Section: Anaesthesiology

Original Research Article

COMPARATIVE STUDY OF 0.5 µg/kg AND 1 µg/kg OF DEXMEDETOMIDINE AS ADDITIVE TO 0.25% BUPIVACAINE 1 ml/kg FOR CAUDAL ANALGESIA IN PAEDIATRIC INFRAUMBILICAL SURGERIES

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Abstract

Background: Pain management in paediatric infraumbilical surgeries is crucial for reducing postoperative morbidity. Caudal analgesia with bupivacaine is widely used but has a limited duration. Dexmedetomidine, an alpha-2 adrenergic agonist, may enhance analgesic efficacy when added to bupivacaine. This study aimed to compare the analgesic duration and haemodynamic effects of 0.5 µg/kg versus 1 µg/kg of dexmedetomidine as an adjuvant to 0.25% bupivacaine in caudal blocks. **Materials and Methods:** A prospective, randomised, comparative study was conducted on 60 paediatric patients (2–8 years, ASA I–II) undergoing infraumbilical surgeries at KAPV Govt Medical College, Tiruchirappalli. Patients were divided into two groups: Group A (0.5 µg/kg dexmedetomidine + 0.25% bupivacaine 1 mL/kg) and Group B (1 µg/kg dexmedetomidine + 0.25% bupivacaine 1 mL/kg). Intraoperative and postoperative pain scores, duration of analgesia, sedation levels, and haemodynamic parameters were assessed. **Result:** Group B exhibited significantly longer analgesia (1028 ± 81.47 min vs. 804 ± 55.93 min, p=0.001) and lower FLACC pain scores, with effective pain relief lasting up to 17 hours. Sedation was deeper in Group B, with higher Ramsay scores in the first 4 h postoperatively ($p<0.05$), although no respiratory depression occurred. Group B had a lower intraoperative heart rate (p=0.049, p=0.019, and p=0.001 at 10, 20, and 30 min, respectively) and blood pressure (p=0.003 at 30 min). Postoperatively, diastolic blood pressure remained lower for 2.5 h ($p<0.05$). No major complications were noted. **Conclusion:** The addition of 1 µg/kg dexmedetomidine to caudal bupivacaine significantly prolonged postoperative analgesia and provided better sedation in paediatric infraumbilical surgeries.

INTRODUCTION

The International Association for the Study of Pain defines Pain as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." Pain is one of the most misunderstood, underdiagnosed, and untreated medical problems, particularly in children.[1] Pain is a complex, subjective, perceptual phenomenon with several dimensions, such as intensity, quality, time course, and impact, which each individual uniquely experiences. Inadequate pain relief during childhood may have long-term negative effects, including harmful neuroendocrine responses, disrupted eating and sleep cycles and increased pain perception during subsequent painful experiences.[2]

Surgical trauma not only causes postoperative pain but also results in well-characterised human stress responses. The stress response is mediated by hypothalamus-pituitary-adrenal and sympathoadrenal interactions, which cause increased liberation of catecholamines and catabolic hormones on the one hand and decreased secretion of anabolic hormones. Thus, a catabolic state is produced, and a negative nitrogen balance results if the process continues in the postoperative period. Children receive significantly less medication regardless of pain intensity because round-the-clock opioid analgesics increase the risk of sedation and respiratory depression. Postoperative pain control is important in paediatric patients because poor pain control may result in increased morbidity and mortality.[3]

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Paediatric anaesthesiologists must remain at the forefront of the knowledgeable and safe use of pain interventions for infants and children and integrate pain management into the overall perioperative plan. The management of acute postoperative pain in paediatric patients can be accomplished using a multimodal approach. Neuraxial blocks are virtually free of measurable haemodynamic effects and are particularly well tolerated by young children. So, these approaches have become routine in infra-umbilical surgeries.[4]

The most common technique of epidural analgesia in children is caudal analgesia, which is commonly used in lower abdominal, urological, and lower limb surgeries. The ease of performing the block and the extensive safety record of its use in children are the reasons for the popularity of caudal analgesia in paediatric patients. They can be combined with general anaesthesia to reduce the requirement for volatile agents and opioids, allowing rapid, pain-free recovery with minimal postoperative vomiting and early resumption of oral intake. Depending on the volume, dose, or concentration of the local anaesthetic, caudal epidural blocks result in a sympathetic block, sensory analgesia, and motor block. Single-dose caudal analgesia with bupivacaine is very safe and has been effectively used in paediatric surgical procedures for the provision of postoperative analgesia.[5]

The major drawback is the relatively limited duration of postoperative analgesia with bupivacaine alone. Different methods, such as the use of adjuvants, have been attempted to increase the duration of analgesia with bupivacaine. Dexmedetomidine, a newer member of alpha-2 adrenergic agonist groups, is highly specific and selective for alpha-2 receptors. The addition of dexmedetomidine prolongs the duration of action of bupivacaine after intrathecal and epidural administration in patients and causes sedation without respiratory depression.[6]

Given the complexity of the pain mechanism, effective pain treatment requires multimodal therapies that target multiple sites along the pain pathways. Pain can be treated at the peripheral level using local anaesthetics, NSAIDs, or opioids.[7] At the spinal cord level, it can be treated with local anaesthetics, opioids, alpha 2 agonists, and cortical-level opioids. Most cases of moderate-to-severe pain are best treated with a combination of analgesic techniques.

This study aimed to compare the efficacy and safety of caudal epidural administration of dexmedetomidine 0.5 mg/kg with 0.25% bupivacaine versus dexmedetomidine 1 mg/kg with 0.25% bupivacaine for providing intraoperative and postoperative pain relief in children undergoing infra umbilical surgeries.

MATERIALS AND METHODS

This prospective randomised comparative study included 60 patients scheduled for infra-umbilical surgeries in the Department of Anesthesiology at KAPV Govt Medical College, Tiruchirappalli, from January 2019 to September 2019. The study was conducted after obtaining approval from the Institutional Ethics Committee, and informed consent was obtained from all the patients.

Inclusion Criteria

Paediatric patients aged 2–8 years with American Society of Anesthesiologists (ASA) Physical Status I–II who were scheduled for elective infraumbilical surgeries were included.

Exclusion Criteria

Patients with a history of parent/guardian refusal, allergy to any of the study drugs, infection at the injection site, known coagulopathies or ongoing anticoagulation therapy, or congenital abnormalities of the lower spine and meninges were excluded.

Methods: Patients were randomised into two groups: Group A received 0.5 µg/kg dexmedetomidine with 0.25% bupivacaine (1 mL/kg), and Group B received 1 µg/kg dexmedetomidine with 0.25% bupivacaine (1 mL/kg). Surgery commenced 10 min after caudal block administration. Patients with a ≥20% increase in heart rate and blood pressure from baseline were considered to have an inadequate caudal block. They were administered fentanyl (2 µg/kg IV), after which they were excluded from the study. Patients were kept nil per oral for six hours preoperatively, and a preoperative dose of oral midazolam (0.5 mg/kg) was administered 20 minutes before surgery.

Anaesthetic management included securing IV access and administering Ringer's lactate based on the 4-2-1 rule. Standard monitors (ECG, SpO2, and NIBP) were connected, and preoxygenation with 100% oxygen was performed for three minutes. Premedication consisted of intravenous (IV) glycopyrrolate (0.02 mg/kg), followed by induction with propofol (2 mg/kg) and neuromuscular blockade using atracurium (0.5 mg/kg). The airway was secured using an appropriately sized endotracheal tube or laryngeal mask airway. Anaesthesia was maintained with a mixture of oxygen and nitrous oxide (1:2), sevoflurane (1–2%), and atracurium. Surgery began 10 min after the caudal block, with fentanyl rescue and exclusion criteria applied for cases of inadequate block.

Intraoperative monitoring included heart rate, blood pressure (systolic, diastolic, and mean arterial pressure), and ETCO2 every five minutes for one hour. Neuromuscular blockade was reversed with glycopyrrolate (0.008 mg/kg) and neostigmine (0.04 mg/kg), and extubation was performed after thorough suctioning. Postoperatively, the analgesia duration was recorded as the time from the caudal block to the first need for rescue analgesia. Pain was assessed using the FLACC scale at 0, 1, 2, 3, 4, 6-, 8-, 12-, and 24 hours post-extubation, with scores ≥4 warranting diclofenac (1–2 mg/kg) or ibuprofen (4–8 mg/kg). Sedation was evaluated using the Ramsay Sedation Scale at these same intervals.

Vital parameters, including pulse rate and NIBP, were monitored, and complications, such as nausea,

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vomiting, urinary retention, and respiratory depression, were documented. Bradycardia (HR <60/min) was treated with atropine, hypotension (systolic BP <70 + [2 × age in years] with altered tissue perfusion) was managed with fluid boluses, and respiratory depression (SpO2 <95%) was noted. Oral feeds were allowed after six hours, and neurological evaluation was performed before discharge.

Figure 1: CONSORT diagram

The equipment and drugs used included various sizes of laryngoscopes, gum elastic bougie, Guedel's airway, Ringer's lactate, midazolam syrup, glycopyrrolate, propofol, atracurium, sevoflurane, ephedrine, and emergency drugs. The monitoring devices included ECG, NIBP, SpO2, and temperature monitors. Syringes (2, 5, and 10 mL), IV cannula (22G and 24G), IM needles (23G), endotracheal tubes, and laryngeal mask airways were used. The medications included dexmedetomidine (50 mcg/mL, 1 mL ampoule) and bupivacaine (0.5%, 20 mL vial).

Statistical analysis: Data are presented as mean, standard deviation, frequency, and percentage. Continuous variables were compared using the independent sample t-test. Significance was defined as $p < 0.05$ using a two-tailed test. Data analysis was performed using IBM SPSS version 21.0.

RESULTS

The age and weight distributions were comparable between the groups, with a mean age of approximately 5 years and a mean weight of approximately 15 kg. The duration of surgery was also similar, ranging from 25 to 60 min, with mean durations of 37.50 ± 7.740 min in Group A and 41.83 ± 10.866 min in Group B. However, the mean duration of analgesia was significantly longer in Group B (1028.00 ± 81.469 min) than in Group A (804.00 ± 55.931 min, p=0.001) [Table 1].

Table 1: Demographic and clinical parameters.

	Mean±SD		P-value
	Group A	Group B	
Age (In years)	5.67±1.936	6.13±1.479	0.298
Weight	15.17±3.185	15.73±3.216	0.496
Duration of surgery	37.50±7.740	41.83±10.866	0.08
Duration of analgesia	804.00±55.931	1028.00±81.469	0.001

In Group A, there were 25 (83%) boys and 5 (17%) girls, whereas in Group B, there were 29 (97%) boys and one (3%) girl. The gender distribution was similar in both groups. Among the 60 children, 26 in each group underwent surgeries involving the thoracolumbar dermatomes, requiring a maximum block level of T10, while the remaining 34 surgeries in both groups involved the sacral dermatomes [Table 2].

Table 2: Distribution of gender and types of surgeries

		Frequency (%)	
		Group A	Group B
Gender	Male	25 (83%)	29 (97%)
	Female	5 (17%)	1 (3%)
Surgeries	Herniotomy	8 (27%)	5 (17%)
	PVSL	16 (54%)	11 (37%)
	Orchidopexy	4 (13%)	7 (23%)
	Appendicectomy	1 (3%)	1 (3%)
	Lithotripsy	0	1 (3%)
	Urethroplasty	1 (3%)	5 (17%)

The baseline and pre-incision heart rates were comparable between the groups. Five minutes after the incision, the heart rates were similar in both groups. Intraoperatively, heart rates at 5-minute intervals differed significantly between the groups, with significant differences observed at 10 min (p = 0.049), 20 min (p = 0.019), and 30 min (p = 0.001). Bradycardia requiring atropine intervention was observed in two children during the study [Figure 2].

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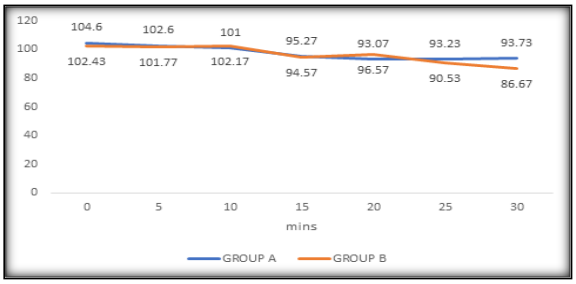

Figure 2: Intra-operative heart rate

The mean systolic and diastolic blood pressures were comparable between the groups before the incision. Intraoperatively, the systolic blood pressure was significantly lower in Group B at 30 min (p = 0.003) [Figure 3].

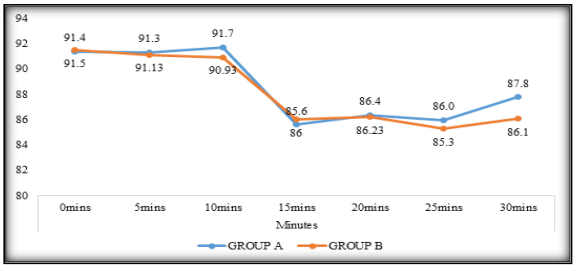

Figure 3: Intra-operative systolic blood pressure

The mean diastolic pressure was significantly lower in Group B than in Group A at 20, 25, and 30 min postoperatively (p < 0.05) [Figure 4].

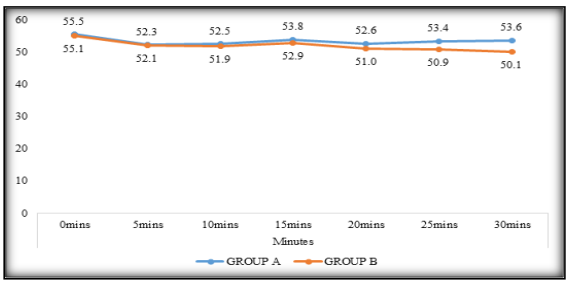

Figure 4: Intra-operative diastolic blood pressure

The mean arterial pressure was significantly lower in Group B than in Group A at 10, 25, and 30 min postoperatively (p < 0.05) [Figure 5].

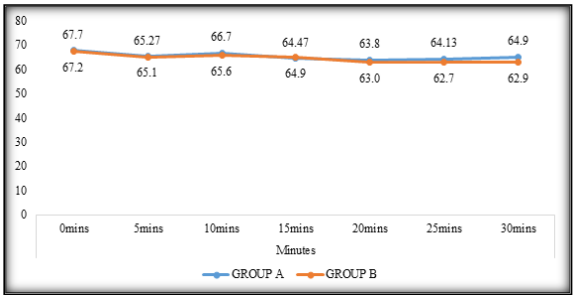

Figure 5: Intra-operative mean arterial pressure

At 30 min postoperatively, the mean heart rate was significantly higher in Group B than in Group A (p = 0.001). However, from 1 to 24 h postoperatively, heart rates remained comparable between the two groups [Figure 6].

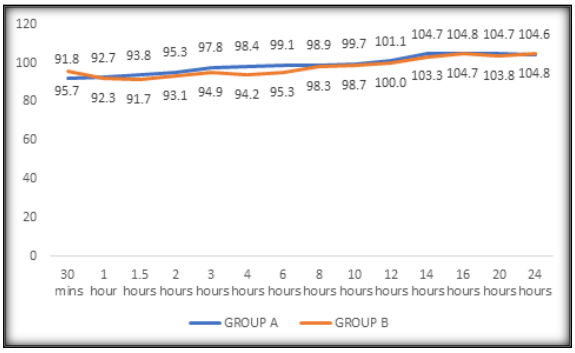

Figure 6: Post-operative heart rate

The mean systolic blood pressure remained comparable between the groups throughout the postoperative period [Figure 7].

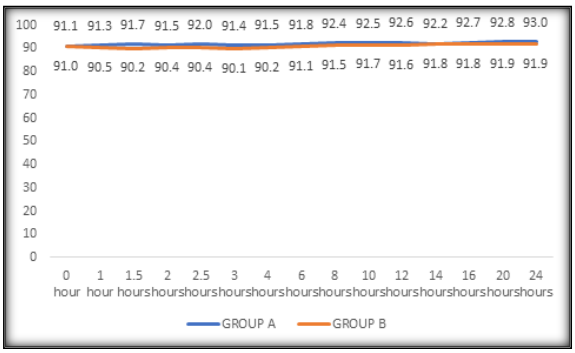

Figure 7: Post-operative systolic blood pressure

Postoperatively, the mean diastolic blood pressure differed significantly between the groups from 30 min to 2.5 h (p < 0.05) but remained comparable from 3 to 24 h [Figure 8].

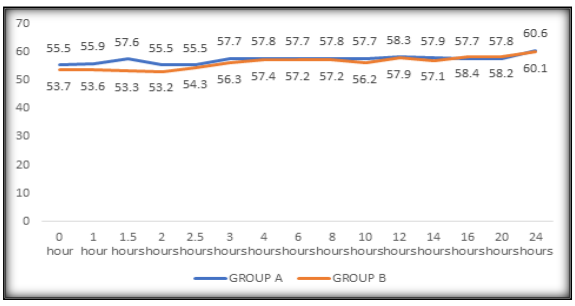

Figure 8: Post-operative diastolic blood pressure

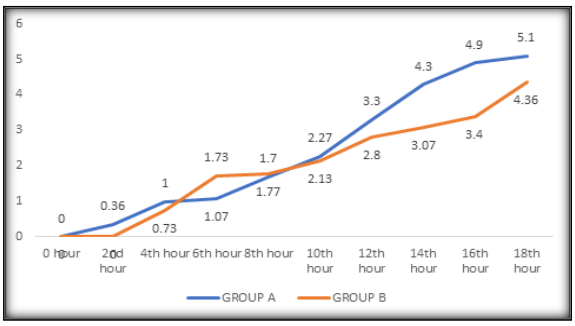

Figure 9: FLACC score

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The FLACC scores were significantly lower in Group B than in Group A at all assessed time points ($p < 0.05$). Effective analgesia (FLACC score <4) was maintained for up to 13 h in Group A and 17 h in Group B [Figure 9].

FLACC scores assessed every 4 h were significantly lower in Group B, indicating superior analgesia. A FLACC score of 4 was reached at the 13th hour in 21 patients in Group A, whereas in Group B, it was attained at the 17th hour in 19 patients, reflecting prolonged analgesic efficacy in Group B [Table 3].

Table 3: Distribution for FLACC score

FLACC Score	Zero		One		Two		Three		Four		≥ Five	
Hours	A	B	A	B	A	B	A	B	A	B	A	B
0 hour	30	30										
2 hours	19	16	11	14								
4 hours		8	30	22								
6 hours			28	8	2	22						
8 hours			10	7	19	23	1					
10 hours					22	26	8	4				
12 hours						6	21	24	9			
14 hours								28	21	2	9	
16 hours								19	3	10	27	1
18 hours									1	20	29	10

Ramsay sedation scores were significantly higher in Group B than in Group A during the first four postoperative hours ($p < 0.05$). Adequate sedation persisted for up to 5 h in Group A and 6 h in Group B [Figure 10].

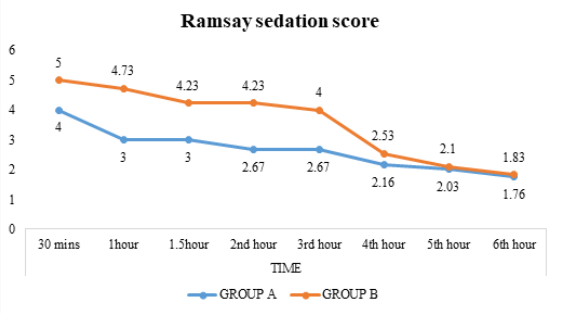

Figure 10: Ramsay sedation score

DISCUSSION

Our study found that a single pre-surgical caudal injection of bupivacaine with dexmedetomidine (1 µg/kg) provided effective and prolonged analgesia for infraumbilical and perineal surgeries. This aligns with Al-Zaben et al., who reported improved postoperative analgesia and delayed first analgesic request with dexmedetomidine added to caudal bupivacaine in paediatric infraumbilical surgery.8 Similarly, Goudarzi et al. found prolonged analgesia with dexmedetomidine-lidocaine in paediatric lower abdominal surgeries.[9] The synergistic effect of bupivacaine and dexmedetomidine in our study is consistent with Mostafa et al. and Yao et al., who reported extended sensory block and reduced pain scores with dexmedetomidine in caudal and intrathecal anaesthesia.[10,11]

The mean age of participants in both groups was comparable, averaging around five years, with an age range of 3–8 years. All children were premedicated with intraoral midazolam (0.5 mg/kg), as recommended by Hosalli et al. The majority of procedures performed were inguinal hernia repair, hydrocele repair, orchidopexy, and urethroplasty. The marginal decrease in blood pressure observed in our study can be attributed to the physiological effects of anaesthesia induction and the successful administration of a caudal block.[12]

Hosalli et al. demonstrated that 1 mL/kg of 0.25% bupivacaine with epinephrine effectively provided sensory blockade over 13 dermatomes in children undergoing high procedures. Similarly, in our study, a caudal injection volume of 1 mL/kg was sufficient for both thoracolumbar and sacral surgeries.12 Other studies have also used a comparable volume of local anaesthetic for thoracolumbar surgery. Dexmedetomidine has been widely used in paediatric patients without significant respiratory or hemodynamic complications. While haemodynamic side effects are generally less pronounced in children than in adults, they may be dose-dependent, as reported by Konakci et al. The primary side effects of neuraxial dexmedetomidine include hypotension and bradycardia.[13]

The antihypertensive effect of dexmedetomidine is mediated by the stimulation of α2 inhibitory neurones in the medullary vasomotor centre of the brainstem, leading to decreased norepinephrine turnover and reduced sympathetic outflow from the central nervous system. Bradycardia occurs due to increased vagal tone and reduced sympathetic activities. Compared to clonidine, dexmedetomidine has an eight-fold greater affinity for α2 receptors and exhibits higher selectivity for α2a receptors, which are primarily responsible for its sedative and analgesic effects. Our study corroborates previous findings regarding the haemodynamic effects of dexmedetomidine.

In our study, the mean duration of analgesia was 1028 min in Group B (bupivacaine with 1 µg/kg dexmedetomidine) and 804 min in Group A (bupivacaine with 0.5 µg/kg dexmedetomidine). These results are consistent with findings from El-Hennawy et al., who reported that the addition of clonidine or dexmedetomidine to bupivacaine

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prolongs the duration of analgesia in paediatric caudal blocks.[14]

Xiang et al. found that caudal dexmedetomidine significantly increased the duration of postoperative analgesia in children undergoing hernia sac traction. Similarly, in our study, effective analgesia, as indicated by a FLACC score of less than 4, was maintained for 12-13 hours in Group A and 15-17 hours in Group B postoperatively. These results confirm that dexmedetomidine enhances the duration of analgesia when added to bupivacaine.[15]

Pain assessment using the FLACC scale was performed at 1, 2, 3, 4, 6, 8, 12, and 24 h after caudal block administration, following the methodology of Meenakshi et al. The duration of postoperative analgesia was defined as the interval between caudal block administration and the first requirement for supplementary analgesia. When the FLACC score exceeded 4, analgesia was supplemented with either diclofenac sodium suppository (1-2 mg/kg) or syrup ibuprofen (4-8 mg/kg).[16] Our findings align with those of Anand et al., who reported that ropivacaine combined with dexmedetomidine provided analgesia for up to 16 h postoperatively. In contrast, ropivacaine alone was effective only until the 6th hour ($p<0.001$).[17]

Sedation was assessed at multiple time intervals (30 min, 1 h, 1.5 h, 2 h, 3 h, 4 h, 5 h, and 6 h postoperatively) using Ramsay's sedation score. A score of at least 2 (cooperative, oriented, tranquil) was considered adequate sedation, and no patient exhibited a score of 6 (unresponsiveness). These results are consistent with the findings of Anand et al., who reported superior sedation in the ropivacaine-dexmedetomidine group compared to the ropivacaine-only group.[17] Similar findings were observed in studies by El-Hennawy et al., confirming that dexmedetomidine enhances sedation when added to bupivacaine.[14]

CONCLUSION

Caudal administration of dexmedetomidine (1 µg/kg) with 0.25% bupivacaine provided superior intraoperative and postoperative analgesia compared to dexmedetomidine (0.5 µg/kg) with 0.25% bupivacaine in paediatric infraumbilical surgeries, with notable differences in haemodynamic parameters. However, the incidence of side effects was lower with the 0.5 µg/kg dose of dexmedetomidine.

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