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ORIGINAL ARTICLE

Compare the Analgesic Effects of Clonidine and Dexmedetomidine Added to Bupivacaine for Caudal Analgesia in Children Undergoing Lower Abdominal Surgeries: A Double-Blind Randomized Trial

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ABSTRACT

Background: Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in pediatric anaesthesia. When adjuvants are added to local anaesthetic agents, quality and duration of caudal analgesia are enhanced. This study was conducted to compare analgesic effects of adjuvants clonidine and dexmedetomidine when added to bupivacaine for caudal analgesia amongst children undergoing lower abdominal surgeries.

Material and Methods: It was a hospital based randomized double blinded prospective study, conducted among children aged between 1 and 10 years with ASA grade 1 and 2 who underwent elective infra umbilical surgery. Children were allocated into group three groups group B (received 0.25% bupivacaine 1 ml/kg), group C (received clonidine 1 mcg/kg with 0.25% bupivacaine 1 ml/kg) and group D (received dexmedetomidine 1mcg/kg with 0.25% bupivacaine 1 ml/kg)

Results: The duration of postoperative analgesia was longest in group D (13.20 hours) when compared with group C (10.47hrs) and group B (6.73 hours) and the difference was statistically significant ($p<0.001$). There was a significant difference between the groups in the FLACC score measured second hourly in the post operative period. FLACC score was lowest in the group D and highest in the group B ($p<0.001$). This was because of the improved quality of analgesia provided by adding adjuvant dexmedetomidine to local anaesthetic solution.

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Conclusion: This study showed that clonidine and particularly dexmedetomidine when combined with bupivacaine significantly improved the quality and duration of caudal analgesia.

KEYWORDS

• Caudal • Local anaesthetic • Adjuvants • Bupivacaine • Clonidine • Dexmedetomidine

INTRODUCTION

Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in pediatric anesthesia.[1] It is a reliable and safe technique that can be used with general anesthesia for intraoperative and postoperative analgesia in patients undergoing abdominal and lower limb surgery.[2] Furthermore, it is easy to perform in younger children with high success rate than in adults. The main disadvantage of caudal anesthesia is the short duration of action after a single injection of local anaesthetic agent. Prolongation of caudal analgesia using a single shot technique has been achieved by the addition of various adjuvants.[3]

Various adjuvants have been tried but addition of adjuvants which are safer with least adverse events should be preferred. It has been suggested that alpha-2 agonists improve the characteristics of local anaesthetic solutions through several possible mechanisms such as vasoconstriction,[4] facilitation of the C-fibre blockade by the local anaesthetic solution[5] or by an action, at spinal cord level, caused by slow retrograde axonal transport along the nerve.[5] Alpha-2 agonists provide pain relief by independent mechanism not like opioids. Clonidine is a centrally acting selective partial alpha-2 adrenergic agonist (220:1 alpha-2 to alpha-1) whereas dexmedetomidine is a highly selective alpha-2 agonist (1620:1 alpha-2 to alpha-1).[6] This study was conducted to compare analgesic effects of adjuvants clonidine and dexmedetomidine when added to bupivacaine for caudal analgesia amongst children undergoing lower abdominal surgeries. Objectives were to determine the quality and duration of analgesia of bupivacaine alone and following addition of clonidine and dexmedetomidine in caudal analgesia and to study incidence of adverse effects.

MATERIALS AND METHODS

This study design was a randomized, double blinded prospective study conducted at a tertiary care teaching hospital. After approval from hospital ethics committee, ninety children scheduled for elective infra umbilical surgeries were included in the study. Written informed consent was taken from parents. Children were randomized into three groups of 30 each. Children with ASA physical status I & II, aged between 1 and 10 years, scheduled for elective infra umbilical surgery were assessed for eligibility. Children with history of developmental delay and mental retardation, coagulopathy, allergy to study medications, infection at the site of caudal block, skeletal deformities in the caudal region and parental refusal were excluded from the study.

Each child participating in the study underwent thorough preoperative evaluation. Complete blood count was done for all children as an institutional protocol. Standard preoperative fasting guidelines were followed.[7] On the day of surgery all children were premedicated with oral Midazolam (0.5mg/kg), 30 minutes before induction. The subjects were randomly and evenly assigned into three groups B, C and D.

Group B: Bupivacaine 0.25% (1 ml/ kg)

Group C: Clonidine 1 mcg/ kg with bupivacaine 0.25% (1 ml/ kg)

Group D: Dexmedetomidine 1 mcg/ kg with bupivacaine 0.25% (1 ml/ kg)

Once the child was sedated, inhalational induction with sevoflurane (4-8%) in oxygen was performed, intravenous line was secured, and standard ASA monitoring were attached. A neuromuscular blocking agent (Inj. Atracurium 0.5mg/kg i.v.) was given to facilitate endotracheal intubation. After intubation, child was placed in lateral decubitus position and a single shot caudal

block was performed according to the group under sterile conditions using 23 G needle by standard loss of resistance technique. The drug to be injected in the caudal block was prepared by an anaesthesiology senior resident unaware of the nature of study, as per patient's weight and group assigned.

Anesthesia was maintained using sevoflurane with 50% medical air in oxygen and minimal alveolar concentration (MAC) was maintained between 1.0-1.2. No other narcotics, analgesics, antiemetics or sedatives were used intra-operatively. All surgeries were started at least 10 minutes after performing caudal block to allow the action of caudal analgesia since no other analgesia had been used. Meanwhile, this time was used for cleaning, draping and preparation for surgery.

Block was considered successful when there is a decrease in heart rate more than 10% from preoperative heart rate, absence of heart rate increasing upon incision, no intraoperative or postoperative opioid supplementation. If caudal block was unsuccessful, rescue analgesia of Inj. Fentanyl 1-2 mcg/ kg i.v. was given and patients were omitted from the study. Intraoperative hypotension, bradycardia, anesthesia time, operating time were noted. Anesthesia time was the time from induction to extubation, operating time was from skin incision to closure. All patients were reversed with Inj.Neostigmine 50 mcg/ kg i.v. and Inj.Glycopyrolate 10 mcg/kg i.v. and shifted to PACU. Hypotension and bradycardia were defined as 20% decrease in MAP or HR respectively from preoperative values. Pediatric observational FLACC[8] pain scale (*Table 1*) with 0–10 score range were used (*Table 2*). Pain was assessed upon arrival to PACU and every 2 hours, till the score was more than 4. If the FLACC score was more than 4 in PACU, the block was considered failure and Inj. Fentanyl 1-2 µgm/ kg i.v. was given to the child & omitted from study.

All Children stayed in PACU until fully awake and comfortable, then moved to the ward. If the FLACC pain scale score was more than 4 in the ward, paracetamol suppository 30mg/kg was given per rectally. The duration of adequate caudal analgesia (from the time of caudal injection to the first time the FLACC pain scale score more than 4) were recorded. Nausea, vomiting, urinary retention, and FLACC pain scale were continuously monitored in PACU and the ward. Vomiting was treated with 100 mcg/kg i.v. of Inj. Ondansetron. Postoperative urinary retention was defined as inability to void urine for 8 hours post-surgery.[9] Bradycardia was treated with Inj. Atropine 20 mcg/kg, and hypotension with fluid bolus and vasopressors if needed.

Table 1: FLACC observational pain assessment scale

Categories	Scoring		
	0	1	2
Face	Smile or no particular expression	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
Cry	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 talking to, distractable	Difficult to console

Table 2: FLACC score pain intensity classification

0	No pain
1-3	Mild
4-7	Moderate
8-10	Severe

RESULTS

A sample size of 30 per group was calculated with a 5% alpha error, a correlation coefficient of 0.8, and 80% study power. Statistical analysis was conducted using SPSS version 25.0. Variables like age, weight, intraoperative heart rate, mean arterial pressure variation between the groups, duration of anaesthesia, duration of surgery, duration of analgesia were analysed using ANOVA. Gender distribution and ASA grade distribution in all three groups were analysed using Fischer-exact test. The

demographic profile of the patients (age, sex and weight), anesthesia time and surgery time in group B, group C and group D were comparable. Gender, ASA grade and type of surgeries were also comparable across all three groups. Duration of analgesia recorded was highest in group D with p value < 0.001 (*Table 3*).

No significant difference was found in the mean heart rate between groups B, C, and D (*Table 4*). All three groups demonstrated a reduction in heart rate approximately 10 minutes following caudal analgesia, attributable to the efficacy of the caudal analgesia and the sympathetic blockade induced by the caudal block. Significant difference was noted in mean blood pressure (MAP) among groups B, C, and D (*Table 5*). The significant difference in MAP is seen after 15 minutes of caudal block depicting the systemic absorption of the drug.

Utilizing the Kruskal-Wallis test, a p-value of less than 0.05 indicated a significant difference between the median FLACC grades in groups B, C, and D (*Tables 6 & 7*). FLACC score was lowest in the group D and highest in the group B. No significant episodes of nausea, vomiting and urinary retention (*Figure 3*) postoperatively in any group but incidences of urinary retention were more with dexmedetomidine group.

Table 3: Demographic profile, surgeries, duration of anaesthesia, duration of surgery and duration of block

	Group B	Group C	Group D	P value
Characteristics				
Age (years)	3.8±2.02	4.24±2.15	3.59±2.36	0.504
Sex (M: F)	26:4	27:3	29:1	0.522
Weight (kg)	14.33±3.54	14±3.86	13.42±4.88	0.686
ASA grade (I/II)	22/8	25/5	20/10	0.371
Surgical procedures				
Herniotomy	12	15	10	
Urethroplasty	4	7	8	
Circumcision	6	4	4	
Orchidopexy	3	1	8	
ASARP	2	1	3	
Gonadectomy	-	1	-	
Herniotomy & Orchidopexy	-	1	-	
Anal dilatation	1	-	-	
Internal sphincter	1	-	-	
Biopsy				
Thiersch wiring	1	-	-	
Duration of anesthesia (min)	59.83±18.31	60±18.89	63.33±18.3	0.71
Duration of surgery (min)	40±15.76	39.33±16.44	40.33±15.14	0.71
Duration of analgesia (hr)	6.73±0.98	10.47±1.01	13.20±1.45	<0.001

Data are expressed as mean±SD. p value < 0.05 is considered statistically significant.
ASARP – Anterior sagittal anorectoplasty

Table 4: Comparison of mean heart rate in group B, group C and group D

Number of patients		Group B		Group C		Group D		P-value
		Mean	SD	Mean	SD	Mean	SD	
Preoperative	30	101.97	9.05	104.40	7.28	105.13	11.43	0.398
0 min	30	103.37	9.60	107.37	8.05	104.93	11.56	0.289
10 min	30	99.87	10.71	107.37	12.25	105.27	13.53	0.054
20 min	30	96.57	7.33	102.13	12.16	99.73	11.98	0.137
30 min	30	96.07	6.95	99.23	12.10	96.37	9.73	0.39
40 min	30	93.73	6.80	95.39	12.35	94.72	8.67	0.816
50 min	30	93.79	8.91	96.53	12.69	94.83	9.93	0.735
60 min	30	94.38	8.86	96.92	12.03	94.60	10.85	0.783
70 min	30	95.56	6.39	94.44	10.62	96.00	9.20	0.928
80 min	30	97.17	7.44	95.33	9.35	98.00	9.39	0.846
90 min	30	89.00	8.49	90.50	4.65	95.75	1.71	0.209

Table 5: Comparison of mean blood pressure in group B, group C and group D

Number of patients		Group B		Group C		Group D		P-value
		Mean	SD	Mean	SD	Mean	SD	
Preoperative	30	62.73	4.68	60.50	3.79	61.40	6.37	0.234
0 min	30	62.10	4.79	60.83	4.72	60.17	6.50	0.375
10 min	30	60.33	4.24	57.63	4.60	56.30	6.02	0.008
20 min	30	59.20	5.59	56.07	4.59	53.23	6.21	< 0.001*
30 min	30	58.13	6.02	54.07	5.06	51.27	6.51	< 0.001*
40 min	30	58.12	6.35	52.71	5.16	51.52	7.08	< 0.001*
50 min	30	57.89	6.90	53.47	5.56	51.52	9.07	0.027*
60 min	30	56.25	6.08	54.38	5.45	51.40	8.26	0.145
70 min	30	57.33	6.69	51.44	3.84	51.80	6.03	0.063
80 min	30	57.83	8.11	49.83	4.88	50.80	6.66	0.092
90 min	30	63.00	7.07	47.50	4.36	54.50	9.71	0.118

* Significant (ANOVA test used)

Table 6: Comparison of FLACC score in group B, group C and group D

0		FLACC score					Total
		1	2	3	≥4		
	Group B	6	24	0	0	0	30
2nd hr	Group C	30	0	0	0	0	30
	Group D	30	0	0	0	0	30
	Group B	0	1	17	12	0	30
4th hr	Group C	7	23	0	0	0	30
	Group D	21	9	0	0	0	30

table cont....

0		FLACC score					Total
		1	2	3	≥4		
	Group B	0	0	0	11	19	30
6th hr	Group C	0	13	17	0	0	30
	Group D	1	27	2	0	0	30
	Group B	0	0	0	0	30	30
10th hr	Group C	0	0	0	8	22	30
	Group D	0	1	22	6	1	30
	Group B	0	0	0	0	30	30
14th hr	Group C	0	0	0	0	30	30
	Group D	0	0	0	3	27	30

Table 7: Comparison of median FLACC score in group B, group C and group D

FLACC at	Median FLACC			P-value
	Group B	Group C	Group D	
2nd hr	1	0	0	< 0.001
4th hr	2	1	0	< 0.001
6th hr	4	2	1	< 0.001
8th hr	4	2	1	< 0.001

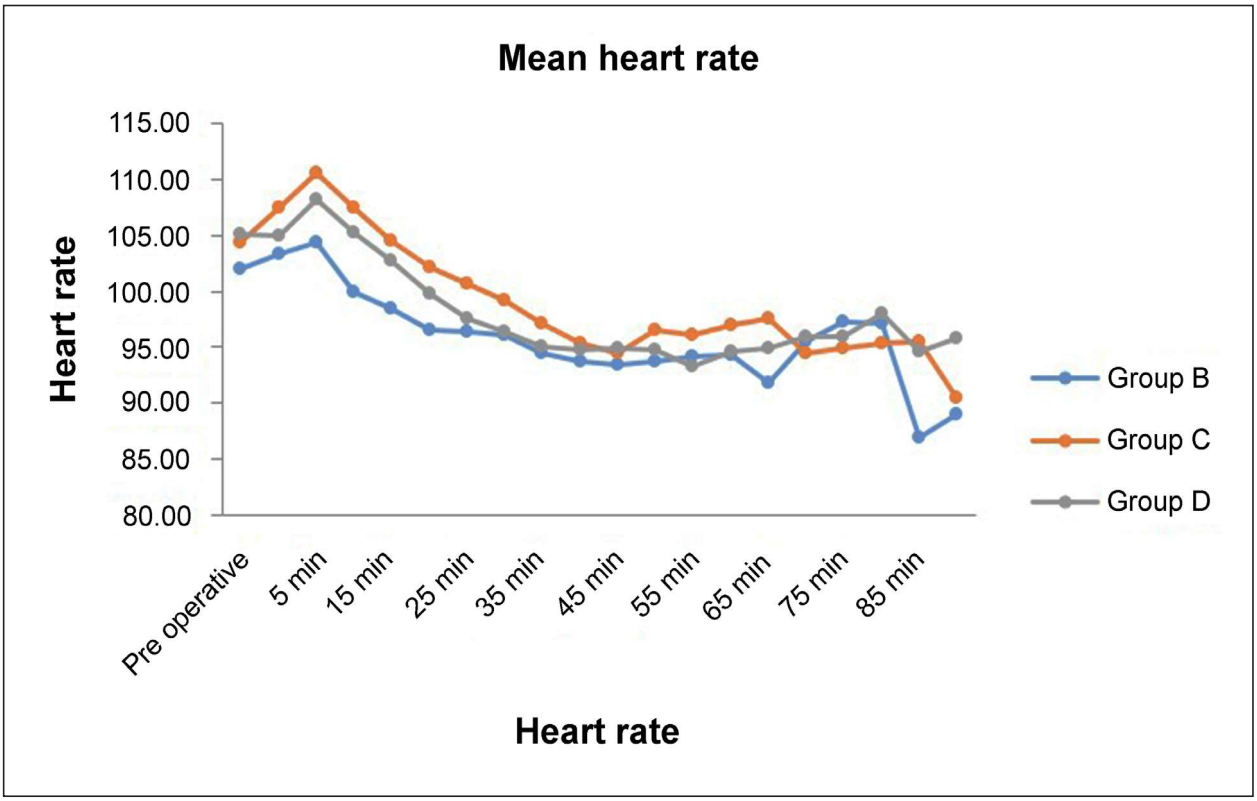

Figure 1: Comparison of mean heart rate in group B, group C and group D

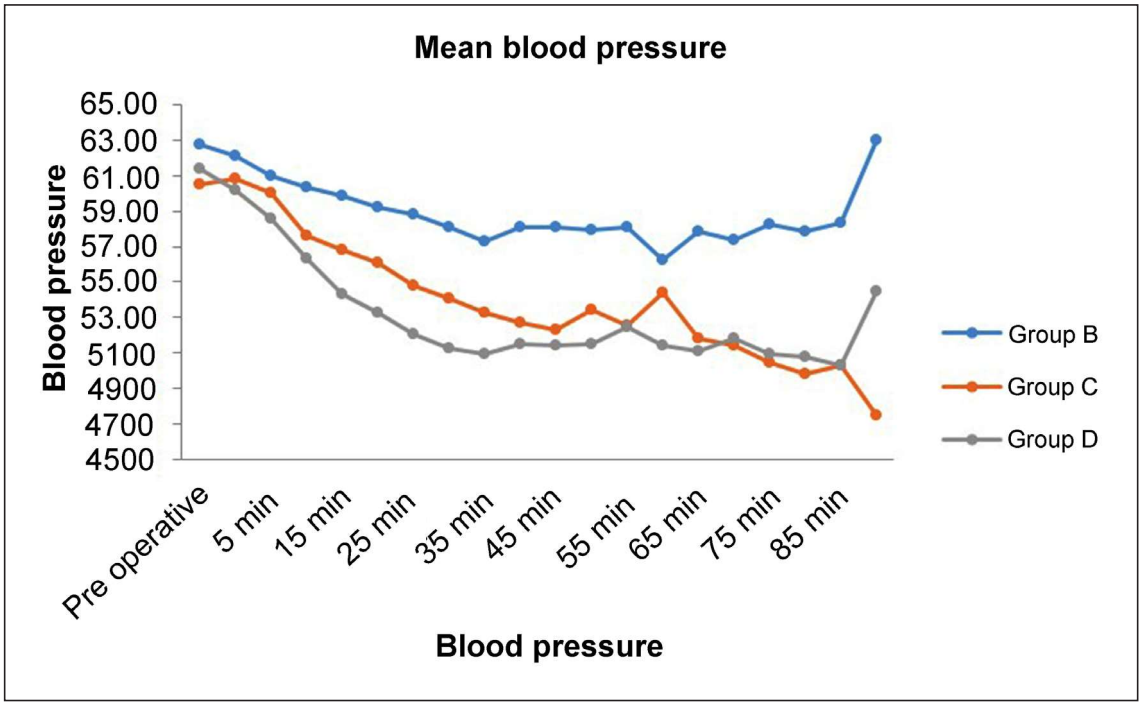

Figure 2: Comparison of mean blood pressure in group B, group C and group D

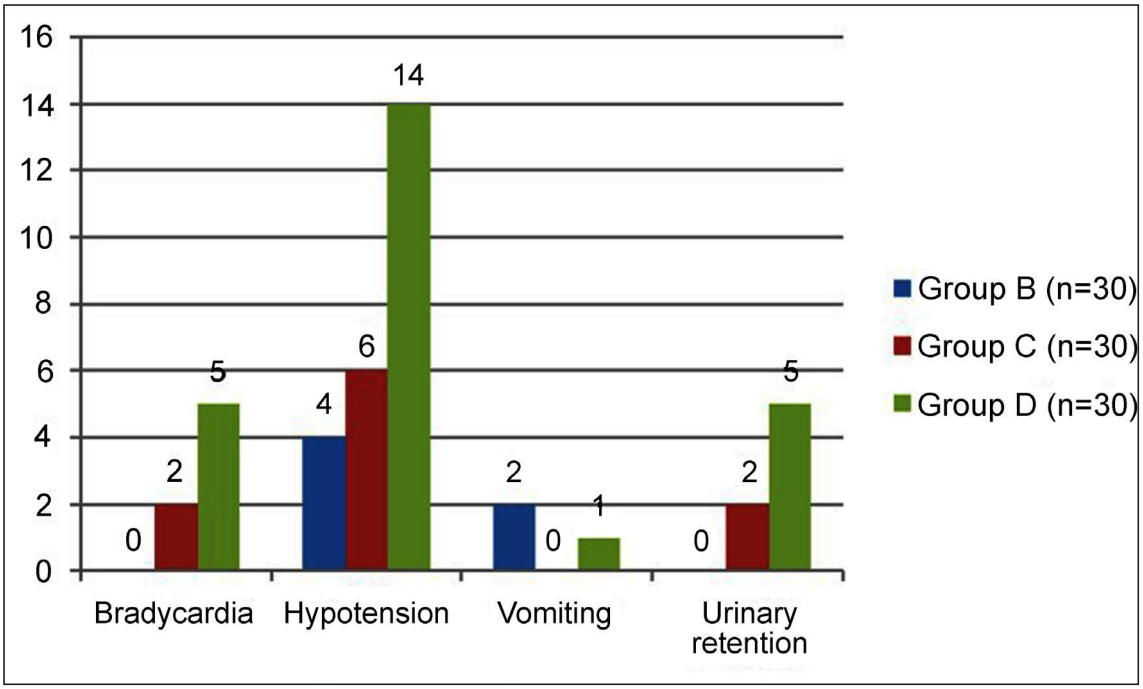

Figure 3: Incidence of adverse effects in group B, C & D

DISCUSSION

The present study was conducted to compare the quality and duration of analgesia when clonidine and dexmedetomidine were added to bupivacaine as adjuvants in pediatric caudal analgesia. The peri-operative haemodynamic remained stable across the three groups. Caudal clonidine (1 µg/kg) with 0.25% bupivacaine (1 ml/kg) and predominantly caudal dexmedetomidine 1 mcg/kg with 0.25% bupivacaine (1 ml/kg) for pediatric lower abdominal surgeries achieved significant duration of postoperative pain relief when

compared with caudal bupivacaine alone. Incidence of bradycardia was more with dexmedetomidine group than with clonidine but not statistically significant. None of these patients required atropine for bradycardia. Incidence of hypotension was significantly higher with dexmedetomidine than with clonidine, but all patients were managed with fluid bolus and none requiring vasopressors. Hypotension was more after 15 minutes of caudal block which significantly correlates with systemic absorption of dexmedetomidine. Children in the clonidine and dexmedetomidine groups exhibited better sedation compared to those in the bupivacaine group, due to the sedative and analgesic properties of clonidine and dexmedetomidine. FLACC score in group clonidine & dexmedetomidine were significantly low which may be due to their alpha-2 agonist property.

Our study was like the one conducted by El-Hennawy *et al*.[10] who showed that addition of dexmedetomidine or clonidine to caudal bupivacaine significantly prolonged analgesia in children undergoing lower abdominal surgeries with no significant advantage of dexmedetomidine over clonidine and without an increase in incidence of side-effects. The primary difference was that we used clonidine and dexmedetomidine at a dosage of 1 mcg/kg rather than 2 mcg/kg, achieving comparable outcomes.

Our study findings align with those of Goyal V *et al*,[11] demonstrating that the addition of dexmedetomidine as an adjuvant to Bupivacaine prolongs the duration of caudal analgesia and enhances hemodynamic stability without increasing adverse effects in pediatric patients undergoing infraumbilical surgeries. Parameswari *et al*[12] also evaluated adding clonidine to bupivacaine for prolonging caudal analgesia in children undergoing infra umbilical surgical procedures. They concluded that the mean duration of analgesia was significantly longer in the clonidine group.

This study also found that adding clonidine or dexmedetomidine to bupivacaine significantly prolonged analgesia duration without causing significant postoperative complications such as bradycardia, hypotension, respiratory depression, vomiting, or urinary retention, as indicated by other studies.[13,14]

CONCLUSION

The present study has shown that caudal clonidine 1 mcg/kg and dexmedetomidine 1 mcg/kg with 0.25% bupivacaine 1 ml/kg for pediatric lower abdominal surgeries achieved significantly increased postoperative pain relief, which resulted in a better quality of sleep and prolonged duration of arousable sedation following sevoflurane anaesthesia. There was a significantly increased incidence of intraoperative hypotension in dexmedetomidine group with 1 mcg/kg, but none required vasopressors. No episodes of clinically significant postoperative complications were observed in any of the groups. Hence, we found dexmedetomidine and clonidine to be safe and effective adjuvants for caudal analgesia in pediatric surgery.

Conflict of interest: Nil

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