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# **ORIGINAL ARTICLE**

# **Comparative Study Between Dexmedetomidine and Magnesium Sulphate as Adjuvants to Bupivacaine for Caudal Analgesia in Pediatrics**

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#### Abstract

*Background*: Assessing children's postoperative pain is complicated by the presence of a powerful emotional component.

*Purpose*: To match the safety and duration of postoperative pain relief using caudal magnesium sulfate and dexmedetomidine as adjuvants with bupivacaine 0.25 % in pediatric patients undergoing infraumbilical surgeries.

Patients and methods: Sixty children cases with American Society of Anesthesiologists classes I and II, weighing up to 20 kg, were enrolled in this randomized controlled prospective trial at Al-Azhar University Hospitals (Assiut). Each of the three groups consisted of 20 patients: group A (dexmedetomidine), group B (magnesium), and group C (control).

*Results*: Our study showed that onset of the caudal block was faster in group A than group B and group C, also was faster in group B than group C, but the difference was not statistically significant. Also, duration of the caudal block was highly significant longer duration of the caudal block in group A and group B matched to group C. There was no significant difference in heart rate measurements on adding dexmedetomidine or magnesium, but it was significantly lower in cases received dexmedetomidine. Pain score was significantly lower in group A and group B than group C till 12 h postoperatively.

*Conclusion*: In comparison to magnesium sulfate, caudal block is enhanced when dexmedetomidine is administered as an adjuvant with bupivacaine.

Keywords: Caudal analgesia, Bupivacaine, Dexmedetomidine, Magnesium sulfate

# 1. Introduction

T he development of pediatric anesthesia has greatly improved the safety of surgical procedures, decreased the severity of anestheticinduced neurotoxicity, and lengthened the duration of postoperative analgesia.<sup>1,2</sup>

Lignocaine and bupivacaine are just two of the many anesthetics that have been utilized for caudal analgesia in children.<sup>3,4</sup>

Bupivacaine has been used clinically for over 25 years, and its preferential sensory over motor block properties make it ideal for pediatric caudal epidural analgesia.<sup>5</sup>

Magnesium sulfate and dexmedetomidine are just a couple of the many recently developed adjuvants. Magnesium, as a noncompetitive NMDA receptor antagonist and a voltage-dependent calcium ion channel blocker, has been found to be active in lowering postoperative pain in a number of investigations in recent years.<sup>6,7</sup>

#### 2. Patients and methods

This prospective, double-blind, randomized trial took place at the hospitals of Al-Azhar University in Assiut, Egypt, with the agreement of the local ethics council. From the beginning of the year 2022 to the end of the year.

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Sixty children, ranging in weight up to 20 kg and categorized as American Society of Anesthesiologists class I or II, were joined up in this research.

The inclusion criteria were infraumbilical procedures, American Society of Anesthesiologists classes I and II, and pediatric patients weighing up to 20 kg.

The exclusion criteria were refusal by the patient's family, patients with body masses in excess of 20 kg, problems with clotting, a history of neurological or spinal disease, or a birth defect can all increase the risk of developing back pain. Having an infection or sores at the spot where you were punctured, or an allergy to any of the drugs being tested.

## 2.1. Patients' groups

Patients were split at random into three groups of equal size: 20 cases in each of three groups cases in group A (dexmedetomidine group) (N = 20) were given a caudal injection of a solution containing 0.25 % bupivacaine and 1.5 µg/kg of body weight of dexmedetomidine. Twenty patients were randomly assigned to group B (magnesium group), where they were given a caudal injection of a solution containing 0.25 % bupivacaine and 5 mg/kg of magnesium sulfate. Patients in group C (the control group) had a caudal injection of a combination of 0.25 % bupivacaine (2 mg/kg of body weight) and 1 % normal saline (1 ml/kg). Preparation of patients: all cases were given a full blood count, coagulation profile, blood group, and airway evaluation before receiving anesthesia.

#### 2.1.1. Fasting time

Fasting times before surgery are as follows: 2 h for clear fluids, 3 h for breast milk, and 6 h for semisolids and formula.

## 2.1.2. Monitoring

It was at this point that the usual monitoring were put in place in the operation room. (C50 pt monitor; Spacelabs Healthcare, Washington, USA) included pulse oximetry, ECG, capnogram, temperature, and noninvasive blood pressure was applied.

#### 2.1.3. Induction of anesthesia

All of our cases had routine general anesthetic induction utilizing a face mask and 6–8 MAC of sevoflurane. A cannula with a 24/22 G was used. Warmed fluids were administered intravenously. After inserting the I-gel, sevoflurane MAC (1–3) inhalation was used to keep the patient under anesthesia while they breathed on their own.

#### 2.1.4. Intravenous fluids

An infusion of dextrose 5 % in normal saline were administrated at a flow rate of 3-5 ml/kg/h.

#### 2.1.5. Injectable medication preparation: volume

Estimates of the amount were made using (Armitage EN, 1986): 0.5 ml/kg below symphysis pubis, 0.75 ml/kg at level of symphysis pubis, 1 ml/kg) up to symphysis pubis (above symphysis pubis below umbilicus).

#### 2.1.6. Anesthetic agent

The 0.5 % bupivacaine (marcaine, Sunny Group Company, Cairo, Egypt) was diluted with normal saline at a 1 : 1 ratio to produce the 0.25 % bupivacaine (2 mg/kg) used in this study.

#### 2.1.7. Adjuvants

Dexmedetomidine (precedex; Hospira Group Company, USA) in a dose of 1.5  $\mu$ g/kg, magnesium sulfate (Epsom salt, Eipico Group Company, Egypt) in a dose of 5 mg/kg.

#### 2.1.8. Caudal block

A 22 G, 3-cm, single-use needle was inserted into the sacral epidural region to administer the caudal anesthetic. The patient's legs, knees, and neck were flexed in a fetal position. The anesthesiologist's nondominant finger located a triangular depression among the sacral cornua that was above the coccyx and below the sacrum. A slight increase in resistance was felt as the needle was inserted perpendicular to the skin until it reached the sacrococcygeal membrane. The needle was then withdrawn slightly, angled downward from 90 to 45°, and pushed on through the lining of the sacrum and coccyx. When the patient felt less resistance, the needle was lowered parallel to the skin and continued another 1-2 cm to reach the caudal epidural area. The correct placement of the needle was verified by Swoosh test (saline injection, 1–2 ml). A stethoscope could pick up the Swoosh of the saline solution if the needle was in the epidural area. When the needle was not in the right spot, it caused the skin to crepitus or rise. A test using a light aspiration, the caudal block was discontinued if cerebrospinal fluid or blood was aspirated to prevent accidental intravascular or intrathecal injection. Once the correct needle placement verified, the local anesthetic (bupivacaine) was given all at once. After performing a caudal block, the patient was moved for surgery. At the end of the surgery: we cut off the volatile anesthetic. Once cases had established adequate spontaneous ventilation, the I-Gel was removed and they were taken to the recovery

area. If the patient's heart rate or mean arterial pressure changed by more than 20 % from baseline, the block was deemed unsuccessful, and they were removed from the research. If the patient's heart rate or mean arterial pressure dropped by 20 % or more from their baseline values, respectively, they were diagnosed with bradycardia and hypotension, respectively.

# 2.2. Statistical analysis

Mean, SD, minimum, and maximum range were utilized for statistical analysis of numerical data, whereas number and percentage were employed for categorical data. Quantitative variables were analyzed by a one-way analysis of variance for parametric data across the two groups, followed by a post-hoc analysis for the same. For parametric data among two variables in each group, a paired sample *t*-test is performed. The  $\chi^2$  test is used to compare two groups' worth of qualitative data. *P* value less than 0.05 is considered statistically significant.

# 3. Results

Age, weight, sex, and length of operation were just some of the basic demographics listed in Table 1 for the three groups. There was no discernible variation in demographics across the groups (P > 0.05) (Table 2).

We found no statistically significant difference in respiratory rate monitoring among the three study groups both during surgery and afterward, as shown in Table 3.

From the 20th minute of surgery and every 15 min afterward up to 12 h postoperatively, group A had a significantly lower heart rate than group C, as shown in Table 4 (P < 0.05). Group B's heart rate measures were lower than group C's from the 20th minute of surgery and every 15 min afterward for

Table 1. Cases demographic characteristics (N = 60).

	Group A $(N = 20)$	Group B ( <i>N</i> = 20)	Group C ( <i>N</i> = 20)	P value
Age (years)				0.737
Mean $\pm$ SD	$2.8\pm1.9$	$2.5 \pm 2.1$	$3.1 \pm 1.5$	
Range	2-5	2-5	2-5	
Weight (kg)				0.861
Mean $\pm$ SD	$15.1\pm4.8$	$14.6 \pm 4.7$	$15.4\pm4.5$	
Range	12-18	12-17	11.5 - 18	
Duration of surgery				0.383
Mean $\pm$ SD	$68.5 \pm 25.1$	$73.5 \pm 24.2$	$63.2\pm20.4$	
Range	20-105	20-115	25-110	
Sex [n (%)]				0.459
Male	15 (75)	18 (90)	16 (80)	
Female	5 (25)	2 (10)	4 (20)	

12 h postoperatively. Despite the fact that this was not a statistically significant change (P > 0.05) (Fig. 1).

Table 5 showed that summarized caudal block data of the three groups. It showed that onset of the caudal block: it was faster in group A (mean value 7.4 min) than group B (mean value 7.6 min) and group C (mean value 7.88 min), also was faster in group B than group C, however, statistical analysis revealed no discernible distinction (P > 0.05). The caudal block duration varied significantly throughout the three groups (P < 0.001).

The values of the FLACC scores for the three groups were shown in Table 1. After 12 post-operative hours, the FLACC score was significantly lower in groups A and B matched to group C (P < 0.05). When comparing the two groups at the same postoperative time points (30 min, 1, 2, 3 h), group A had a lower FLACC score (0.7, 1.1, 1.6, 1.4) than group B (0.8, 1.5, 2.1, 1.9).

Table 6 found that Ramsay sedation score values of the three groups. It showed that: during the first 3 h postoperative, there were statistical significant higher sedation scores in group A (4.5, 3.7, 3.4, 2.9) and group B (4.3, 3.8, 3.6, 2.7) than group C (control group: 3.5, 2.7, 2.4, 2) with *P* value less than 0.001 at (30 min, 1 h, 2 h, 3 h), respectively. At the 6th hour postoperatively, there were statistically significant higher sedation scores in group A (3) than group B (2) with *P* value less than 0.001 (Table 7).

Scores on the PAED scale for the three categories were tabulated below. Comparing groups A and B with group C revealed significantly lower PAED values in groups A and B than in group C at 5, 15, and 30 min postoperatively (3.5, 3, 2.5, and 4, 3.5, 3, respectively; P < 0.001). In the long run, the difference among the three groups disappears (Fig. 2).

In Table 8, we saw that the following complications required close observation: consciousness or movement may be disrupted by vomiting, bradycardia, hypotension, or both. One patient each in groups A and C experienced postoperative vomiting, while two patients in group B experienced it at a rate of 10 %; similarly, one patient in groups A and C experienced bradycardia, but none did in group C.

# 4. Discussion

There were no statistically significant variations in age, weight, sex, or operation length between the three groups in this investigation.

Sixty children between the ages of one and eight were included in a randomized controlled trial by Gupta and Sharma.<sup>8</sup> These children were all

	Group A (1	Group A ( $N = 20$ )		N = 20)	Group C (1	Group C ( $N = 20$ )	
	Mean	SD	Mean	SD	Mean	SD	
Baseline	27	2.1	26.1	2.2	27	0.665	0.654
At induction	26.5	2.2	26.1	2.4	26.5	0.565	0.873
At skin incision	24.9	2.3	24.3	2.2	24.9	0.532	0.865
5 min intraoperative	24.1	2.4	23.2	2.3	24.1	0.542	0.765
10 min intraoperative	24.6	2.5	23.3	2.3	24.6	0.498	0.732
15 min intraoperative	24.9	2.2	24.3	2.3	24.9	0.654	0.742
20 min intraoperative	27	2.4	26.1	2.1	27	0.873	0.698
25 min intraoperative	23.6	2.2	22.6	2.3	23.6	0.865	0.854
30 min intraoperative	24.3	2.3	23.3	2.1	24.3	0.765	0.673
45 min intraoperative	24.3	2.3	23.3	2.1	24.3	0.732	0.665
60 min intraoperative	24.4	2.3	23.4	2.2	24.4	0.742	0.565
75 min intraoperative	25	2.1	24.4	2.1	25	0.698	0.532
90 min intraoperative	24.9	2.3	24.3	2.3	24.9	0.854	0.665
At discharge	30.6	2.1	29.3	2.4	30.6	0.673	0.565
30 min postoperative	28	2.1	27.1	2.5	28	0.665	0.532
1 h postoperative	27.1	2.2	26.1	2.4	27.1	0.565	0.542
2 h postoperative	24.9	2.1	24.3	2.1	24.9	0.532	0.498
3 h postoperative	24.1	2.3	23.2	2.2	24.1	0.542	0.654
6 h postoperative	24.6	2.4	23.3	2.3	24.6	0.498	0.873
12 h postoperative	25.5	2.5	24.2	2.3	25.5	0.654	0.865
24 h postoperative	26	2.4	24.6	2.4	26	0.773	0.765

Table 2. Mean respiratory rate in the studied groups.

## Table 3. Mean heart rate in the studied groups.

	Group A (l	N = 20)	Group B (N	V = 20)	Group C (1	N = 20)	P value	
	Mean	SD	Mean	SD	Mean	SD		
Baseline	132	2.1	132	2.1	138	2.2	0.654	
At induction	119	2.2	128	2.2	134	2.4	0.603	
At skin incision	117	2.3	120	2.3	129	2.2	0.065	
5 min intraoperative	115	2.4	123	2.4	127	2.3	0.065	
10 min intraoperative	110	2.5	118	2.5	129	2.3	0.6	
15 min intraoperative	108	2.4	118	2.2	128	2.3	0.437	
20 min intraoperative	109	2.1	119	2.4	125	2.1	0.03	
25 min intraoperative	102	2.2	112	2.2	122	2.3	0.04	
30 min intraoperative	98	2.3	108	2.3	117	2.1	0.003	
45 min intraoperative	94	2.4	104	2.3	119	2.1	0.03	
60 min intraoperative	93	2.5	103	2.3	115	2.2	0.04	
75 min intraoperative	87	2.2	97	2.1	107	2.1	0.003	
90 min intraoperative	103	2.4	107	2.3	113	2.3	0.66	
At discharge	107	2.2	110	2.1	117	2.4	0.06	
30 min postoperative	108	2.3	118	2.1	122	2.5	0.03	
1 h postoperative	109	2.3	119	2.2	127	2.4	0.04	
2 h postoperative	110	2.3	120	2.1	132	2.1	0.003	
3 h postoperative	111	2.1	121	2.3	140	2.2	0.654	
6 h postoperative	118	2.3	128	2.4	132	2.3	0.424	
12 h postoperative	122	2.3	128	2.5	133	2.3	0.065	
24 h postoperative	123	1.4	130	3.1	134	3.3	0.765	

Table 4. Caudal block characteristics (N = 60).

	Group A ( $N = 20$ )	Group B ( $N = 20$ )	Group C ( $N = 20$ )	P value	P1 A vs. C	P2 B vs. C	P3 A vs. B
	(mean $\pm$ SD)	(mean $\pm$ SD)	(mean $\pm$ SD)				
Onset of caudal block (min)	$7.41 \pm 1.12$	$7.6 \pm 1.47$	$7.88 \pm 1.96$	0.632	0.608	0.837	0.921
Duration of caudal block (min)	$434.6 \pm 33.7$	$425.4 \pm 31.5$	$315.9 \pm 25.86$	< 0.001	< 0.001	< 0.001	0.609
Paracetamol dosage (mg)	$163.5 \pm 44.2$	$177.2 \pm 68.4$	$154.7 \pm 52.8$	0.446	0.873	0.418	0.721

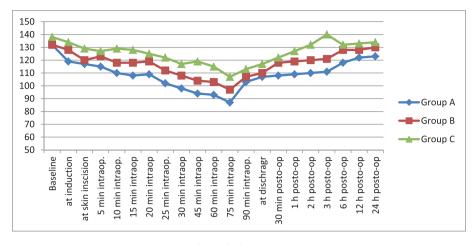


Fig. 1. HR in the studied groups. HR, heart rate.

scheduled to undergo infraumbilical procedures. Each child was randomly randomized to receive either ropivacaine (0.25 %) (1 ml/kg) + tramadol (2 mg/kg) or ropivacaine (0.25 %) (1 ml/ kg) + dexmedetomidine (2  $\mu$ g/kg). Analgesic effects lasted substantially longer in group RD (780.29 71.21 min) group RT ± than in  $(654.20 \pm 78.38 \text{ min}) (P < 0.0001).$ 

In accordance with this study as regard dexmedetomidine (1.5  $\mu$ g/kg) added to caudal bupivacaine (0.25 %) (1 ml/kg) in children increased the duration of analgesia, as found by Fares et al.<sup>9</sup> in their study. Their research was conducted on 40 pediatric cases, weighting between 10 and 40 kg, scheduled for major abdominal cancer surgeries. They observed the mean  $\pm$  SD of duration of analgesia were longer

Table 5. FLACC score of the studied groups (N = 60).

	Group A ( <i>N</i> = 20) [median (range)]	Group B (N = 20) [median (range)]	Group C ( <i>N</i> = 20) [median (range)]	P value	P1 A vs. C	<i>P</i> 2 B vs. C	P3 A vs. B
At 30 min postoperative	0.7 (0-1)	0.8 (0-2)	1.4 (0-2)	0.01 (S)	0.023	0.034	0.795
At 1 h postoperative	1.1 (0-1)	1.5 (0-2)	2.2 (1-3)	<0.001 (HS)	< 0.001	0.011	0.092
At 2 h postoperative	1.6 (0-2)	2.1 (0-3)	2.7 (2-3)	<0.001 (HS)	< 0.001	< 0.001	0.124
At 3 h postoperative	1.4 (0-2)	1.9 (1-3)	2.4 (2-3)	<0.001 (HS)	< 0.001	0.032	0.074
At 6 h postoperative	2.1 (1-3)	2.6 (2-3)	4.2 (3-5)	<0.001 (HS)	< 0.001	< 0.001	0.05
At 12 h postoperative	2.7 (2-3)	3.1 (0-4)	2.9 (1-4)	0.724 (NS)	0.834	0.721	0.683
At 24 h postoperative	3.1 (1-4)	3.3 (2-5)	3.4 (2-5)	0.737 (NS)	0.762	0.893	0.869

Table 6. Ramsay sedation score of the studied groups (N = 60).

	Group A ( <i>N</i> = 20) [median (range)]	Group B ( <i>N</i> = 20) [median (range)]	Group C ( <i>N</i> = 20) [median (range)]	P value	P1 A vs. C	<i>P</i> 2 B vs. C	P3 A vs. B
At 30 min postoperative	4.5 (3-5)	4.3 (3-5)	3.5 (3-4)	<0.001 (HS)	<0.001	<0.001	0.752
At 1 h postoperative	3.7 (2-4)	3.8 (2-4)	2.7 (2-3)	<0.001 (HS)	< 0.001	< 0.001	0.926
At 2 h postoperative	3.4 (2-4)	3.6 (2-4)	2.4 (2-3)	<0.001 (HS)	< 0.001	< 0.001	0.429
At 3 h postoperative	2.9 (2-3)	2.7 (2-3)	2 (2-3)	<0.001 (HS)	< 0.001	< 0.001	0.784
AT 6 h postoperative	2.8 (2-3)	2.2 (2-3)	2.3 (2-3)	<0.001 (HS)	< 0.001	0.654	< 0.001
At 12 h postoperative	1.8 (1-2)	1.7 (1-2)	1.6 (0-2)	0.74 (NS)	0.839	0.893	0.649
At 24 h postoperative	1.5 (1-2)	1.6 (0-2)	2 (2–2)	0.37 (NS)	0.753	0.747	0.791

Table 7. PAED scale score of the studied groups (N = 60).

	Group A ( $N = 20$ ) [median (range)]	Group B (N = 20) [median (range)]	Group C ( $N = 20$ ) [median (range)]	P value	<i>P</i> 1 A vs. C	<i>P</i> 2 B vs. C	<i>P</i> 3 A vs. B
At 5 min	3.5 (3-5)	4 (2-6)	6.5 (5-12)	<0.001 (HS)	<0.001	<0.001	0.439
At 15 min	3 (2-4)	3.5 (2-5)	5.5 (3-9)	<0.001 (HS)	< 0.001	< 0.001	0.358
At 30 min	2.5 (2-4)	3 (2-3)	5 (3-8)	<0.001 (HS)	< 0.001	< 0.001	0.364
At 45 min	2 (1-3)	2 (1-3)	2.5 (1-4)	0.829 (NS)	0.787	0.801	0.912
At 60 min	2 (1-2)	1.5 (1–2)	2 (1–3)	0.871 (NS)	0.752	0.917	0.826

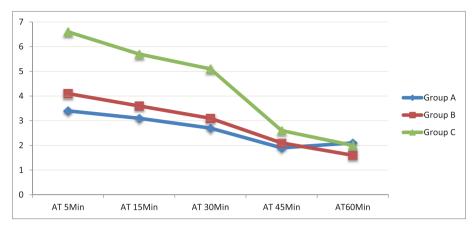


Fig. 2. Median of PAED scale score in the studied groups.

Table 8. Postoperative complications.

	Group A	Group B	Group C
	(N = 20) [n (%)]	-	(N = 20) [n (%)]
Bradycardia	1 (5)	1 (5)	0
Hypotension	1 (5)	0	0
Hypoxia	0	0	0
Vomiting	1 (5)	2 (10)	1 (5)
Prolonged motor powe	0 r	0	0
DCL	0	0	0

in group BD (19.20  $\pm$  4.61 h) than in group B (6.60  $\pm$  3.44 h) with high significant difference with *P* value less than 0.001.

Regarding perioperative hemodynamics, this study discovered a statistically significant difference in heart rate among groups A and C from 20 min into surgery to 12 h postoperatively. Group A had lower heart rates. Even though there was no statistically significant difference among group B and group C, group B did worse than group C at the same periods.

Additionally, throughout intraoperative and postoperative observation periods, there were no statistically significant differences in respiratory rate or oxygen saturation among both study groups as well as the control group.

Consistent with our findings, Fares et al.<sup>9</sup> demonstrated the impact of combining caudal bupivacaine (0.25 %) (1 ml/kg) with dexmedetomidine (1.5  $\mu$ g/kg). In the first 30 min of surgery, the heart rates of patients in the bupivacaine–dexmedetomidine group dropped significantly more than those in the bupivacaine group with *P* value less than 0.001.

As regard the onset of caudal block: it was faster in group A than groups B and C, also was faster in group B than group C. The difference was not statistically significant with *P* value of 0.146.

Our results showed agreement with She et al.<sup>10</sup> compared in their study the start of 212 children

given levobupivacaine at several doses with and without dexmedetomidine, aged 1–3 years, weighted 8–18 kg, scheduled for elective inguinal hernia repair or hydrocele. The patients were divided into group  $L_{0.25}$  received caudal levobupivacaine 0.25 %, group  $L_{0.20}$  received caudal levobupivacaine 0.20 %, or Group LD received caudal levobupivacaine 0.20 % plus dexmedetomidine 2 µg/kg. The start time of caudal block in children was not significantly altered by the addition of dexmedetomidine to levobupivacaine.

In the first 12 h following surgery, the FLACC score was lower in group A than in group C, and there were statistically significant differences among groups B and C. At all postoperative time intervals (30 min, 1, 2, 3 h), group A had lower FLACC scores (0, 1, 2, 3) than group B (1, 1, 2, 2). It was in line with Goyal et al.<sup>11</sup> who looked into combining bupivacaine and dexmedetomidine for caudal anesthesia in kids. Throughout the first 12 h postoperatively, patients in group B (the intervention group) had significantly lower FLACC ratings than those in the control group (group A) (P < 0.0001).

In terms of assessing postoperative sedation using the Ramsay sedation score, both group A (4, 4, 3, 3) and group B (4, 4, 3, 2, 5) fared better than the control group (3, 2, 5, 2, 2) at 30 min, 1 h, 2 h, and 3 h after surgery (P < 0.001).

Our results were in line with those of Fares et al.,<sup>9</sup> who investigated the impact of combining caudal bupivacaine (0.25 %) (1 ml/kg) with dexmedetomidine (1.5 g/kg) on sedation scores. Forty young people who were going to have significant abdominal cancer procedures were used in their study. The average sedation level in both groups was 3, and while it declined in both groups over the first 4 h after surgery, it reduced more in group A. Patients in both groups showed similar levels of sedation up to 24 h after surgery.<sup>2</sup>

As regard to postoperative complications: one (5 %) patient in group B and two (10 %) patients in group A experienced postoperative vomiting. One group A patient experienced intraoperative brady-cardia 60 min after block delivery; this was treated with intravenous (0.02 mg) atropine.

Whereas in our study, the occurrence of vomiting was greater in group A (10 %) matched to group B (5 %) and group C (0 %), Goyal et al.<sup>11</sup> found that the occurrence of vomiting as well as nausea was greater in group A (control group) (33 %) matched to group B (dexmedetomidine group) (16 %).

## 4.1. Conclusion

For children undergoing infraumbilical surgeries, dexmedetomidine is preferable to magnesium sulfate as an adjuvant because it improves caudal block, increases the duration of postoperative analgesia, and decreases postoperative EA, all with minimal side effects.

# **Consent statement**

A written informed consent was taken from the parents of all patients who were candidate for the scientific research. All patients were allowed to refuse or withdraw from the research at any time without any effect on medical service production.

# **Conflicts of interest**

There are no conflicts of interest.

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