	0.948	
	D	100.600 ± 17.8			
50min	Ν	91.286 ± 17.6			
	F	92.44 ± 14.4	0.065	0.949	
	D	90.846 ± 12.70			
60min	Ν	$54.000 \pm 7,5$			
	F	95.111 ± 12.7	2.775	0.002	
	D	96.286 ± 13.7			
70min	Ν	66.00 ± 11.8			
	F	$95.12 \pm 13,8$	2.407	0.045	
	D	$103.75 \pm 15,8$			
80min	Ν	60.00 ± 25			
	F	88.43 ± 27.9	1.251	0.300	
	D	96.50 ± 25.7			
90min	Ν	67.00 ± 23.34			
	F	99.23 ± 26.7	1.407	0.393	
	D	106.00 ± 22.65			

There was no statistically significant difference between the three groups regarding SBP except after 60 and 70 minutes after caudal block there was a significant difference as SBP is decreased in the group N more than in both group (F and D) as shown in table (3).

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	adi ve bybtome	olood pressure (SDI) in the three groups		
Time (Group	Mean	Std. Deviation	T test	P value
0.5 H	N	95.33	6.814		
	F	93,44	7.543	1.544	0.128
	D	92.33	8.172		
1 H	N	75.33	7.761		
	F	88.33	6.334	2.499	0.015
	D	99.00	5.477		
1.5 H	N	50.45.	5.632		
	F	82.22	5.456	4.284	<0.001
	D	89.33	6.397		
2 H	N	80.33	6.261		
	F	90.33	7.343	2.421	0.019
	D	96.67	8.503		
4 H	N	84.67	7.303		
	F	97.22	7.543	2.249	0.028
	D	99.00	8.710		
6 H	Ν	93.33	6.065		
	F	92.45	5,076	0.849	0.399
	D	92.00	6.103		
8 H	N	95.00	5.085		
	F	95.34	4.788	0.648	0.519
	D	94.00	6.747		
10 H	N	93.33	7.581		
	F	93.43	6.543	0.986	0.328
	D	91.67	5.307		
12 H	N	95.17	5.673		
	F	94.67	5.745	0.765	0.321
	D	91.65.	92.74.		

Table (4): Postoperative systolic blood pressure (SBP) in the three groups

Postoperative systolic blood pressure (SBP) in the three groups showed a significant deference between the three groups in SBP at 1, 1.5, 2 and 4 hours postoperatively (Table 4).



Figure (1): Relation of intraoperative H.R. in the three groups There was no statistically significant difference between the three groups as regards intraoperative heart rate (HR) as shown in figure (1).



There was no statistically significant difference between the three groups regarding HR in postoperative period (Figure 2).

Time Grou	ıp	Mean	Std. Deviation	T test	P value
0.5 H	N	2.73	2.664		
	F	2.21	2.13	2.393	0.070
	D	3.03	1.326		
1 H	N	1.23	1.870		
	F	1.45	1.77	2.522	0.084
	D	2.30	1.368		
2 H	Ν	1.43	1.478		
	F	2.33	1.333	3.060	0.003
	D	4.47	.900		
4 H	Ν	1.50	1.570		
	F	1.66	1.654	1.891	0.064
	D	2.57	2.661		
6 H	Ν	1.53	1.592		
	F	2.55	1.232	5.710	<0.001
	D	4.27	2.083		
8 H	Ν	1.20	1.972		
	F	2.66	2.121	5.110	<0.001
	D	4.43	1.357		
10 H	Ν	3.40	2.621		
	F	3.45	1.654	1.922	0.060
	D	4.37	1.850		
12 H	N	3.40	2.513		
	F	3.66	1.876	0.066	0.947
	D	3.43	1.135		

Table (5): The relation of FLACC pain score between the three groups

There was a significant difference between the three groups at 2, 6 and 8 hours postoperatively otherwise no significant difference (table 5).

Time	Group N(n=30)			Group F(n=30)			Group D(N=30)			P value			
	0	-1	+1	+2	0	-1	+1	+2	0	-1	-1	2	
0.5H	2	23	5	0	5	11	14	0	4	10	2	0	0.008
1H	4	23	3	0	10	12	8	0	10	11	7	0	0.016
1.5H	12	17	1	0	18	11	1	0	17	10	1	0	0.289
2H	23	7	0	0	18	12	0	0	18	13	0	0	0.165
4H	20	9	0	1	19	8	3	0	19	7	3	0	0.252
6H	18	9	3	0	10	8	12	0	11	7	13	0	0.021
8H	17	7	6	0	15	4	11	0	14	5	11	0	0.299
10H	18	9	3	0	23	5	2	0	22	4	3	0	0.377
12H	16	10	4	0	13	8	9	0	12	13	0	0	0.293

Table (6): Comparing Richmond Agitation Sedation scale between the three groups

Table (6) showed that there was a significant difference where the sedation score was (-1) at $\frac{1}{2}$ hour and 1 hour and agitation (+1) is significant at 6 hours.

Table (7): Time to 1st rescue (hours) and total dose of (mg)

	Group D (n=30)	Group D (n=30) Group F (n=30)		P value	
Time to first rescue analgesia in hours	4.8 ± 6.4	6.8 ± 2.6	10 ± 4.6	< 0.001	
Total dose of paracetamol in first 24 hour	532.32 ± 64.5	243.35 ± 74.8	100.5 ± 65.5	< 0.05	

The first time for postoperative requirement was significantly longer in N group (10 ± 4.6 hours) compared to both group D (4.8 ± 6.4 hours) and group F (6.8 ± 2.6 hours) (p value > 0.001). The total dose of postoperative supplementary analgesia (intravenous infusion) in the first 12 h was significantly lower in N group (100.5 ± 65.5 mg) in comparison with both group D (532.32 ± 64.5 mg) and group F(243.35 ± 74.8 ml) (P < 0.05).

DISCUSSION

Caudal block is one of the most common regional anesthetic techniques used in children. Even when using long acting agents like levobupivacaine, it is considered a safe and straightforward treatment, but its key drawback is its relatively short time of operation ⁽¹³⁾.

In our study age, sex, and body weight, the three classes were not statistically significant during the perioperative time: the heart rate and systolic blood pressure were measured at different intervals. Group N has more stable haemodynamics than Group F and D, especially during the postoperative period. There was no major difference between the three groups intraoperatively, except after 60 and 70 minutes, when group N encountered hypotension due to a different form of activity (bleeding) and a different period of operation than the other two groups. These findings corroborate those of Mahendru et al. (14), who compared the intravenous administration of fentanyl, clonidine, and dexmedetomidine in lower limb surgeries and found that mean arterial pressure (MAP) and heart rate (H.R.) were comparable between the groups during the intraoperative and postoperative times. Dutt et al. compared the hemodynamic effects of incorporating fentanyl or dexmedetomidine to caudal

ropivacaine in pediatrics undergoing lower abdominal and lower limb surgeries. They concluded that the two groups were equivalent. Also **Nasr and Abdelhamid** (¹⁶⁾ compared the effectiveness of caudal dexmedetomidine to caudal fentanyl on the stress response and postoperative analgesia and found that the dexmedetomidine community had significantly lower HR and chart.

As regards pain score, there was a substantial difference in postoperative FLACC pain score between groups N (1.43 1.478) and F (2.331.333) in the first hour (P value was 0.003) and lower than group D, suggesting more potent analgesia in group N at 6 and 8 hours. In contrast to groups F (14) and D, only two children in group N took a paracetamol suppository as a supplementary analgesic at 6 hours. Miller et al. (17) compared caudal 0.25 percent levobupivacaine 1 ml/kg versus caudal 0.25 percent levobupivacaine 1 ml/kg plus 0.2 mg/kg nalbuphine. Analgesia lasted slightly longer in the caudal nalbuphine group. These results are consistent with those of **Xiang** *et al.* ⁽¹⁸⁾, who investigated the impact of adding dexmedetomidine to ropivacaine in caudal block in children undergoing inguinal hernia repair and found that adding dexmedetomidine o caudal bupivacaine could reduce the response to hernial sac traction, extend the duration of postoperative

analgesia. Another study compared caudal 0.25 ml/kg percent bupivacaine 1 to 2 g/kg dexmedetomidine nalbuphine 0.2 and mg/kg dexmedetomidine and nalbuphine 0.2 mg/kg nalbuphine. The nalbuphine community had a 6.700.38 hours average period of analgesia ⁽⁶⁾. It took 5.8 0.88 hours in our analysis. This is equivalent to the previous studies. Gupta and Pratap⁽¹⁹⁾ compared dexmedetomidine 2g/kg in combination with ropivacaine 0.2 percent to fentanyl 2g/kg. They concluded that dexmedetomidine had lower pain scores and a longer period of analgesia.

Dutt *et al.* ⁽¹⁵⁾ **and Nasr and Abdelhamid** ⁽¹⁶⁾ compared caudal fentanyl or dexmedetomidine on lower abdominal and limb surgeries and cardiac surgery in pediatrics, respectively, and found that the pain score was lower and the period of postoperative analgesia was longer in the dexmedetomidine community. **El-Feky** *et al.* ⁽²⁰⁾ found that caudal dexmedetomidine and caudal dexamethasone applied to local anesthetics were good alternatives in prolonging postoperative analgesia with lower pain scores when compared to caudal local anesthetic alone or added to caudal fentanyl.

As regards sedation in our study, nalbuphine caused more sedation than fentanyl and more than dexamethasone. These findings support those of Anand et al.⁽²¹⁾, who looked at the effects of dexmedetomidine added to caudal ropivacaine in pediatric lower abdominal surgeries and discovered that the dexmedetomidine community had significantly better postoperative pain relief, better sleep quality, and a longer period of arousal sedation. Saadawy et al. (22) found that addition of dexmedetomidine to bupivacaine in caudal block in children had a better quality of sleep and a longer period of sedation. However, when Dutt et al. (15) compared caudal fentanyl to dexmedetomidine, they found that the dexmedetomidine group had a higher sedation score. However, this disparity was attributed to a high dexmedetomidine dose (2 g/kg). Gaitini et al. ⁽²³⁾ used the updated Children's Hospital of Eastern Ontario Pain Score (mCHEOPS) score to compare the effects of adding fentanyl to bupivacaine versus bupivacaine alone on postoperative analgesia. In comparison to our results, they discovered that pain scores (as calculated by mCHEOPS) were comparable in both groups. There were no statistically meaningful discrepancies between the two groups in terms of the first intravenous fentanyl administration period or the amount of patients who needed fentanyl. There were no major variations in the duration of the first dose or the number of patients who received paracetamol in ward between the two classes.

Dutt *et al.* ⁽¹⁵⁾ who compared the side effects of dexmedetomidine and fentanyl caudally and found no significant differences. However, this finding varies from that of **Bajwa** *et al.* ⁽²⁴⁾, who tested the

addition of either fentanyl or dexmedetomidine to epidural analgesia in lower limb surgeries and found that the frequency of postoperative nausea and vomiting was significant. Mohamed et al. (25) investigated the efficacy of caudal nalbuphine in postoperative pain compared nalbuphine plus bupivacaine (BN group) to bupivacaine alone (B group) in single-shot CB. The patient's pain intensity was assessed using the Pain Discomfort Scale. The period of analgesia was longer in the BN group, with a time-to-first-analgesic-request of longer in the BN group versus in the B group. Also they assessed sedation scores, and they discovered that the BN group had higher sedation scores at 30 minutes and 1 hour postoperatively. Their postoperative pain relief findings were consistent with those of the current research, and no respiratory depression was observed. In comparison to our study, there were no adverse effects recorded in theirs. This can be explained by the fact that they used a lower dosage of nalbuphine (0.1 mg/kg) than we did (0.2 mg/kg), as well as a higher concentration of bupivacaine (0.25 percent vs. 0.125 percent in our sample), which may explain the frequency of adverse effects and the discrepancy in hemodynamics between our study and theirs.

Salama (26) used single-shot CB to compare nalbuphine, dexmedetomidine, and bupivacaine in distinct classes. They discovered that three dexmedetomidine and nalbuphine are safe additives used in caudal epidural analgesia/anesthesia in children to boost and extend caudal analgesia's analgesic profile. They found that postoperative FLACC pain levels were substantially lower in the BD group and to a lesser degree in the BN group than in the B group (P 0.001). The first time for the postoperative analgesic requirement in the BD group was substantially longer in the BD group (16.89 0.74 h) and lesser in the BN group (6.70 0.38 h) than in the B (control) group (4.84 0.70 h) (P 0.001). In the first 24 hours, the cumulative dose of postoperative supplementary analgesia (intravenous paracetamol) in the BD group (128.75 32.72 mg) and to a lesser degree in the BN group (263.25 69.99 mg) was significantly lower than in the control group (276.25 94.41 mg) (P 0.001). Patients in the BD and BN groups were more sedated in the first 6 hours than those in the control group. In comparison to our results, they discovered that no adverse effects were observed in any of the patients within the first 24 hours. There were no postoperative hallucinations, nausea, vomiting, allergies, or significant changes in HR or blood pressure recorded.

There were two unsuccessful cases where the caudal treatment was challenging in terms of side effects (subcutaneous injection). They were treated with intravenous fentanyl and were not included in the study. Other complications such as hypotension, nausea, and vomiting were equally prevalent in both classes (P-value 0.157, 1, and 0.149, respectively).

CONCLUSION

The addition of nalbuphine to levobupivacaine in a caudal block for hypospadias repair resulted in a more extended period of postoperative analgesia and more sedation time than fentanyl and dexamethasone, as well as more hemodynamic stability.

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