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COMPARATIVE POSTOPERATIVE ANALGESIC EFFICACY OF CAUDAL ROPIVACAINE WITH DEXMEDETOMIDINE VERSUS CAUDAL ROPIVACAINE WITH NALBUPHINE USING FLACC SCALE IN PEDIATRIC INFRAUMBILICAL SURGERIES

Anaesthesiology

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ABSTRACT

Background: Effective pain management in pediatric infraumbilical surgeries is crucial to prevent short- and long-term complications. Dexmedetomidine and Nalbuphine are commonly used adjuvants to enhance caudal analgesia. **Aims & Objectives:** This study aimed to compare the postoperative analgesic efficacy and hemodynamic stability of caudal Ropivacaine with Dexmedetomidine versus Nalbuphine in pediatric patients. **Methods:** This prospective observational study included 60 pediatric patients aged 1-8 years, undergoing elective infraumbilical surgeries. Patients were randomly divided into two groups: Dexmedetomidine (1 µg/kg) and Nalbuphine (0.2 mg/kg), both combined with 0.25% Ropivacaine. Postoperative analgesia was assessed using the FLACC scale, and hemodynamic parameters were monitored over 24 hours. **Results:** Ninety percent of patients in the Dexmedetomidine group experienced analgesia lasting up to 18 hours, significantly longer than in the Nalbuphine group, where 46.66% experienced pain within 9 hours. Dexmedetomidine also maintained lower FLACC scores and better hemodynamic stability, with fewer complications. **Conclusions:** Dexmedetomidine provides superior postoperative analgesia and better hemodynamic stability compared to Nalbuphine in pediatric infra umbilical surgeries, making it a more effective and safer choice.

KEYWORDS

Pediatric analgesia; Dexmedetomidine; Nalbuphine; Infraumbilical surgery; FLACC scale.

INTRODUCTION

Effective pain management in pediatric patients undergoing infraumbilical surgeries is a critical component of perioperative care, as inadequate pain relief can lead to significant short- and long-term consequences.[1,2] The International Association for the Study of Pain (IASP) defines pain as a complex and subjective experience that not only encompasses the physical sensation but also includes an emotional response, making it a challenging aspect of pediatric care. Children are particularly vulnerable to the effects of poorly managed postoperative pain, which can impact their recovery, cause behavioral changes, and potentially lead to chronic pain conditions.[3] Therefore, ensuring effective and safe pain relief is not only a medical imperative but also a moral obligation, especially for pediatric patients.[3]

Caudal epidural analgesia has emerged as a widely used technique in pediatric anesthesia due to its ability to provide localized pain relief with minimal systemic side effects.[4,5] Among the various agents used for caudal analgesia, ropivacaine, a long-acting amide local anesthetic, is favored for its selective action on pain fibers and reduced cardiotoxicity. However, the effectiveness of ropivacaine alone is often limited by the duration of analgesia, prompting the use of adjuvants to prolong its effects.[6] Dexmedetomidine, an α2-adrenergic receptor agonist, has gained popularity for its ability to enhance postoperative pain control while minimizing respiratory depression. Its analgesic and sedative properties make it a valuable adjunct in pediatric caudal anesthesia. On the other hand, nalbuphine, a mixed opioid agonist-antagonist, offers effective analgesia with a lower risk of respiratory depression compared to traditional opioids, making it another potential candidate for enhancing caudal analgesia in pediatric patients.[7,8]

This study aims to compare the postoperative analgesic efficacy of caudal ropivacaine combined with dexmedetomidine versus nalbuphine in pediatric patients undergoing infraumbilical surgeries. By utilizing the FLACC (Face, Legs, Activity, Cry, Consolability) scale, a reliable and widely accepted tool for assessing pain in young children, this research seeks to determine which combination provides superior pain relief, hemodynamic stability, and overall patient comfort. The findings are expected to contribute valuable insights into optimizing pediatric pain management strategies, ultimately improving postoperative outcomes and enhancing the quality of care for children undergoing infraumbilical surgical procedures.

MATERIALS & METHODS

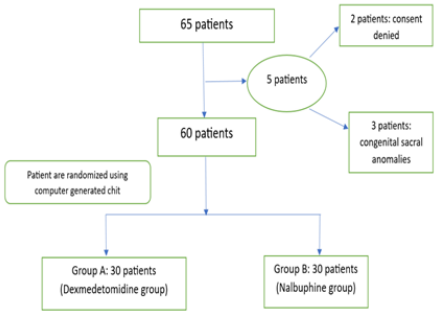
This prospective observational study was conducted on pediatric patients aged 1-8 years, of either sex, with American Society of Anesthesiologists (ASA) physical status I-II, who were scheduled for elective infraumbilical surgeries under general anesthesia. The study was conducted in the Department of Anesthesiology and Critical Care Medicine at Nehru Hospital, B.R.D. Medical College, Gorakhpur, from March 2023 to February 2024. Ethical clearance was obtained from the Institutional Ethical Committee, and informed written consent was secured from the guardians of all pediatric patients participating in the study.

The study included a total of 60 patients, divided into two groups of 30 each. The patients were randomized using a computer-generated random number sequence, with group allocation concealed in sealed opaque envelopes. Group A received 0.25% ropivacaine with dexmedetomidine at a dose of 1 µg/kg, while Group B received 0.25% ropivacaine with nalbuphine at a dose of 0.2 mg/kg. The dose of ropivacaine for both groups was calculated using the modified Armitage formula. Randomization and drug preparation were done in the operating room by the attending anesthesiologist, who was the only individual aware of the group allocation.

Preoperative evaluation included a detailed medical history, physical examination, and routine laboratory investigations. Patients were kept nil per os (NPO) as per standard fasting guidelines, and premedication was administered according to institutional protocols. General anesthesia was induced with intravenous propofol, and muscle relaxation was achieved with vecuronium, followed by endotracheal intubation. After surgery, the caudal block was performed with the patient in the lateral decubitus position, using a 23G hypodermic needle to inject the study drug solution into the caudal epidural space.
Postoperatively, patients were monitored for analgesic efficacy, defined as the duration until the FLACC (Face, Legs, Activity, Cry, Consolability) score reached 4 or more, indicating the need for rescue analgesia. Monitoring included continuous assessment of vital signs, pain scores, and sedation levels using the Ramsay Sedation Scale at predefined intervals. Adverse effects such as nausea, vomiting, respiratory depression, hypotension, and bradycardia were recorded and managed accordingly.

Statistical analysis was performed using SPSS version 28.0. Continuous variables were presented as mean ± standard deviation (SD), and categorical variables as frequencies and percentages. The unpaired t-test was used to compare normally distributed continuous

variables, while the Mann-Whitney U test was employed for non-normally distributed data. Categorical variables were analyzed using the chi-square test or Fisher's exact test as appropriate. A p-value of less than 0.05 was considered statistically significant.



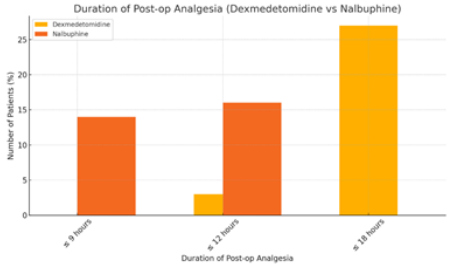
RESULTS

Table 1 Socio-demographic Characteristics and Surgical Details of the Study Population

Characteristics	Categories	Frequency (N)	Percentage (%)	p-value
Age (Years)	1-2	25	41.7%	0.021
	3-4	14	23.3%	
	5-6	9	15.0%	
	7-8	12	20.0%	
Gender	Male	39	65.0%	0.020
	Female	21	35.0%	
ASA Grade	I	58	96.7%	<0.001
	II	2	3.3%	
Diagnosis	Hernia	23	36.6%	<0.001
	Loop Ileostomy	14	23.3%	
	Hypospadias	6	10.0%	
	Other Diagnoses (16 categories)	17	28.3%	
Surgical Procedure	Hernioplasty	23	38.3%	<0.001
	Loop Closure	14	23.3%	
	Hypospadias Repair	6	10.0%	
	Other Procedures (11 categories)	17	28.3%	

Table 2 Postoperative Analgesia Duration and FLACC Pain Scores for Nalbuphine and Dexmedetomidine Groups

Parameters	Dexmedetomidine (N=30)	Nalbuphine (N=30)	p-value
Duration of Post-op Analgesia			
≤ 9 hours	0 (0%)	14 (46.66%)	<0.001
≤ 12 hours	3 (10%)	16 (54.44%)	<0.001
≤ 18 hours	27 (90%)	0 (0%)	<0.001



FLACC Pain Scores	Dexmed	Nalbuphine	P value
1 hour	0 ± 0	0 ± 0	NA
2 hours	0 ± 0	0 ± 0	NA
3 hours	0 ± 0	0 ± 0	NA
4 hours	0 ± 0	0 ± 0	NA
5 hours	0 ± 0	0 ± 0	NA
6 hours	0 ± 0	0 ± 0	NA
9 hours	0 ± 0	0.73 ± 1.53	0.0003
12 hours	0.4 ± 1.221	3.47 ± 1.042	<0.0001
18 hours	1.93 ± 0.813	2.07 ± 0.640	<0.001
24 hours	1.33 ± 0.942	1.93 ± 0.365	0.015

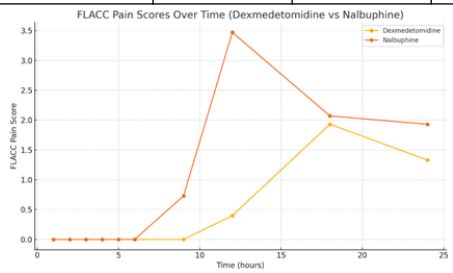
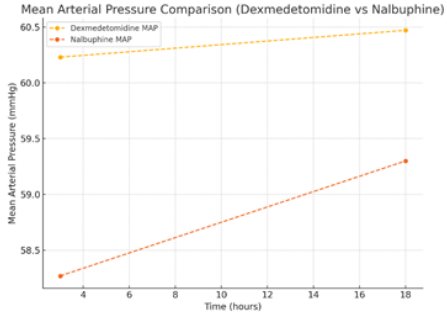
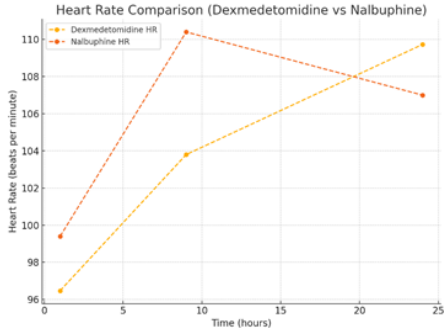


Table 3 Comparison of Sedation Scores, Heart Rate, Mean Arterial Pressure, SpO2 Levels, and Complications Over 24 Hours Post-Caudal Block in Pediatric Patients

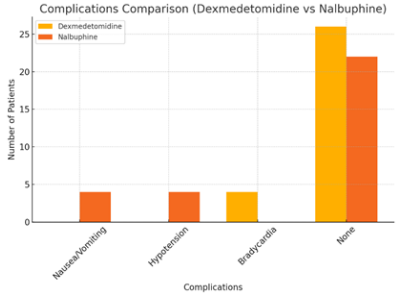
Parameters	Time Point	Dexmedetomidine (N=30)	Nalbuphine (N=30)	p-value
Sedation Scores	1-24 hours	2 (consistent)	2 (consistent)	0.343

PARAMETER	TIME POINT	DEXMEDETOMIDINE	NALBUPHINE	P VALUE
Heart Rate (HR)	1 hour	96.47 ± 16.76	99.4 ± 12.00	0.278
	9 hours	103.8 ± 9.70	110.4 ± 16.33	0.008
	24 hours	109.73 ± 10.17	107 ± 12.17	0.190
Mean Arterial Pressure (MAP)	3 hours	60.23 ± 2.92	58.27 ± 3.25	0.001
	18 hours	60.47 ± 2.94	59.3 ± 3.11	0.032
SpO2 Levels	1-24 hours	98.2 (consistent)	97.9 (consistent)	0.652





PARAMETER		DEXMED	NALBUPHINE	P VALUE
Complications	Nausea/Vomiting	0	4 (13.33%)	0.333
	Hypotension	0	4 (13.33%)	0.333
	Bradycardia	4 (13.33%)	0	0.333
	None	26 (86.66%)	22 (73.33%)	-



DISCUSSION

In our study, 90% of the patients in the Dexmedetomidine group experienced postoperative analgesia lasting up to 18 hours, whereas in the Nalbuphine group, 46.66% of patients had analgesia lasting only up to 9 hours, with no patients achieving 18 hours of analgesia. **Gupta PK et al.[9] (2018)** reported that adding 2 µg/kg of Dexmedetomidine to Ropivacaine in pediatric caudal blocks resulted in 85% of patients experiencing analgesia for up to 16 hours, which is slightly lower but comparable to our finding of 90% experiencing up to 18 hours of analgesia in the Dexmedetomidine group. Conversely, their study indicated significantly shorter analgesia duration in patients receiving Nalbuphine, similar to our findings.

In our study, the Dexmedetomidine group consistently had lower FLACC pain scores, with scores remaining at 0 up to 6 hours post-surgery, and significantly lower pain scores at 9 and 12 hours compared to the Nalbuphine group ($p=0.0003$ and $p<0.0001$, respectively). **Kalsotra S et al.[10] (2019)** found that the addition of Dexmedetomidine to Ropivacaine significantly reduced pain scores in pediatric patients, with most patients maintaining FLACC scores of 0 for up to 6 hours postoperatively, aligning closely with our findings. Additionally, their study observed a more pronounced reduction in pain scores at 12 hours, similar to the differences noted in our study.

In our study, the heart rate remained more stable in the Dexmedetomidine group compared to the Nalbuphine group, with significant differences at the 9-hour mark (103.8 ± 9.70 vs. 110.4 ± 16.33; $p=0.008$). **Anand VG et al.[11] (2011)** observed that Dexmedetomidine maintained stable heart rates during the postoperative period, with minimal fluctuations compared to a control group. Their findings support our observation of better hemodynamic stability with Dexmedetomidine, particularly at critical time points such as 9 hours post-surgery.

In our study, mean arterial pressure was significantly more stable in the Dexmedetomidine group at both the 3-hour and 18-hour marks, with p-values of 0.001 and 0.032, respectively. **Kundu R et al.[12] (2015)** also reported more stable MAP readings in the Dexmedetomidine group, particularly in the early postoperative hours, which is consistent with our findings of better MAP control in the Dexmedetomidine group.

In our study, complications such as nausea and vomiting were observed in 13.33% of patients in the Nalbuphine group, with no such cases in the Dexmedetomidine group. However, bradycardia occurred in 13.33% of the Dexmedetomidine group, with none in the Nalbuphine group. **Salama AK et al.[13] (2016)** also reported a lower incidence of postoperative nausea and vomiting in the Dexmedetomidine group compared to Nalbuphine, aligning with our findings. They also noted incidences of bradycardia in the Dexmedetomidine group, although these were clinically manageable and did not lead to adverse outcomes, which parallels the findings in our study.

In summary, the present study's findings are consistent with previous research, which reinforces the efficacy of Dexmedetomidine in providing prolonged postoperative analgesia, maintaining better hemodynamic stability, and minimizing complications compared to Nalbuphine in pediatric infraumbilical surgeries. These comparisons underscore the advantages of using Dexmedetomidine as an adjuvant in pediatric anesthesia.

CONCLUSION

The study demonstrated that Dexmedetomidine provided significantly superior postoperative analgesia compared to Nalbuphine, with 90% of patients in the Dexmedetomidine group maintaining effective pain relief for up to 18 hours, while 46.66% of patients in the Nalbuphine group experienced pain within 9 hours. FLACC pain scores were consistently lower in the Dexmedetomidine group, particularly at 9 and 12 hours post-surgery, highlighting its effectiveness in controlling postoperative pain. Hemodynamic stability was also better maintained in the Dexmedetomidine group, with lower heart rates and more stable mean arterial pressures at critical time points, alongside a lower incidence of complications such as nausea, vomiting, and hypotension. Although bradycardia was observed in 13.33% of patients in the Dexmedetomidine group, it was not clinically significant. Overall, Dexmedetomidine proved to be a more effective and safer option for postoperative analgesia in pediatric infraumbilical surgeries compared to Nalbuphine.

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